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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2021–0020]

RIN 1601–AB21

Electronic Payments for FOIA Requests

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: The Department of Homeland Security (DHS or Department) is updating its regulations related to the payment of fees arising from Freedom of Information Act (FOIA) and Privacy Act of 1974 requests to add the option for requesters to submit electronic payments via the Department's FOIA processing system, which can be made using *pay.gov*, or as otherwise directed by DHS and its components.

DATES: This final rule is effective November 30, 2026.

FOR FURTHER INFORMATION CONTACT: Roman Jankowski, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528, (202) 343–1717, *Privacy@hq.dhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of Homeland Security has authority under 5 U.S.C. 301 and 552, and 6 U.S.C. 112(e) to issue Freedom of Information Act and Privacy Act regulations. That authority has been delegated to the Chief Privacy Officer of the Department pursuant to 6 U.S.C. 142 and DHS Del. No. 13001, Rev. 01 (. June 2, 2020). Most recently, DHS updated its procedures for submitting requests under the Freedom of Information Act and Privacy Act, 5 U.S.C. 552a, and under the Judicial Redress Act of 2015 (JRA) (5 U.S.C. 552a note), at 6 CFR part

5, subparts A and B, on December 23, 2025 (90 FR 59945).

II. Discussion of Changes

This rule updates Title 6, part 5, paragraphs 5.11(a) and 5.21(d), which describe how FOIA and Privacy Act/JRA fees are assessed and how to submit payment. The current rule generally requires requesters to pay for their FOIA and Privacy Act/JRA requests using a check or money order made payable to the Treasury of the United States. In addition to check and money orders (when permitted), DHS and its components are now adding electronic payment as a permissible payment type for FOIA and Privacy Act/JRA requests. Electronic payments can be made via *pay.gov*, or any other electronic payment platform selected by DHS and its components. By adding electronic payments, DHS and its components will increase options for requesters, who may have limited access to checks or money orders. Further, the inclusion of electronic payments will remove steps for requesters, like the need to obtain money orders or write checks and mail physical payments, and increase processing efficiency for the Department and its components.

III. Regulatory History

DHS did not publish a notice of proposed rulemaking for this rule. Under 5 U.S.C. 553(b)(A), this final rule is exempt from notice and public comment rulemaking requirements because the change involves rules of agency organization, procedure, or practice. In addition, under 5 U.S.C. 553(b)(B), an agency may bypass notice and comment requirements if it finds, for good cause, that notice and comment is impracticable, unnecessary, or contrary to the public interest. DHS finds that notice and comment is unnecessary here because adding a payment type to the existing list of payment types to pay for a FOIA or Privacy Act/JRA request is an agency procedural update that will not alter the rights or interests of parties, but will improve the efficient operations of the agency by reducing the need to receive and process physical checks and money orders. DHS also believes that adding this option, which is widely used by the public in other contexts, will increase convenience for the public without removing any currently available

option. Specifically, electronic payments may be preferable to checks and money orders to many potential requesters because they eliminate the need to mail the payment and allow for better tracking of payments. DHS is retaining the option for requesters to pay by check or money order.

III. Regulatory Analyses

A. Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14192 (Unleashing Prosperity Through Deregulation)

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 14192 establishes a policy that the executive branch be “prudent and financially responsible in the expenditure of funds, from both public and private sources, and [] alleviate unnecessary regulatory burdens placed on the American people.”

The Office of Management and Budget (OMB) has not designated this rule a “significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed this rule. This rule is also not subject to Executive Order 14192 because the rule is not significant under Executive Order 12866 and because it is related to agency organization, management, or personnel. See OMB Memorandum M–25–20, “Guidance Implementing Section 3 of Executive Order 14192, titled ‘Unleashing Prosperity Through Deregulation’” (Mar. 26, 2025).

DHS has considered the costs and benefits of this rule. This rule will not impose any new costs on the government or the public. The rule's benefits include potentially increased efficiency in processing payments for FOIA and Privacy Act/JRA requests. Specifically, DHS expects that many requesters will choose the electronic payment option over check or money order, thus reducing the number of physical payments the Department will need to receive and process, and freeing personnel to work on other matters.

Requesters will have more flexibility in paying FOIA and Privacy Act/JRA request fees, and those who pay electronically may also experience a shorter lag time between making a payment and DHS sending a response.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no written statement was deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, and section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 note, agencies must consider the impact of their rulemakings on “small entities” (small businesses, small organizations, and local governments). The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. DHS has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. DHS does not believe this rule imposes any additional direct costs on small entities.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (as amended), 5 U.S.C. 804(2). The Office of Management and Budget’s Office of Information and Regulatory Affairs has not found that this rule is likely to result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

National Environmental Policy Act

DHS reviews regulatory actions to determine whether the National Environmental Policy Act (NEPA) applies to them and, if so, what degree of analysis is required. DHS Directive

023–01 Rev. 01 (Directive) and Instruction Manual 023–01–001–01 Rev. 01 (Instruction Manual) establish the procedures that DHS and its Components use to comply with NEPA.

NEPA allows Federal agencies to establish, in their NEPA implementing procedures, categories of actions (“categorical exclusions”) that experience has shown do not, individually or cumulatively, have a significant effect on the human environment and, therefore, do not require an environmental assessment or environmental impact statement. The Instruction Manual, Appendix A, lists the DHS categorical exclusions.

Under DHS NEPA implementing procedures, for an action to be categorically excluded, it must satisfy each of the following three conditions: (1) the entire action clearly fits within one or more of the categorical exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect.

This rule is strictly procedural and is limited to updating the method by which requesters pay the fee associated with FOIA requests. DHS has reviewed this rule and finds that it clearly fits within categorical exclusion A3(a) as an administrative or procedural rule that will have no significant effect on the environment, is not part of a larger Federal action, and does not present extraordinary circumstances that create the potential for significant environmental impacts. Therefore, the rule is categorically excluded from further NEPA review.

List of Subjects in 6 CFR Part 5

Classified Information, Courts, Freedom of information, Government employees, Privacy.

For the reasons stated in the preamble, DHS amends Chapter I part 5 of Title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

■ 1. The authority citation for part 5 continues to read as follows:

Authority: 6 U.S.C. 101 *et seq.*; Pub. L. 107–296, 116 Stat. 2135; 5 U.S.C. 301; 6 U.S.C. 142; DHS Del. No. 13001, Rev. 01 (June 2, 2020).

Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a and 552 note.

■ 2. Amend § 5.11 by revising paragraph (a) to read as follows:

§ 5.11 Fees.

(a) *In general.* Components shall charge for processing requests under the FOIA in accordance with the provisions of this section and with the OMB Guidelines. Components will ordinarily use the most efficient and least expensive method for processing requested records. In order to resolve any fee issues that arise under this section, a component may contact a requester for additional information. A component ordinarily will collect all applicable fees before sending copies of records to a requester. If you make a FOIA request, it shall be considered a firm commitment to pay all applicable fees charged under § 5.11, up to \$25.00, unless you seek a waiver of fees. Requesters must pay fees by check or money order made payable to the Treasury of the United States, or by electronic payment through *pay.gov*, or as otherwise directed by DHS and its components.

* * * * *

■ 2. Amend § 5.21 by revising paragraph (d) to read as follows:

§ 5.21 Requests for Access to Records.

* * * * *

(d) *Agreement to pay fees.* DHS and components shall charge for processing requests under the Privacy Act or JRA. DHS and components will ordinarily use the most efficient and least expensive method for processing requested records. DHS may contact a requester for additional information in order to resolve any fee issues that arise under this section. DHS ordinarily will collect all applicable fees before sending copies of records to a requester. If one makes a Privacy Act or JRA request for access to records, it will be considered a firm commitment to pay all applicable fees charged under § 5.29, up to \$25.00. The component responsible for responding to a request ordinarily will confirm this agreement in an acknowledgement letter. When making a request, an individual may specify a willingness to pay a greater or lesser amount. Requesters must pay fees by check or money order made payable to the Treasury of the United States, or by electronic payment through *pay.gov*, or as otherwise directed by DHS and its components.

* * * * *

Roman Jankowski,
Chief Privacy Officer, Department of Homeland Security.

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA–2025–5571; Airspace
Docket No. 25–AWP–172]

RIN 2120–AA66

**Amendment of Class D and
Establishment of Class E Airspace;
Chandler and Phoenix, AZ**

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D airspace and establishes Class E airspace at Chandler and Phoenix, AZ. This action is the result of biennial airspace reviews pursuant to FAA Order JO 7400.2R, Procedures for Handling Airspace Matters. The name and geographic coordinates of the Mesa Gateway Airport, Phoenix, AZ, are also being updated to coincide with the FAA's aeronautical database. This action brings the airspace into compliance with FAA orders and supports instrument flight rule (IFR) procedures and operations.

DATES: Effective 0901 UTC, February 18, 2027. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the notice of proposed rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from www.federalregister.gov.

FAA Order JO 7400.11M, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class D airspace and establishes Class E airspace at the affected airports to support IFR operations.

History

The FAA published an NPRM for Docket No. FAA–2025–5571 in the **Federal Register** (90 FR 59081; December 18, 2025) proposing to amend the Class D airspace and establish Class E airspace at Chandler and Phoenix, AZ. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. The FAA appreciates the public's participation in the rulemaking process. Ninety-six comments were received and all comments have been reviewed and considered. The following responses are provided.

The airspace requirements for airports with public instrument procedures and air traffic control towers (ATCT) are outlined in FAA Order JO 7400.2R and 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points. The FAA only designates controlled airspace required under FAA orders and 14 CFR part 71 and makes every effort to respect and protect the public's right of transit.

A majority of the airports within the Phoenix area have not received a complete airspace review in 25 years or longer. During that timeframe, instrument procedures and FAA orders and regulations governing airspace requirements have changed, thus requiring the airspace modification to bring the airspace into compliance with FAA orders and regulations and to support IFR operations. The changes to FAA orders and regulations require the modification and expansion of the controlled airspace at Chandler Municipal Airport and Mesa Gateway Airport.

Two comments expressed general dissatisfaction with the proposal without identifying any specific aspects to which they object or making any recommendations on how to revise the proposal. Due to the lack of specificity, the FAA is unable to provide a detailed response but acknowledges the general objections.

Fifty-nine comments raised concerns regarding the impact the proposed airspace modifications would have on VFR operations within the Phoenix area. The majority of these comments did not provide recommendations for how to revise the proposal or recommended either leaving the current airspace in place or reducing the current controlled airspace. All of these 59 comments expressed dissatisfaction with raising the vertical limits of the Chandler, AZ, Class D airspace from 3,000 feet MSL to 3,700 feet MSL and the possible safety implications of leaving only 300 feet between the top of the Chandler, AZ, Class D airspace and the bottom of the Phoenix, AZ, Class B airspace. A comment from the Arizona Pilots Association objects to the lateral increase in the Chandler Municipal Airport Class D airspace, which "would close the distance" between that Class D airspace and the Phoenix Sky Harbor International Airport Class B airspace, further constraining and concentrating VFR traffic.

The proposed modification to the vertical limit was derived from FAA Order JO 7400.2R, paragraph 17–2–8 which states that "Class D areas should normally extend upward from the surface up to and including 2,500 feet AGL." As such, reducing the vertical limit from what was proposed is not consistent with the referenced FAA order. In response to the safety concern expressed in the comments, the vertical limit of the Class D airspace at Chandler, AZ, is being raised from 3,000 feet MSL to up to but excluding 4,000 feet MSL rather than 3,700 feet MSL as initially proposed. This change eliminates the possibility of VFR traffic attempting to transit through the 300-foot area between the Chandler, AZ, Class D and the Phoenix, AZ, Class B airspace. Aircraft will still be able to transit the same area but will need to contact Chandler FAA Contract Tower (FCT) for clearance. The FAA believes that positive control of aircraft transiting this area is in the best interest of safety and will eliminate the risk of midair collisions expressed in the comments.

Twenty-five comments stated concerns regarding the impact of the proposed airspace changes on Pegasus Airpark. The following is the categorization of the comments: 6

expressed dissatisfaction without providing recommendations for modifying the proposal; 18 recommended increasing the exclusion area from the proposed 1.2-mile radius to a 1.5-mile radius; 5 recommended an exclusion area that matches or is smaller than the one proposed; 1 suggested increasing the exclusion area from a 1.2-mile radius to a 1.8-mile radius; 1 suggested increasing the exclusion area from a 1.2-mile radius to a 2-mile radius; and 2 suggested increasing the exclusion area from a 1.2-mile radius to a 3-mile radius.

The FAA acknowledges the comments expressing general dissatisfaction but is unable to respond further to comments lacking specificity or a recommendation for modifying the proposal. The suggestions to increase the exclusion area cited an increase in high-performance aircraft operating at Pegasus Airpark that need more uninhibited airspace to remain clear of the Mesa Gateway Airport, Phoenix, AZ, Class D airspace. The proposed exclusion area is equal to the airspace area currently outside of the Mesa Gateway Airport, Phoenix, AZ Class D airspace. Therefore, it does not shrink the airspace available for these operations.

Pursuant to Advisory Circular (AC) 90–66C, Non-Towered Airport Flight Operations, it is the responsibility of the airport owners and operators to coordinate the establishment of nonstandard traffic patterns with the FAA. The airport owner is then responsible for publishing the traffic pattern information in the Chart Supplement. The operator of the Pegasus Airpark has not accomplished this, so a standard traffic pattern is assumed and the appropriate Class G airspace provided. The air traffic manager (ATM) at Mesa Gateway Airport was asked to consider an increase in the exclusion area. However, as there have not been any incursions into the Class D airspace in the area of Pegasus Airpark; Pegasus Airpark has not made any coordination request to accommodate a larger air traffic pattern; and the proposed exclusion area is equal to the area currently outside of the Mesa Gateway Airport Class D airspace, the ATM does not believe that an increase in the exclusion area is needed at this time. If the situation changes and the proper coordination is complete, the issue of expanding the exclusion area may be revisited.

Twenty-eight comments objected to the potential impact of the proposed airspace changes on Stellar Airpark. The following is the categorization of the comments: 19 expressed dissatisfaction

without providing recommendations for how to modify the proposal; 5 recommended an exclusion area that matched the proposal; and 1 comment stated the Stellar Airpark is not a VFR airport. The FAA is unable to respond to the comments expressing general dissatisfaction without details or providing any recommendations as it is impossible to address them without specifics.

Many comments cited an increase in high-performance aircraft operating at Stellar Airpark that needed more Class G airspace to remain clear of the Chandler Municipal Airport, Chandler, AZ Class D airspace. One comment objected to the airspace changes because they would allegedly frustrate the ability of VFR pilots to continue using the same visual landmarks for navigation. And one comment expressed concern with the impact on a privately funded instrument approach procedure at Stellar Airpark. The proposed exclusion area provides for a standard cutout for VFR airports and accommodates the public instrument procedures into Stellar Airpark.

As previously stated, pursuant to AC 90–66C, it is the responsibility of the airport owners and operators to coordinate the establishment of nonstandard traffic patterns with the FAA. The airport owner is then responsible for publishing the traffic pattern information in the Chart Supplement. The Stellar Airpark operator has not accomplished this, and there is no information regarding traffic patterns in the Stellar Airpark Chart Supplement entry, so a standard traffic pattern is assumed and the appropriate Class G airspace provided. If the situation changes and the proper coordination is complete, the issue of expanding the exclusion area may be revisited.

The FAA also confirms Stellar Airpark's status as a VFR airport. While Stellar Airpark does have instrument procedures—which were considered in the development of Chandler, AZ Class D exclusion area—that does not make Stellar Airpark an IFR or controlled airport. Stellar Airpark is an uncontrolled airport, and operators are required to take off and land following visual flight rules, thus Stellar Airpark is an uncontrolled, VFR airport.

Seventeen comments stated that the proposed airspace changes would increase the workload of pilots and would increase air traffic controller workloads beyond the capabilities of the affected air traffic facilities [i.e., Chandler Municipal Airport FCT, Mesa Gateway Airport FCT, and Phoenix TRACON (P50)]. The ATMs from

Chandler Municipal Airport FCT and Mesa Gateway Airport FCT, and management from P50 and the Albuquerque Air Traffic Services District participated in the planning of the airspace changes. These ATMs understand the added responsibilities the airspace changes will have on the air traffic controllers and have complete confidence that these facilities are capable of handling the responsibilities. Regarding the increased workload on the pilots, the airspace changes are required by and consistent with FAA orders and regulations.

Six comments alleged that there was no coordination with airspace stakeholders, including the ATMs at Chandler Municipal Airport FCT, Mesa Gateway Airport FCT, Falcon Field Air Traffic Control Tower (ATCT), P50, or the airport managers at Pegasus Airpark and Stellar Airpark, and that the assigned airspace specialist was not familiar enough with the Phoenix airspace to understand the impacts of the proposed changes. The ATMs from Chandler Municipal Airport FCT and Mesa Gateway Airport FCT requested the biennial airspace reviews of their respective airspaces. These ATMs and the P50 Airspace Manager participated in numerous meetings regarding these amendments and the proposal to ensure that the local conditions were taken into consideration and adjustments were made in accordance with their recommendations and consistent with FAA orders and regulations. The ATM from Falcon Field was not included in these efforts as the airspace is outside of that ATM's geographic area of responsibility. Coordination for Class D and Class E airspace involves the air traffic facility providing control to the affected area. The FAA obtains input from other stakeholders through the rulemaking comment period, which occurred. The personnel assigned to this effort have the requisite training and experience with the FAA orders and regulations regarding airspace and applicable requirements.

One comment questioned whether a safety risk management assessment was completed for this proposal. The standards codified in FAA Order JO 7400.2R, including all amendments, receive a safety risk management assessment. Accordingly, compliance with FAA Order JO 7400.2R when making changes to the National Airspace System satisfies the FAA and ICAO requirements for safety risk management. All changes comply with FAA Order JO 7400.2R.

One comment from Hughes Aerospace Corporation opined that the proposed Class E airspace extending upward from

700 feet above the surface at Stellar Airpark is insufficient and requested a review of the proposed Class E airspace. All data submitted by the commenter was reviewed; however, the official data from the FAA databases showed higher values than those submitted by the commenter. Class E airspace extending upward from 700 feet above the surface must be designated to accommodate arriving IFR operations below 1,500 feet above the surface and departing IFR operations from 700 feet above the surface until they reach 1,200 feet above the surface. The data used for these computations are contained within FAA Form 8260-9, Part D, Airspace.

The commenter's concern is that the initial approach fix, JEWLZ, and holding pattern for the RNAV (GPS) RWY 35 would not be contained in the Class E airspace extending upward from 700 feet above the surface. The altitude requirement for JEWLZ is no lower than 3,000 MSL (mean sea level), equivalent to 1,821 feet AGL (above ground level), which places JEWLZ in the existing Class E airspace extending upward from 1,200 feet above the surface. The holding pattern for RNAV (GPS) RWY 35 is restricted to an altitude no higher than 4,000 feet MSL (2,821 AGL) and no lower than 3,000 feet MSL (1,821 AGL), so the entire holding pattern is within the existing Class E airspace extending upward from 1,200 feet above the surface.

The FAA reviewed the RNAV (GPS) RWY 35 into Stellar Airpark, as requested, and determined that the instrument approach procedure is contained in the appropriate airspace pursuant to FAA Order JO 7400.2R, and the proposed Class E airspace extending upward from 700 feet above the surface for Stellar Airpark is sufficient and correct.

One comment questioned the need to increase the Class D airspace associated with Mesa Gateway Airport. FAA Order JO 7400.2R requires that Class D airspace is of adequate dimensions to: (a) allow an aircraft departing the airport at a standard rate of climb to reach the adjoining airspace while maintaining a 700 feet AGL clearance from the terrain in the area; and (b) protect the instrument approach procedures below 1,000 feet AGL and any departure procedure until the aircraft reaches the next adjoining airspace. In this case, the adjoining airspace for both (a) and (b) is the Class E airspace extending upward from 700 feet above the surface. The Class D airspace at 5.4 miles meets all requirements outlined in FAA Order JO 7400.2R.

One comment stated, "Now normally, a busy Class B area one would request Flight Following—however the FAA policy of the PHX Traccon has been to not grant these VFR FF requests." The commenter did not provide or cite evidentiary support for this claim. It is FAA policy that flight following services are provided upon request as allowed by the air traffic controller workload. The P50 ATM and the General Manager for the Albuquerque Air Traffic Services District were contacted regarding this comment, and their response is, "flight following is and will continue to be granted to all pilots, upon request and workload."

One comment stated that the proposed airspace change would create an overlap between the current Falcon Field, Mesa, AZ, Class D airspace and the proposed Mesa Gateway Airport, Phoenix, AZ, Class D airspace. The FAA reviewed the airspace and confirmed there is no overlap. Other comments objected to the elimination of the existing corridor of Class G airspace between the Class D airspace associated with Falcon Field and Mesa Gateway Airport. However, as described earlier, the expansion of the Mesa Gateway Airport Class D airspace is required for compliance with FAA Order JO 7400.2R.

One comment stated that it would be helpful to have a graphical depiction of the proposed airspace. Pursuant to FAA Order JO 7400.2R, graphical depictions are only required for Class B and Class C airspace proposals. Moreover, providing graphical depictions of every Class D airspace proposal is not feasible considering the high volume of Class D airspace amendments throughout the National Airspace System.

One comment from Brandon Esquer, a member of the P50 National Air Traffic Controllers Association (NATCA), stated that the expansion of the Chandler Municipal Airport Class D airspace is unnecessary and not in compliance with FAA orders. This commenter asserted that the existing IFR transitional airspace is adequate. The commenter's interpretation of the FAA orders and requirements is correct but incomplete. The commenter cited a requirement to protect departures to the lateral limits of the Class D airspace and into the transitional Class E airspace, which is correct. More specifically, the complete requirement for Class D airspace contained in FAA Order JO 7400.2R is that the airspace is sufficiently sized to: (a) allow an aircraft departing the airport at a standard rate of climb to reach the adjoining airspace while maintaining a 700 feet AGL clearance from the terrain in the area; and (b)

protect the instrument approach procedures below 1,000 feet AGL and any departure procedures until the aircraft reaches the next adjoining airspace. In this case, the adjoining airspace for both (a) and (b) is the Class E airspace extending upward from 700 feet above the surface.

In the case of Chandler Municipal Airport, aircraft are unable to maintain a 700 feet AGL clearance above terrain in the Class D surface area within the current 4-mile radius and reach the Class E airspace extending upward from 700 feet above the surface. Additionally, the departure procedure for runways 04L and 04R at Chandler Municipal Airport is a climbing left hand turn to heading 220° to intercept the Stanfield VORTAC 350° radial, then southbound to the Stanfield VORTAC. Prior to this final rule, in the Chandler Municipal Airport Class D airspace aircraft would exit the Chandler Municipal Airport Class D airspace, enter the Mesa Gateway Airport Class D airspace, and re-enter the Chandler Municipal Airport Class D airspace before finally exiting the Chandler Municipal Airport Class D airspace at 3,000 feet MSL directly into a VFR flyway. With the airspace modified by this final rule, aircraft can maintain the required 700 feet AGL terrain clearance within the Class D surface area, and an aircraft on the departure procedure for runways 04L 04R can turn back into the Class D airspace upon reaching the 4.8-mile Class D airspace boundary and exiting the Class D airspace when reaching 4,000 feet MSL.

Furthermore, FAA Order JO 7400.2R requires that departure procedures within the Class D airspace maintain 700 feet AGL clearance of terrain and include airspace 1.8 NM either side of the track to be flown. The requirement within Class E airspace extending upward from 700 feet above the surface is to provide airspace 1.8 NM either side of the track to be flown. For Class E airspace extending upward from 1,200 feet above the surface, the requirement is to provide airspace 4 NM either side of the track to be flown. The expansion of the Chandler Municipal Airport Class D airspace to 4.8 miles meets all the requirements for Class D airspace contained in FAA Order JO 7400.2R, using the Mesa Gateway Airport Class D airspace to protect the eastern area of the departure procedure without requiring additional airspace.

Additionally, raising the vertical limit of the Class D airspace up to but excluding 4,000 feet MSL further protects the IFR aircraft on the departure procedure and reduces the risk of a midair collision with aircraft

operating VFR. The FAA appreciates the comment from this NATCA member; however, his interpretation of FAA orders is incomplete. The expansion of the Chandler Municipal Airport Class D airspace is needed to bring the airspace into compliance with FAA orders and regulations and will enhance safety of aircraft operating IFR from Chandler Municipal Airport by reducing the possibility of midair collisions.

Lastly, a comment from the Mesa Gateway Airport Authority (MGAA) cited five concerns: (1) the proposal does not take into account the volume of training and general aviation operations in the area; (2) the proposed airspace changes for the Mesa Gateway Airport Class D airspace will reduce the arrival and departure capacity and create bottlenecks, forcing complex procedures that will increase taxiing, runway crossings, and create delays; (3) the proposed airspace changes will adversely impact the VFR flyway and VFR traffic; (4) the proposal constitutes an isolated rulemaking that is not harmonized with the Phoenix Area Modernization Plan (PAMP); and (5) the proposal will have an adverse economic impact on Mesa Gateway Airport. The FAA provides the following responses.

The FAA acknowledges MGAA's concerns about impacts to other operations in the area, including the VFR flyway. The FAA only designates controlled airspace as required under FAA orders and 14 CFR part 71 and makes every effort to respect and protect the public's right of transit. However, the changes are required to bring the airspace into compliance with FAA orders and regulations and to support IFR operations in the Phoenix area.

The FAA also acknowledges MGAA's concerns that the proposed airspace changes will reduce the arrival and departure capacity at the Mesa Gateway Airport. The FAA designed the airspace for Mesa Gateway Airport based on the current instrument procedures, bringing the airspace into compliance with current FAA orders and regulations. There are no new instrument procedures in development, and the airspace change does not require new, complex procedures to be developed or implemented at Mesa Gateway Airport. The expansion of the airspace allows aircraft to maintain 700 feet AGL clearance from the terrain required by FAA Order JO 7400.2R. Additionally, the FAA does not agree that expanding the Class D airspace will create ground delays predicted by MGAA (*e.g.*, air traffic bottleneck, increased taxi times, increased runway crossing requirements, air traffic delays, etc.) as the airspace change accommodates

existing procedures and operations at the airport and does not change or impact taxi procedures.

The FAA also acknowledges the ongoing work of the PAMP. The review and amendment of the Mesa Gateway Airport Class D airspace was requested by Mesa Gateway Airport FCT ATM. The Director of Operations for the Central Service Area Air Traffic Services was aware of the pending airspace amendment and has monitored the progress and possible impact of the PAMP. Additionally, the FAA is not bypassing any environmental process. Modification of Class D airspace requires an independent environmental review, which has been completed and is summarized in the Environmental Review section of this action.

Lastly, the FAA declines to alter the proposal based on the claim that the airspace changes will have an adverse economic impact on Mesa Gateway Airport. The FAA does not have statutory authority to consider economic factors as part of its airspace designations. Further, the comment from MGAA did not explain how the expansion of the Class D airspace at Mesa Gateway Airport would result in adverse economic impacts, instead providing only a general explanation of how Mesa Gateway Airport contributes to the economy of the area. The airspace change expands the Class D airspace to support the existing instrument procedures. It does not add or change any instrument procedures or otherwise directly impact operations at Mesa Gateway Airport.

Differences From the NPRM

Subsequent to publication of the NPRM, a typographical error was discovered in the NPRM. In the Chandler, AZ, Class D airspace legal description, "latitude" was used instead of "longitude." Correction of this typographic error does not change the boundaries of the airspace as they currently exist or as proposed or impose any additional requirements on users of the airspace. Accordingly, the FAA finds good cause that recirculating this action for public comment is unnecessary.

In response to the comments received on the NPRM and in the interest of safety, the vertical limit of the Chandler, AZ, Class D airspace is being raised from the current limit of 3,000 feet MSL up to but excluding 4,000 feet MSL rather than 3,700 feet MSL as proposed in the NPRM. This will close the gap between the expanded Class D airspace and the overlying Class B airspace, reducing hazards to Class B operations and preventing VFR pilots from

attempting to navigate through the narrow gap without communicating with air traffic control. The Administrative Procedure Act (APA) authorizes agencies to dispense with ordinary notice and comment requirements for rules when the agency for "good cause" finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. 553(b)(B). This change is made in response to a valid safety concern raised by the numerous comments received on the NPRM. The FAA finds good cause that recirculating this action for public comment is unnecessary, as the change directly responds to dozens of comments already received.

Incorporation by Reference

Class D and E airspace designations are published in paragraphs 5000 and 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11M, dated July 30, 2026, and effective September 15, 2026. These amendments will be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11K, which lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points, is publicly available as listed in the **ADDRESSES** section of this document.

The Rule

This action amends 14 CFR part 71 by modifying the Class D airspace and establishing Class E airspace extending upward from 700 feet above the surface at Chandler, Arizona, and Phoenix, Arizona, due to biennial airspace reviews conducted pursuant to FAA Order JO 7400.2R.

For the Chandler Municipal Airport, Chandler, AZ, Class D airspace this action: (1) increases the radius from 4 miles to 4.8 miles; (2) increases the vertical limit from 3,000 feet MSL to up to but excluding 4,000 feet MSL; (3) removes Williams Gateway Airport and the associated exclusion area as they are no longer required; (4) adds an exclusion area west of longitude 111°53'41" W; (5) updates the airspace legal description header from "Chandler Municipal Airport, AZ" to "Chandler, AZ" to comply with changes to FAA Order JO 7400.2R; and (6) updates the outdated term of "Airport/Facility Directory" to "Chart Supplement."

For the Mesa Gateway Airport, Phoenix, AZ, this action: (1) increases the radius from 5 miles to 5.4 miles; (2) adds an exclusion area for the Chandler

Municipal Airport Class D airspace; (3) adds an exclusion area within a 1.2-mile radius of Pegasus Airpark, Queen Creek, AZ; (4) updates the name of the airport from Williams Gateway Airport to Mesa Gateway Airport and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database; (5) updates the airspace legal description header from "Chandler, AZ" to "Phoenix, AZ" to coincide with the FAA's aeronautical database; and (6) updates the outdated term of "Airport/Facility Directory" to "Chart Supplement."

This action establishes Class E airspace extending upward from 700 feet above the surface at Stellar Airpark, Chandler, AZ, within a 13.9-mile radius of the airport.

This action establishes Class E airspace extending upward from 700 feet above the surface at Mesa Gateway Airport, Phoenix, AZ: (1) within a 7.9-mile radius of the airport; (2) within 4 miles northeast and 8 miles southwest of the 136° bearing for the Mesa Gateway: RWY 30C-LOC extending from the 7.9-mile radius of the airport to 17.7 miles southeast of the Mesa Gateway: RWY 30C-LOC; and (3) within 7.9 miles northeast and 4 miles southwest of the 136° bearing from the airport extending from the 7.9-mile radius of the airport to 12.6 miles southeast of the airport.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Order 2100.6B, "Policies and Procedures for Rulemakings" (March 10, 2025); and (3) is expected to result in, at most, de minimis costs from compliance with applicable operating requirements or minor flight rerouting for operators choosing to navigate around the controlled airspace. Since these amendments are routine and the expected impact to operators is de minimis, the FAA certifies that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA

Order 1050.1G, "FAA National Environmental Policy Act Implementing Procedures," Paragraph B-2.5(a). This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11M, Airspace Designations and Reporting Points, dated July 30, 2026, and effective September 15, 2026, is amended as follows:

Paragraph 5000 Class D Airspace

AWP AZ D Chandler, AZ [Amended]

Chandler Municipal Airport, AZ
(Lat. 33°16'09" N, long. 111°48'40" W)

That airspace extending upward from the surface up to but excluding 4,000 feet MSL within a 4.8-mile radius of Chandler Municipal Airport, excluding that portion west of longitude 111°53'41" W. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Chart Supplement.

* * * * *

AWP AZ D Phoenix, AZ [Amended]

Mesa Gateway Airport, AZ
(Lat. 33°18'28" N, long. 111°39'20" W)
Pegasus Airpark, AZ
(Lat. 33°12'31" N, long. 111°37'02" W)

That airspace extending upward from the surface to and including 3,900 feet MSL within a 5.4-mile radius of Mesa Gateway Airport, excluding that portion within the Chandler Municipal Airport, Chandler, AZ, Class D airspace; and excluding that portion within a 1.2-mile radius of Pegasus Airpark; and excluding that portion within the Phoenix, AZ, Class B airspace. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and

times will thereafter be continuously published in the Chart Supplement.

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Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth

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AWP AZ E5 Chandler, AZ [Establish]

Stellar Airpark, AZ
(Lat. 33°17'56" N, long. 111°54'57" W)

That airspace extending upward from 700 feet above the surface within a 13.9-mile radius of Stellar Airpark.

* * * * *

AWP AZ E5 Phoenix, AZ [Establish]

Mesa Gateway Airport, AZ
(Lat. 33°18'28" N, long. 111°39'20" W)

Mesa Gateway: RWY 30C-LOC
(Lat. 33°19'13" N, long. 111°40'09" W)

That airspace extending upward from 700 feet above the surface within a 7.9-mile radius of Mesa Gateway Airport; and within 4 miles northeast and 8 miles southwest of the 136° bearing from the Mesa Gateway: RWY 30C-LOC extending from the 7.9-mile radius of the Mesa Gateway Airport to 17.7 miles southeast of the Mesa Gateway: RWY 30C-LOC; and within 7.9 miles northeast and 4 miles southwest of the 136° bearing from the Mesa Gateway Airport extending from the 7.9-mile radius of Mesa Gateway Airport to 12.6 miles southeast of the Mesa Gateway Airport.

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Issued in Fort Worth, Texas, on October 28, 2026.

Jerry J. Creecy,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

[FR Doc. 2026–22197 Filed 10–29–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31690; Amdt. No. 4241]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPS) and associated Takeoff Minimums and Obstacle Departure procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or

because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective October 30, 2026. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 30, 2026.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Rune Duke, Manager, Standards Section, Flight Procedures and Airspace Group, Aviation Safety, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg. 26, Room 217, Oklahoma City, OK 73099. Telephone (405) 954–1139.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by establishing, amending, suspending, or removes

SIAPS, Takeoff Minimums and/or ODPs. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The applicable FAA Forms are 8260–3, 8260–4, 8260–5, 8260–15A, 8260–15B, when required by an entry on 8260–15A, and 8260–15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, pilots do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPS, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this

amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on October 23, 2026.

Rune Duke,

Manager, Standards Section, Flight Procedures and Airspace Group, Flight Technologies & Procedures Division, Federal Aviation Administration.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 14 CFR part 97 is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 26 November 2026

Miami, FL, TMB, ILS OR LOC RWY 9R, Amdt 12
 Miami, FL, TMB, RNAV (GPS) RWY 9L, Amdt 1
 Miami, FL, TMB, RNAV (GPS) RWY 9R, Amdt 3
 Miami, FL, TMB, RNAV (GPS) RWY 27L, Amdt 3
 Miami, FL, TMB, RNAV (GPS) RWY 27R, Amdt 1
 San Antonio, TX, SAT, RNAV (GPS) Y RWY 31L, Amdt 2A

Effective 24 December 2026

Yakutat, AK, YAK/PAYA, Takeoff Minimums and Obstacle DP, Amdt 6
 Coalinga, CA, C80, RNAV (GPS) RWY 30, Orig-A
 Salinas, CA, SNS, LOC RWY 31, Amdt 6A
 Victorville, CA, VCV, ETHER ONE, Graphic DP
 Victorville, CA, VCV, Takeoff Minimums and Obstacle DP, Amdt 3
 Ashburn, GA, 75J, RNAV (GPS) RWY 17, Amdt 1
 Ashburn, GA, 75J, RNAV (GPS) RWY 35, Orig-A
 Chicago/Rockford, IL, RFD, RADAR-1, Amdt 11A
 Chicago/Rockford, IL, RFD, RNAV (GPS) RWY 7, Amdt 1F
 Chicago/Rockford, IL, RFD, RNAV (GPS) RWY 25, Amdt 1D
 Wichita, KS, ICT, ILS OR LOC RWY 1L, ILS RWY 1L (SA CAT I), ILS RWY 1L (CAT II), Amdt 3E
 Wichita, KS, ICT, ILS OR LOC RWY 19R, Amdt 6
 Wichita, KS, ICT, RNAV (GPS) Y RWY 1L, Amdt 1E
 Wichita, KS, ICT, RNAV (RNP) Z RWY 1L, Orig-E
 Lexington, KY, LEX, RNAV (GPS) RWY 27, Orig-C
 Joplin, MO, JLN, RNAV (GPS) RWY 18, Amdt 1
 Washington, MO, FYG, RNAV (GPS) RWY 15, Amdt 3
 Washington, MO, FYG, RNAV (GPS) RWY 33, Amdt 3
 Washington, MO, FYG, Takeoff Minimums and Obstacle DP, Amdt 2
 Billings, MT, BIL, RNAV (GPS) RWY 7, Amdt 3
 Billings, MT, BIL, RNAV (GPS) RWY 25, Amdt 3
 Bozeman, MT, BZN, RNAV (GPS) Y RWY 30, Amdt 1
 Bozeman, MT, BZN, RNAV (RNP) Z RWY 30, Amdt 2
 Plentywood, MT, PWD, RNAV (GPS) RWY 12, Orig-E
 Plentywood, MT, PWD, RNAV (GPS) RWY 30, Orig-E
 Kinston, NC, ISO, ILS OR LOC RWY 5, Amdt 14
 Winnemucca, NV, WMC, FESKO TWO, Graphic DP
 Winnemucca, NV, WMC, RNAV (GPS) RWY 15, Amdt 1
 Winnemucca, NV, WMC, RNAV (GPS) RWY 33, Amdt 1

Winnemucca, NV, WMC, Takeoff Minimums and Obstacle DP, Amdt 4
 Portland, OR, PDX, ILS OR LOC RWY 10L, ILS RWY 10L (SA CAT I), ILS RWY 10L (SA CAT II), Amdt 5
 Gettysburg, PA, W05, Takeoff Minimums and Obstacle DP, Amdt 1
 Corsicana, TX, CRS, RNAV (GPS) RWY 14, Amdt 1

[FR Doc. 2026-22222 Filed 10-29-26; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31691; Amdt. No. 4242]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective October 30, 2026. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 30, 2026.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590-0001;
2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Rune Duke, Manager, Standards Section, Flight Procedures and Airspace Group, Aviation Safety, Federal Aviation Administration, Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg 26, Room 217, Oklahoma City, OK 73099. Telephone (405) 954-1139.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P-NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, pilots do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the ADDRESSES section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, October 23, 2026.

Rune Duke,
Manager, Standards Section, Flight Procedures and Airspace Group, Flight Technologies & Procedures Division, Federal Aviation Administration.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 14 CFR part 97 is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

- 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.
- 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * Effective Upon Publication

AIRAC date	State	City	Airport	FDC No.	FDC date	Procedure name
26–Nov–26 ...	CO	EAGLE	EAGLE COUNTY RGNL	6/3749	10/5/2026	RNAV (RNP) Z RWY 25, Orig-A.
26–Nov–26 ...	CO	EAGLE	EAGLE COUNTY RGNL	6/3773	10/5/2026	RNAV (RNP) X RWY 25, Orig-A.

[FR Doc. 2026–22223 Filed 10–29–26; 8:45 am]
BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1211

[Docket No. CPSC–2015–0025]

Safety Standard for Automatic Residential Garage Door Operators

AGENCY: U.S. Consumer Product Safety Commission.
ACTION: Direct final rule.

SUMMARY: In October 2025, updates to the entrapment protection provisions in the UL 325 standard were accepted under the Consumer Product Safety Improvement Act of 1990 (Improvement Act) for inclusion in the Commission’s

mandatory safety regulation for automatic residential garage door operators. In this direct final rule, the Consumer Product Safety Commission (Commission) is amending the Commission’s automatic residential garage door operators mandatory regulation to align with the changes in UL 325.

DATES: The rule is effective on December 29, 2026, unless we receive significant adverse comments by November 30, 2026. If we receive a timely significant adverse comment, we will publish a notification in the **Federal Register**, withdrawing this direct final rule before its effective date. The incorporation by reference of certain material listed in this rule is approved by the Director of the Federal Register as of December 29, 2026. The incorporation by reference of certain other material listed in this rule was

approved by the Director as of May 9, 2016.

ADDRESSES: You can submit comments, identified by Docket No. CPSC–2015–0025, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <https://www.regulations.gov>. Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by email, except as described below.

Confidential Written Submissions: CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such

comments by email to cpsc-os@cpsc.gov.

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: <https://www.regulations.gov>. Do not submit to this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for confidential written submissions.

Docket: For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>, and insert the docket number, CPSC–2015–0025, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Julio Alvarado, Compliance Officer, U.S. Consumer Product Safety Commission, 441 G Street NW, Washington, DC 20548; telephone: (301) 504–7418; email: jalvarado@cpsc.gov; or Jay Kadiwala, Electrical Engineer, U.S. Consumer Product Safety Commission, National Product Testing & Evaluation Center, 5 Research Place, Suite 101–09, Rockville, MD 20850; telephone (301) 987–2517; email: jkadiwala@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 203(a) and (b) of the Improvement Act, Public Law 101–608, states that the entrapment protection requirements of UL 325, “Standard for Safety for Door, Drapery, Gate, Louver, and Window Operators and Systems,” (UL 325), are considered a consumer product safety rule under the Consumer Product Safety Act (CPSA), 15 U.S.C. 2056 Note. On June 19, 1991, as mandated by the Improvement Act, the Commission issued a final rule codifying the provisions of the entrapment protection requirements of UL 325 at 16 CFR part 1211. 56 FR 28050. On December 21, 1992, as directed in section 203(b) of the Improvement Act, the Commission published a final rule to include the additional entrapment protection provisions adopted by UL in UL 325 in the CPSC mandatory standard for automatic residential garage door operators. 57 FR 60449.

Section 203(c) of the Improvement Act requires UL to notify CPSC of any revisions to UL 325, which is the basis for the Commission’s garage door operator (GDO) regulation. When UL

notifies the Commission of a revision, that revision “shall be incorporated in the consumer product safety rule . . . unless, within 30 days of such notice, the Commission notifies [UL] that the Commission has determined that such revision does not carry out the purposes of subsection (b)” of section 203 of the Improvement Act, which initially mandated the UL 325 entrapment protection requirements. As provided in the Improvement Act, the Commission has revised the GDO standard several times following UL notification to the Commission of changes to the entrapment protection requirements of UL 325. The Commission last updated the GDO rule in 2024, to reflect changes made to the entrapment protection provisions of UL 325 up to that time. 89 FR 18538 (Mar. 24, 2024).

On September 23, 2025, UL notified the Commission of revisions to UL 325 regarding the entrapment protection provisions related to residential garage door operators. In October 2025, in accordance with the procedure in the Improvement Act, the Commission accepted for inclusion in its mandatory standard the relevant revisions to UL 325 regarding the entrapment protection requirements for automatic residential GDOs. To implement the revisions to UL 325 for residential GDOs in the Commission mandatory standard, this direct final rule revises the provisions of the GDO rule at 16 CFR part 1211 to reflect the earlier acceptance of the revisions for the entrapment protection requirements for automatic residential GDOs in UL 325, Seventh Edition.¹

II. Changes to UL 325

Since the last update of the mandatory GDO regulation in 2024, there has been one published revision to UL 325: Seventh Edition, published on September 15, 2025. The revisions to UL 325 regarding the entrapment protection requirements for automatic residential GDOs are discussed in detail below.

A. Battery Powered Applications

Two new sections, 33.2.2.11 (GDOs Employing Battery Backup (Vertical Moving Doors)) and 33.2.3.11 (GDOs Employing Battery Backup (Horizontally Sliding Doors)), were added to UL 325. These provisions have new test requirements in sections 33.2.2.12 and 33.2.3.12, respectively, to ensure that the entrapment protection operations function under backup battery power but do not function if there is not enough battery power for the garage door operator to complete an open/close

cycle. In this circumstance, the system verifies there is enough battery charge to perform both an open and close cycle and if the system cannot do that function, the door will remain open and the entrapment protection system rendered inoperable, which causes the door to be inoperable, until the battery is charged or AC mains power is restored. The performance tests are conducted on the battery back-up at the lowest operational voltage (battery must be fully charged and then discharged to the manufacturer’s specified lowest operating voltage) to ensure that the battery has enough stored energy for the operator to detect an object and open the door when there is no AC power. These new requirements support the purpose of the Improvement Act by ensuring the GDO will function to prevent entrapment even when AC power is cut and the system is powered by the battery backup at the lowest operational voltage.

B. Clarifications for Monitoring for Secondary Entrapment Protection for Residential Garage Door Operators Requirements

Residential garage door operator systems monitor the presence of the secondary entrapment protection device to ensure that it is ready for operation at least once during each close cycle. If the secondary entrapment protection device is not detected by the system circuit, is disconnected from the circuit, or there is an error in the device, the door will not operate. Section 33.3.3 of the UL standard currently states “operator shall monitor for the presence and correct operation of the device at least once during each close cycle.”

The revision to section 33.3.3 of UL 325 (contained in 16 CFR 1211.8(c)) also removes the phrase “and correct operation” regarding the secondary entrapment protection device. The UL 325 Technical Committee made this change because there is no practical way to determine what the “correct operation” is to allow for testing to determine whether GDO systems were specifically meeting this requirement. Detecting the presence of the secondary entrapment protection device is sufficient to ensure the secondary entrapment protection device is functional and will respond if the primary system fails.

C. Instruction Manual Section

The revisions to UL 325 sections 60.1.14 (currently contained in 16 CFR 1211.16(a)(10)) and 60.3 (contained in 16 CFR 1211.16(a)(2)) remove inaccurate and misleading references to “residential garage doors.” Section

¹ The Commission voted 3–0 to publish this notification.

60.3.2 states that “[a] residential garage door operator or system shall be provided with complete and specific instructions for . . . satisfactory operation of the door.” This change clarifies that the printed instructions required by UL 325 only apply to a garage door that is part of a residential garage door operator system and not a garage door by itself. This revision allows manufacturers to accurately communicate this information to consumers.

III. Description of the Direct Final Rule

The direct final rule amends 16 CFR part 1211 to include the revisions regarding the entrapment protection requirements for automatic residential GDOs in UL 325, Seventh Edition discussed above. All revisions in the direct final rule concern the GDO regulation in subpart A and D of part 1211. The direct final rule does not change any of the certification (subpart B), or recordkeeping (subpart C) provisions of the GDO regulation.

The revisions to 16 CFR part 1211 are described as follows.

- *Changes to section 1211.4.* Section 1211.4 updates the reference to UL 325:2025 and adds a new paragraph (d) stating the requirements of the rule also cover battery-powered operators, including operators with battery back-up systems.
- *Changes to section 1211.5.* Section 1211.5 updates the reference to UL 325:2025.
- *Changes to section 1211.7.* Section 1211.7 adds new paragraphs (b)(11), (b)(12), (c)(11), and (c)(12) with requirements for vertical and horizontal garage door operators employing a battery back-up system.
- *Changes to section 1211.8.* Section 1211.8(c) deletes the phrase “and correct operation” as the phrase is unnecessary because there is no practical way to determine what the “correct operation” is to allow for testing to determine whether GDO systems were specifically meeting this requirement. Section 1211.8(f) adds language from a previous revision to the standard that was inadvertently left out of the rule to be consistent with the language of the voluntary standard.
- *Changes to section 1211.16.* Section 1211.16(a)(2), (3), and (10)(i) add clarifying language “or system” after garage door operator to indicate it may apply to a whole system and not just the garage door operator, if applicable.
- *Changes to section 1211.16.* Section 1211.40(d)(1) updates the reference UL 325:2025 and adds Supplement C to the incorporation by reference.

This direct final rule amends the mandatory GDO rule at 16 CFR part 1211 to include the revisions to the entrapment protection requirements for automatic residential GDOs in UL 325:2025, Seventh Edition.

IV. Incorporation by Reference

Sections 1211.4, 1211.5, 1211.7, and 1211.40 of the direct final rule incorporate by reference provisions in UL 325:2025. The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss in the preamble of a final rule ways in which material the agency incorporates by reference is reasonably available to interested parties and how interested parties can obtain the material. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR regulations requiring a summary of the material in the voluntary standard, UL 325:2025, *Standard for Door, Drapery, Gate, Louver, and Window Operators and Systems* covers performance requirements, test methods, and labeling requirements for residential garage door operators, drapery, louver, and window operator systems.

UL 325:2025 is copyrighted. UL 325:2025 is reasonably available to interested parties in several ways. A read-only copy of the revised standard UL 325:2025 is available to view at no cost on UL’s website at www.ulstandards.com/IBR/logon.aspx. Additionally, interested parties can purchase a copy of the UL standard from UL, 151 Eastern Avenue, Bensenville, IL 60106, Telephone: 1–888–853–3503 or online at: www.shopulstandards.com. Finally, interested parties can schedule an appointment to inspect a copy of the standard at CPSC’s Office of the Secretary, U.S. Consumer Product Safety Commission, 441 G Street NW, Washington, DC 20548, telephone: 301–504–7479; email: cpsc-os@cpsc.gov.

UL 1998 is also referenced in the amendatory text of this document, but is already approved for use in that section (§ 1211.8).

V. Direct Final Rule Process

The Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA; 5 U.S.C. 551–559) generally requires agencies to provide notice of a rule and an opportunity for interested parties to comment on it, section 553 of the APA provides an exception when the agency “for good cause finds” that notice and comment are “impracticable,

unnecessary, or contrary to the public interest.” *Id.* 553(b)(B).

The Commission concludes that notice and comment are not necessary here because the Commission is taking the limited action of amending the GDO rule to conform the regulation to the relevant changes made to UL 325 that were previously accepted in October 2025 under the Improvement Act. Because this document merely updates the GDO rule to reflect the previously accepted changes to UL 325, the Commission considers this rulemaking to be a non-controversial matter that is not likely to generate comments. Public comment will not impact the acceptance of the substantive changes to UL 325 under the Improvement Act that has previously occurred. Additionally, public comments would not alter substantive changes to the standard or the effect of the revised standard as a consumer product safety standard under section 203(a) of the Improvement Act. Under these circumstances, notice and comment are unnecessary. Therefore, the Commission concludes that the direct final rule process is appropriate.

In Recommendation 2024–6, the Administrative Conference of the United States (ACUS) endorses direct final rulemaking as an appropriate procedure to expedite rules that are noncontroversial and that are not expected to generate significant adverse comments. *See* 89 FR 106406 (Dec. 30, 2024). ACUS recommends that agencies use the direct final rule process when they act under the “unnecessary” prong of the good cause exemption in 5 U.S.C. 553(b)(B). 89 FR 106406, 106409. Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule, because CPSC does not expect any significant adverse comments.

Unless CPSC receives a significant adverse comment within 30 days of this notification, the rule will become effective on December 29, 2026. In accordance with ACUS’s recommendation, the Commission considers a significant adverse comment to be one where the commenter explains why the rule would be inappropriate, “including challenges to the rule’s underlying premise or approach,” or where the commenter explains why the rule would be ineffective or unacceptable without change. *Id.* at 106409. If the Commission receives a significant adverse comment, the Commission will withdraw any portion of this direct final rule related to such a comment. Depending on the comment and other circumstances, the Commission may then incorporate the adverse comment into a subsequent

direct final rule or publish a notice of proposed rulemaking, providing an opportunity for public comment.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612) generally requires agencies to review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603, 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* As discussed in section V. Direct Final Rule Process of this preamble, the Commission has determined that notice and the opportunity to comment are unnecessary for this rule. Therefore, the RFA does not apply. CPSC also notes the limited nature of this document, which merely updates the GDO rule to conform the regulation to the applicable changes made to UL 325 under the Improvement Act.

VII. Paperwork Reduction Act

The current mandatory standard for garage door operators includes labeling and instruction manual requirements that constitute a “collection of information,” as defined in the Paperwork Reduction Act (PRA; 44 U.S.C. 3501–3521). While the rule clarifies language regarding the description of products subject to the rule in the instruction manual section of the rule, the clarifications do not add to the burden hours because the products already require marking and labeling. Because the information collection burden is essentially unchanged, the revision does not affect the information collection requirements or approval related to the standard.

VIII. Effective Date

Because the changes to the entrapment protection requirements of the UL 325 standard are not substantial and the industry has had more almost a year since publication of the revised UL 325 voluntary standard to come into compliance with its entrapment protection revisions, 60 days is sufficient for the effective date. Therefore, the effective date of the direct final rule is December 29, 2026.

IX. Preemption

Section 203(f) of the Improvement Act contains a provision preempting under 15 U.S.C. 2075 those provisions of laws of States or political subdivisions which relate to the labeling of automatic residential garage door openers and those provisions which do not provide

at least the equivalent degree of protection from the risk of injury associated with automatic residential garage door openers as the consumer product safety rule. 15 U.S.C. 2056 Note.

X. Environmental Considerations

Commission rules are categorically excluded from any requirement to prepare an environmental assessment or an environmental impact statement where they “have little or no potential for affecting the human environment.” 16 CFR 1021.5(c). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

XI. Congressional Review Act and Executive Order 12866

Pursuant to the Congressional Review Act (CRA) and Executive Order (E.O.) 12866, the Office of Management and Budget’s Office of Information and Regulatory Affairs has determined that this rule does not qualify as a “major rule,” as defined in 5 U.S.C. 804(2), and is not a significant regulatory action as defined under section 2(f) of E.O. 12866. To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1211

Consumer protection, Imports, Incorporation by reference, Labeling, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Commission amends 16 CFR part 1211 as follows:

PART 1211—SAFETY STANDARDS FOR AUTOMATIC RESIDENTIAL GARAGE DOOR OPERATORS

- 1. The authority citation for part 1211 continues to read as follows:

Authority: 15 U.S.C. 2056 Note; 15 U.S.C. 2063 and 2065.

- 2. In § 1211.4:

- a. Amend paragraph (c) by removing the text “UL 325–2017” and adding, in its place, the text “UL 325:2025”; and,
- b. Add paragraph (d).

The addition reads as follows:

§ 1211.4 General requirements for protection against risk of injury.

* * * * *

(d) These requirements also cover battery-powered operators, including operators with battery back-up systems, with user-replaceable and/or non-user battery subject to the requirement of § 1211.7 and the applicable

requirements of Supplement SC of UL 325:2025 (incorporated by reference, see § 1211.40).

- 3. In § 1211.5 amend the introductory text of paragraph (a) and paragraph (b)(4) by removing the text “UL 325–2017” and adding, in its place, the text “UL 325:2025”.

- 4. Amend § 1211.7 by adding paragraphs (b)(11) and (12) and (c)(11) and (12) to read as follows:

§ 1211.7 Inherent primary entrapment protection requirements.

* * * * *

(b) * * *

(11) An operator employing a battery back-up system shall operate as specified in paragraphs (b)(1), (2), and (3) of this section, as applicable; or the operator is rendered inoperative (any case in which the operator will not complete a full cycle, open, and close, of travel) when tested in accordance with paragraph (b)(12) of this section and the applicable requirements of Supplement SC of UL 325:2025 (incorporated by reference, see § 1211.40).

(12) Compliance with paragraph (b)(11) of this section shall be verified with a fully charged battery, and then with the same battery after it has been discharged per the manufacturer’s recommendations to the operator’s lowest operational voltage.

(c) * * *

(11) An operator employing battery back-up system shall operate as specified in paragraphs (c)(1), (2), and (3) of this section as applicable; or the operator is rendered inoperative (any case in which the operator will not complete a full cycle, open and close, of travel) when tested in accordance with paragraph (c)(12) of this section and the applicable requirements of Supplement SC of UL 325:2025 (incorporated by reference, see § 1211.40).

(12) Compliance with paragraph (c)(11) of this section shall be verified with a fully charged battery, and then with the same battery after it has been discharged per the manufacturer’s recommendations to the operator’s lowest operational voltage.

* * * * *

- 5. In § 1211.8:

- a. Amend the introductory text of paragraph (c) by removing the text “and correct operation”; and
- b. Revise paragraph (f).

The revision reads as follows:

§ 1211.8 Secondary entrapment protection requirements.

* * * * *

(f) An inherent secondary entrapment protection device described in

§ 1211.6(b)(3) shall comply with the applicable requirements in § 1211.13, independent of the primary entrapment protection. The independent primary and secondary entrapment protection devices shall not use the same detection means nor measure the same physical properties. Software used in an inherent secondary entrapment protection device shall comply with UL 1998 (incorporated by reference, see § 1211.40).

■ 6. Amend § 1211.16 by revising paragraphs (a)(2) and (3), and (a)(10)(i) to read as follows:

§ 1211.16 Instruction manual.

* * * * *

(a) * * *

(2) Instructions that clearly detail installation and adjustment procedures required to effect proper operation of the safety means provided shall be provided with each door operator (or system).

(3) A residential garage door operator or system shall be provided with complete and specific instructions for the correct adjustment of the control mechanism and the need for periodic checking and, if needed, adjustment of the control mechanism so as to maintain satisfactory operation of the door.

* * * * *

(10) * * *

(i) Residential garage door operators (or systems), instructions of this section, as applicable.

* * * * *

■ 7. Revise and republish § 1211.40 to read as follows:

§ 1211.40 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Consumer Product Safety Commission (CPSC) and at the National Archives and Records Administration (NARA). Contact CPSC at: Office of the Secretary, 441 G Street NW, Washington, DC 20548; phone (301) 504-7479; email: cpsc-os@cpsc.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from the following sources:

(a) Door and Access Systems Manufacturers' Association, International (DASMA), 1300 Sumner Avenue, Cleveland, OH 44115-2851; phone: (216) 241-7333; email: dasma@dasma.com; website: www.dasma.com/dasma-standards/.

(1) ANSI/DASMA 102, Specifications for Sectional Doors, 2011 revision, dated May 19, 2011; into § 1211.6(c).

(2) [Reserved]

(b) National Fire Prevention Association (NFPA), 1 Batterymarch Park, Quincy, MA 02269-9101; phone: (800) 344-3555; www.nfpa.org/.

(1) NFPA 70, National Electrical Code, 2014 edition, effective August 21, 2013; into § 1211.2(c).

(2) [Reserved]

(c) UL Standards and Engagement (UL), 151 Eastern Avenue, Bensenville, IL 60106; phone: 1-888-853-3503; website: <https://shopulstandards.com/>.

(1) ANSI/CANUL 325:2025 (UL 325:2025), Standard for Safety: Door, Drapery, Gate, Louver, and Window Operators and Systems, Seventh Edition, Revision dated September 15, 2025; into §§ 1211.4(c) and (d); 1211.5; 1211.7(b) and (c).

(2) UL 746C, Standard for Safety: Polymeric Materials—Use in Electrical Equipment Evaluations, Sixth Edition, dated September 10, 2004; into §§ 1211.10(d) and (e); 1211.12(c).

(3) UL 991, Standard for Safety: Tests for Safety-Related Controls Employing Solid-State Devices, Third Edition, dated October 22, 2004; into §§ 1211.4(c); 1211.5(b).

(4) UL 1998, Standard for Safety: Software in Programmable Components, Third Edition, December 18, 2013; into § 1211.8(f).

Note 1 to § 1211.40: If the material listed in this section is not available through the publisher's online store, it may be necessary to contact the publisher directly.

Alberta E. Mills,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2026-22213 Filed 10-29-26; 8:45 am]

BILLING CODE 6355-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. FDA-2026-N-12255]

Medical Devices; Anesthesiology Devices; Classification of the Spinal Imaging System for Neuraxial Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the spinal imaging system for neuraxial

procedures into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the spinal imaging system for neuraxial procedures. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 30, 2026. The classification was applicable on January 19, 2024.

FOR FURTHER INFORMATION CONTACT:

Bradley Quinn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1220, Silver Spring, MD 20993-0002, 301-796-5575, Bradley.Quinn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the spinal imaging system for neuraxial procedures into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval.

We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial

equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On February 1, 2022, FDA received IntuiTap Medical, Inc.’s request for De Novo classification of the VerTouch Spinal Imaging Device. FDA reviewed the request in order to classify the device under the criteria for

classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on January 19, 2024, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 868.1985.¹ We have named the generic type of device “spinal imaging system for neuraxial procedures,” and it is identified as is a sensor and software system that is used to assist in identification of the interspinous space for neuraxial procedures.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR SPINAL IMAGING SYSTEMS FOR NEURAXIAL PROCEDURES

Identified risks to health	Mitigation measures
Inaccurate interspinous space identification leading to: <ul style="list-style-type: none">• Increased pain.• Bleeding.• Unintended dural puncture.• Injury to other deeper structures.	Clinical performance testing; Non-clinical performance testing; Human factors testing; Software verification, validation, and hazard analysis; and Labeling.
Increased procedure time due to improper device use	Clinical performance testing; Human factors testing; Software verification, validation, and hazard analysis; and Labeling.
Electrical shock or interference with other devices	Electrical safety testing; and Electromagnetic compatibility testing.
Adverse tissue reaction	Biocompatibility evaluation.
Infection	Sterilization validation.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls

named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under

section 510(m) of the FD&C Act. At this time FDA has not made this determination for spinal imaging systems for neuraxial procedures. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

¹ FDA notes that the “ACTION” caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to

indicate that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register’s (OFR) interpretations of the Federal Register Act (44

U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 868

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

■ 1. The authority citation for part 868 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 868.1985 to subpart B to read as follows:

§ 868.1985 Spinal imaging system for neuraxial procedures.

(a) *Identification.* A spinal imaging system for neuraxial procedures is a sensor and software system that is used to assist in identification of the interspinous space for neuraxial procedures.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must evaluate:

(i) Rate of neuraxial procedure success across the intended use population;

(ii) Procedure time;

(iii) Adverse events, including pain, bleeding, unintended dural puncture, and injury to other spinal structures; and

(iv) Comparison of performance to manual palpation or alternative method of determination of the target insertion site.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must evaluate the accuracy, repeatability, and resolution of imaging of the underlying anatomy representative of intended use populations.

(3) Human factors testing must demonstrate that the user can correctly use the device based solely on the directions for use.

(4) Software verification, validation, and hazard analysis must be performed. Validation testing must verify and validate proper image construction.

(5) Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.

(6) The patient-contacting components of the device must be demonstrated to be biocompatible.

(7) Performance testing must demonstrate the sterility of any device components intended to be labeled sterile.

(8) Labeling must include a warning that risks inherent to neuraxial procedures under standard of care conditions are still present with use of the device.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22181 Filed 10–29–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. FDA–2026–N–12385]

Medical Devices; Anesthesiology Devices; Classification of the Over-the-Counter Device To Assess Risk of Sleep Apnea

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the over-the-counter device to assess risk of sleep apnea into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the over-the-counter device to assess risk of sleep apnea. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 30, 2026. The classification was applicable on February 6, 2024.

FOR FURTHER INFORMATION CONTACT: Prakhya Singh, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1255, Silver Spring, MD 20993–0002, 301–796–6562, Prakhya.Singh@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the over-the-counter device to assess risk of sleep apnea into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and

remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying

the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On May 31, 2023, FDA received Samsung Electronics Co., Ltd’s request for De Novo classification of the Sleep Apnea Feature. FDA reviewed the request in order to classify the device

under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 6, 2024, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 868.2378.¹ We have named the generic type of device “over-the-counter device to assess risk of sleep apnea,” and it is identified as a device that is intended to provide a notification of the risk of sleep apnea in users who have not been previously diagnosed with sleep apnea. This device uses software algorithms to analyze input sensor signals and provide a risk assessment for sleep apnea. It is not intended to provide a standalone diagnosis, replace traditional methods of diagnosis (e.g., polysomnography), assist clinicians in diagnosing sleep disorders, or be used as an apnea monitor.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR OVER-THE-COUNTER DEVICES TO ASSESS RISK OF SLEEP APNEA

Identified risks to health	Mitigation measures
False negative resulting in failure to assess risk of sleep apnea and delay of further evaluation or treatment.	Clinical performance testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; and Labeling.
False positive resulting in additional unnecessary medical procedures ..	Clinical performance testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; and Labeling.
Misinterpretation and/or overreliance on device output, leading to: <ul style="list-style-type: none"> • Failure to seek treatment despite sleep apnea symptoms. • Discontinuing or modifying treatment for sleep apnea. 	Human factors testing; and Labeling.
Poor quality sensor data input to the device software function resulting in incorrect sleep apnea assessment.	Non-clinical performance testing Software verification, validation, and hazard analysis; and Human factors testing Labeling.
Electrical shock, burn, or interference with other devices (for device hardware components).	Electrical safety testing; Electromagnetic compatibility testing; and Labeling.

¹ FDA notes that the “ACTION” caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to

indicate that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register’s (OFR) interpretations of the Federal Register Act (44

U.S.C. chapter 15), its implementing regulations (16 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR OVER-THE-COUNTER DEVICES TO ASSESS RISK OF SLEEP APNEA—Continued

Identified risks to health	Mitigation measures
Adverse tissue reaction (for device hardware components)	Biocompatibility evaluation.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for over-the-counter devices to assess risk of sleep apnea. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved

under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 868

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

■ 1. The authority citation for part 868 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 868.2378 to subpart C to read as follows:

§ 868.2378 Over-the-counter device to assess risk of sleep apnea.

(a) *Identification.* An over-the-counter device to assess risk of sleep apnea is intended to provide a notification of the risk of sleep apnea in users who have not been previously diagnosed with sleep apnea. This device uses software algorithms to analyze input sensor signals and provide a risk assessment for sleep apnea. It is not intended to provide a standalone diagnosis, replace traditional methods of diagnosis (e.g., polysomnography), assist clinicians in diagnosing sleep disorders, or be used as an apnea monitor.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. This testing must fulfill the following:

(i) Testing must include a study population representative of the intended use population for the device, including subjects symptomatic and asymptomatic of sleep apnea. Any selection criteria or sample limitations must be fully described and justified.

(ii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.

(iii) The assessment must evaluate device performance across all applicable subgroups (e.g., age, sex, body mass index, skin tone).

(iv) The assessment must compare device performance with a clinical comparator device (e.g., polysomnography) to demonstrate the required accuracy and/or sensitivity and specificity of the output measure(s). Justification for the clinical comparator as ground truth must be provided.

(v) For devices with machine learning-based algorithms, the clinical validation must be completed using a dataset that is separate from the training dataset.

(2) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must demonstrate hardware compatibility and the ability of the device software and hardware to provide adequate input signal quality and handle noisy or missing data and poor signal quality.

(3) Performance data must be provided to demonstrate the electromagnetic compatibility and electrical, mechanical, and thermal safety of any device hardware components.

(4) Any device hardware components that are skin-contacting must be demonstrated to be biocompatible.

(5) Software verification, validation, and hazard analysis must be performed. Software documentation must include:

(i) Full characterization of the technical specifications of the software, including the detection algorithm and its inputs and outputs.

(ii) A description of the expected impact of all applicable sensor acquisition hardware characteristics, associated hardware specifications, and processing software; and

(iii) A description of all mitigations for failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy.

(6) Human factors and usability testing must demonstrate the following:

(i) The user can correctly use the device based solely on reading the directions for use; and

(ii) The user can correctly interpret the device output and understand when to seek medical care.

- (7) Labeling must include:
 - (i) A description of what the device measures and outputs to the user;
 - (ii) Hardware platform and operating system requirements;
 - (iii) The type of sensor data used, including specifications of compatible hardware used for data acquisition;
 - (iv) Warnings identifying sensor acquisition factors or subject conditions or characteristics that may impact measurement results;
 - (v) Information for interpretation of the measurements, including a statement that the device is not intended to replace traditional methods of diagnosis (e.g., polysomnography) nor intended to be used as an apnea monitor;
 - (vi) A summary of the clinical performance testing with the device, including both the device's overall performance as well as performance across all relevant subgroups.

Grace R. Graham,
*Deputy Commissioner for Policy, Legislation,
and International Affairs.*

[FR Doc. 2026-22182 Filed 10-29-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2026-N-12213]

Medical Devices; General and Plastic Surgery Devices; Classification of the Software-Aided Adjunctive Diagnostic Device for Use by Physicians on Lesions Suspicious for Skin Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative

devices, in part by reducing regulatory burdens.

DATES: This order is effective October 30, 2026. The classification was applicable on January 12, 2024.

FOR FURTHER INFORMATION CONTACT:

Rudy Andriani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4540, Silver Spring, MD 20993-0002, 240-402-6030, Rudy.Andriani@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section

207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On February 2, 2023, FDA received DermaSensor Inc.'s request for De Novo classification of the DermaSensor device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable

assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the

general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on January 12, 2024, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 878.1830.¹ We have named the generic type of device “software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer,” and it is identified as a prescription device that uses a software algorithm to analyze optical or other

physical properties of a skin lesion and returns a classification of the skin lesion. The device is intended for use by a physician not trained in the clinical diagnosis and management of skin cancer as an adjunctive second-read device following identification of a suspicious skin lesion. It is not for use as a standalone diagnostic and is not for use to confirm a clinical diagnosis.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR SOFTWARE-AIDED ADJUNCTIVE DIAGNOSTIC DEVICE FOR USE BY PHYSICIANS ON LESIONS SUSPICIOUS FOR SKIN CANCER

Identified risks to health	Mitigation measures
False negative results, leading to failure to treat cancer and cancer progression, or false positive results, leading to unnecessary referrals and/or medical procedures.	Clinical performance testing; Postmarket surveillance; Non-clinical performance testing; and Labeling.
False results or failure to generate a result due to use error or improper device use.	Precision testing; Human factors testing; and Labeling.
False results or failure to generate a result due to device failure or malfunction.	Non-clinical performance testing; Precision testing; Software verification, validation, and hazard analysis; and Labeling.
Electrical, thermal, mechanical, or light exposure-related injury	Electrical, mechanical, and thermal safety testing; Software verification, validation, and hazard analysis; and Labeling.
Interference with other devices	Electromagnetic compatibility testing.
Adverse tissue reaction	Biocompatibility evaluation.
Infection and cross-contamination	Cleaning and disinfection validation; and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

At the time of classification, software-aided adjunctive diagnostic devices for use by physicians on lesions suspicious for skin cancer are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this

time FDA has not made this determination for software-aided adjunctive diagnostic devices for use by physicians on lesions suspicious for skin cancer. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under

OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

¹ FDA notes that the “ACTION” caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to

indicate that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register’s (OFR) interpretations of the Federal Register Act (44

U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 878.1830 to subpart B to read as follows:

§ 878.1830 Software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer.

(a) *Identification.* A software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer is a prescription device that uses a software algorithm to analyze optical or other physical properties of a skin lesion and returns a classification of the skin lesion. The device is intended for use by a physician not trained in the clinical diagnosis and management of skin cancer as an adjunctive second-read device following identification of a suspicious skin lesion. It is not for use as a standalone diagnostic and is not for use to confirm a clinical diagnosis.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Data obtained from premarket clinical performance validation testing and postmarket surveillance acquired under anticipated conditions of use must demonstrate that the device performs as intended in the intended patient population, unless FDA determines based on the totality of the information provided for premarket review that data from postmarket surveillance is not required.

(i) Data must demonstrate superior accuracy of device-aided users' diagnostic characterization of the indicated lesions compared to the accuracy of unaided users.

(ii) Clinical testing must evaluate patients across a range of skin phototypes, risk factors, and anatomic areas that represents the intended use population.

(iii) Standalone device performance testing must demonstrate the accuracy of the device output relative to ground truth, including the following:

(A) Testing must demonstrate at least 90 percent sensitivity of the device output for lesions with high metastatic potential, or an alternative clinical consideration must be provided to justify lower sensitivity. Clinical justification must be provided for the reported specificity.

(B) Lesions must be selected by representative users and include a justified quantity and range of mimic lesions per diagnosis.

(C) Justification must be provided for the determination of ground truth.

(D) Testing must include a representative range of individuals with diverse risk factors (including age, body site, skin phototype, and other clinical factors), and analysis of standalone performance must include subgroup analysis by relevant risk factors.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including compatibility testing of the device software with specific signal or image acquisition hardware. Testing must include a description of compatible hardware and processes, pre-specified compatibility testing protocols, and dataset(s).

(3) Performance testing must demonstrate device precision, including repeatability and reproducibility of device performance, across operators and challenging use conditions.

(4) Performance testing must demonstrate the electrical safety, mechanical safety, thermal safety, and electromagnetic compatibility of any electrical components of the device.

(5) Performance testing must validate reprocessing instructions for reusable components of the device.

(6) The patient-contacting components of the device must be demonstrated to be biocompatible.

(7) Software verification, validation, and hazard analysis must be performed.

(8) Human factors assessment must demonstrate that the device can be safely and correctly used by intended users.

(9) Labeling must include:

(i) A summary of standalone and clinical performance testing conducted with the device that describes performance measures, including sensitivity and specificity, and statistical confidence intervals, as well as performance of the device for all clinically relevant subgroups within the intended use population;

(ii) A description of the patient population that was used in development or training of the device algorithm;

(iii) Device limitations or subpopulations for which the device may not perform as expected or for whom the device has not been validated;

(iv) Information for interpretation of the device outputs detailing the risks associated with misinterpretation of the device outputs;

(v) Warnings to avoid unsafe exposure to any energy-emitting components of the device, *e.g.*, excluding lesions close to the eye;

(vi) A statement that the device is not intended for use as a standalone diagnostic; and

(vii) Instructions for device maintenance and validated methods and instructions for reprocessing of any reusable components.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22179 Filed 10–29–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 892**

[Docket No. FDA–2026–N–12254]

Medical Devices; Radiology Devices; Classification of the Radiology Software for Referral of Findings Related to Fibrotic Lung Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the radiology software for referral of findings related to fibrotic lung disease into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the radiology software for referral of findings related to fibrotic lung disease. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 30, 2026. The classification was applicable on January 12, 2024.

FOR FURTHER INFORMATION CONTACT: Jessica Lamb, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3672, Silver Spring, MD 20993–0002, 301–796–6167, Jessica.Lamb@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Upon request, FDA (the Agency or we) has classified the radiology software for referral of findings related to fibrotic lung disease into class II (special controls), which we have determined

will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food

and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 29, 2022, FDA received Imvaria, Inc.'s request for De Novo classification of the Fibresolve device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on January 12, 2024, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 892.2085.¹ We have named the generic type of device "radiology software for referral of findings related to fibrotic lung disease," and it is identified as a prescription image processing device that analyzes computed tomography images to suggest the presence of disease or of an imaging finding suggestive of disease. The output of this device is intended to be used as adjunctive information as part of a referral pathway in the overall diagnostic assessment process.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR RADIOLOGY SOFTWARE FOR REFERRAL OF FINDINGS RELATED TO FIBROTIC LUNG DISEASE

Identified risks to health	Mitigation measures
False positive findings leading to harmful incorrect and/or delayed management of a patient with an alternative underlying fibrotic lung disease.	Clinical performance testing; Postmarket surveillance; and Labeling.
False negative findings leading to harmful incorrect and/or delayed management of a patient with a fibrotic lung disease.	Clinical performance testing; Postmarket surveillance; and Labeling.

¹ FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to

indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44

U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR RADIOLOGY SOFTWARE FOR REFERRAL OF FINDINGS RELATED TO FIBROTIC LUNG DISEASE—Continued

Identified risks to health	Mitigation measures
Incorrect and/or delayed patient management due to the device being misused to analyze images from an unintended patient population or from images acquired with incompatible imaging hardware or image acquisition parameters.	Clinical performance testing; Postmarket surveillance; and Labeling.
Incorrect and/or delayed patient management due to misinterpretation of device output or overreliance on device output for radiological image interpretation.	Labeling.
Device failure leading to the absence of results, delay of results, or incorrect results, leading to inaccurate or delayed patient assessment.	Software verification, validation, and hazard analysis.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

At the time of classification, radiology software for referral of findings related to fibrotic lung disease are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for radiology software for referral of findings related to fibrotic lung disease. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of

information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

PART 892—RADIOLOGY DEVICES

- 1. The authority citation for part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Add § 892.2085 to subpart B to read as follows:

§ 892.2085 Radiology software for referral of findings related to fibrotic lung disease.

(a) *Identification.* Radiology software for referral of findings related to fibrotic lung disease is a prescription image processing device that analyzes computed tomography images to suggest the presence of disease or of an imaging finding suggestive of disease. The

output of this device is intended to be used as adjunctive information as part of a referral pathway in the overall diagnostic assessment process.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Data obtained from premarket clinical performance validation testing and postmarket surveillance acquired under anticipated conditions of use must demonstrate that the device performs as intended when used to analyze data from the intended patient population, unless FDA determines based on the totality of the information provided for premarket review that data from postmarket surveillance is not required. The following must be met:

(i) Validation report(s) must include a detailed description of the data, criteria, and methods used to define the reference standard that were used to evaluate device performance. The reference standard used in the clinical validation must be justified for the condition named in the device's indications for use.

(ii) The performance of the device must be compared to an appropriate clinical control, (e.g., the performance or agreement of clinicians performing the same task).

(iii) The performance assessment must be based on pre-specified diagnostic accuracy measures (e.g., receiver operator characteristic plot, sensitivity, specificity, positive/negative predictive values, diagnostic likelihood ratios).

(iv) Test datasets must contain a sufficient number of cases from important cohorts (i.e., subsets defined by clinically relevant demographics, confounders, effect modifiers, concomitant diseases, challenging cases such as early disease, and subsets defined by image acquisition characteristics) such that the performance estimates and confidence intervals of the device for these individual subsets can be characterized

for the intended-use population and imaging equipment.

(2) Software verification, validation, and hazard analysis must be performed. Software documentation must include a detailed technical description of all image analysis algorithms, including the model inputs and outputs, each major component or block, and any model limitations.

(3) Labeling must include:

(i) A detailed description of the clinical environment and context of use, including information on interpretation of outputs within the intended workflow;

(ii) A detailed description of compatible imaging hardware and imaging protocols;

(iii) A detailed summary of the performance testing for each device output, including test methods, dataset characteristics, testing environment, results (with confidence intervals), and a summary of sub-analyses on case distributions stratified by relevant confounders;

(iv) According to the timeframe specified in any postmarket surveillance protocol approved by FDA to satisfy the requirements in paragraph (b)(1) of this section, a detailed summary of the postmarket surveillance data must be provided, including updates to the labeling to accurately reflect device performance based upon data collected during the postmarket surveillance experience; and

(v) Limiting statements that indicate:

(A) A description of situations in which the device may fail or may not operate at its expected performance level (e.g., the impact of poor image quality on device performance or degraded performance in certain subpopulations), as applicable, including any limitations in the dataset used to train, tune, and test the algorithm during device development;

(B) A discussion of what the device detects in the context of diagnosing fibrotic lung disease; and

(C) A warning that users should use the device in conjunction with other clinical and diagnostic findings, including information obtained by alternative methods and clinical evaluation, as appropriate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-22180 Filed 10-29-26; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1743]

Schedules of Controlled Substances: Placement of Centanafadine in Schedule III

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule; request for comments.

SUMMARY: On July 24, 2026, the United States Food and Drug Administration (FDA) approved a new drug application for Simtriyo (centanafadine) for the treatment of attention-deficit/hyperactivity disorder in adults and pediatric patients aged 6 years and older, weighing at least 20 kg. The Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place centanafadine, chemically known as (1R,5S)-1-(naphthalen-2-yl)-3-azabicyclo[3.1.0]hexane, in schedule III of the Controlled Substances Act (CSA). In accordance with the CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing centanafadine, including its salts, isomers (whether optical, positional, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible in schedule III of the CSA.

DATES: This rule is effective October 30, 2026. Comments must be submitted electronically or postmarked on or before November 30, 2026. The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received on or before November 30, 2026.

ADDRESSES: Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). To ensure proper handling of comments, please reference “Docket No. DEA-1743” on all correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration (DEA)

encourages commenters to submit comments electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

• *Paper comments:* Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrisette Drive, Springfield, VA 22152.

• *Hearing requests:* All requests for hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be filed with the DEA Administrator, who will make the determination of whether a hearing will be needed to address such matters of fact and law in the rulemaking. Such requests must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. For informational purposes, a courtesy copy of requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

• *Paperwork Reduction Act comments:* All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to Docket No. DEA-1743.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control

Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: In this Interim Final Rule (IFR), the Drug Enforcement Administration (DEA) is adding centanafadine, including its salts, to schedule III of the Controlled Substances Act (CSA).

Posting of Public Comments

All comments received in response to this docket are considered part of the public record. DEA will make comments available for public inspection online at <https://www.regulations.gov>, unless reasonable cause is given. Such information includes personal or business identifying information (such as name, address, State or Federal identifiers, etc.) voluntarily submitted by the commenter.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made publicly available should submit two copies of the comment. One copy must be marked “CONTAINS CONFIDENTIAL INFORMATION” and should clearly identify all PII or business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked “TO BE PUBLICLY POSTED” and must have all claimed confidential PII and business information already redacted. DEA will post only the redacted comment on <https://www.regulations.gov> for public inspection. DEA generally will not redact additional information contained in the comment marked “TO BE PUBLICLY POSTED.” The Freedom of Information Act applies to all comments received.

For easy reference, an electronic copy of this document and supplemental information to this IFR are available at <http://www.regulations.gov>.

Request for Hearing or Appearance; Waiver

Pursuant to 21 U.S.C. 811(j)(3), an interested person may “request a hearing.” Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559.¹ Interested persons, as defined in 21 CFR 1300.01(b), may file requests for a

hearing in conformity with the requirements of 21 CFR 1308.44(a) and 1316.47(a), and such requests must:

(1) state with particularity the interest of the person in the proceeding;

(2) state with particularity the objections or issues concerning which the person desires to be heard; and

(3) state briefly the position of the person with regard to the objections or issues. Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(c), together with a written statement of position on the matters of fact and law involved in any hearing.²

All requests for hearings and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above. The decision whether a hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator. If a hearing is needed, DEA will publish a notice of hearing on the IFR in the **Federal Register**.³ Further, once the Administrator determines a hearing is needed to address such matters of fact and law in rulemaking, he will then designate an Administrative Law Judge (ALJ) to preside over the hearing. The ALJ’s functions shall commence upon designation, as provided in 21 CFR 1316.52.

In accordance with 21 U.S.C. 811 and 812, the purpose of a hearing would be to determine whether centanafadine meets the statutory criteria for placement in schedule III.

Legal Authority

Under the CSA, as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (section 2(b) of Pub. L. 114–89), DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the Food and Drug Administration (FDA). As provided in 21 U.S.C. 811(j), this expedited scheduling is required where both of the following conditions apply: (1) The Secretary of the Department of Health and Human Services (HHS) has advised DEA that a New Drug Application (NDA) has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system (CNS), and that it appears that such drug has an abuse potential; and (2) the Secretary of HHS recommends that DEA

control the drug in schedule II, III, IV, or V pursuant to 21 U.S.C. 811(a) and (b). In these circumstances, DEA is required to issue an IFR controlling the drug within 90 days.

Subsection 811(j)(2) states that the 90-day timeframe starts the later of (1) the date DEA receives HHS’s scientific and medical evaluation and scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Subsection 811(j)(3) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause therefore. Thus, the purpose of subsection 811(j) is to speed the process by which DEA schedules newly approved drugs that are currently either in schedule I or not controlled (but which have sufficient abuse potential to warrant control) so that such drugs may be marketed without undue delay following FDA approval.⁴

Subsection 811(j)(3) further provides that the IFR shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, DEA must issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811(b) through (d), and 812(b).

Background

Centanafadine is a new molecular entity with CNS activity, acting as a novel triple reuptake inhibitor that targets norepinephrine, dopamine, and serotonin. Its mechanism of action has some similarities to schedule II stimulants like cocaine.

On November 24, 2025, Otsuka Pharmaceutical Development and Commercialization, Inc. (Sponsor) submitted an NDA for centanafadine to FDA. On July 24, 2026, FDA approved the NDA for centanafadine for the treatment of attention-deficit/hyperactivity disorder (ADHD) in adults and pediatric patients aged 6 years and older, weighing at least 20 kg. Centanafadine will be formulated as extended-release capsules for once-daily oral administration.

Determination To Schedule Centanafadine

On July 18, 2026, DEA received from HHS a scientific and medical evaluation entitled “Basis for the Recommendation to Control Centanafadine and Its Salts in Schedule III of the Controlled Substances Act” and a scheduling recommendation. Pursuant to 21 U.S.C.

⁴ Given the parameters of subsection 811(j), in DEA’s view, it would not apply to a reformulation of a drug containing a substance currently in schedules II through V for which an NDA has recently been approved.

¹ 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D.

² 21 CFR 1316.49.

³ 21 CFR 1308.44(b), 1316.53.

811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of centanafadine, along with HHS's recommendation to control centanafadine under schedule III of the CSA.

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). DEA concluded that centanafadine meets the 21 U.S.C. 812(b)(3) criteria for placement in schedule III of the CSA.

Pursuant to subsection 811(j), and based on HHS's scheduling recommendation, the approval of the NDA by HHS/FDA, and DEA's determination, DEA is issuing this IFR to schedule centanafadine as a schedule III controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its scheduling action. Please note that both DEA and HHS analyses are available in their entirety under "Supporting Documents" in the public docket for this IFR at <https://www.regulations.gov>, under Docket Number "DEA-1743." Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

1. Its Actual or Relative Potential for Abuse

According to HHS, because centanafadine has not been legally marketed in the United States or any other country, the legitimate drug channels for centanafadine are limited to the research conducted with the drug, and to manufacturing facilities and the supply chain to produce centanafadine for legitimate drug research. HHS further notes that, because centanafadine has not been legally marketed in the United States or any other country, abuse of centanafadine would be limited to incidents during the conduct of clinical studies or following diversion of supplies from research or manufacturing activities of centanafadine. According to HHS, suspected diversion of centanafadine occurred in one of the thirty-seven clinical studies conducted during the development of centanafadine. Three subjects in the study were suspected of abusing or diverting centanafadine based on medication handling irregularities. DEA's National Forensic Laboratory Information System (NFLIS)-

Drug⁵ data show that there is no report of law enforcement encounters of centanafadine in the United States. Centanafadine is a triple reuptake inhibitor that targets the specific transporters of norepinephrine (NET), dopamine (DAT), and serotonin (SERT), and it is a CNS stimulant. HHS states that centanafadine produces self-administration in rats and full generalization to amphetamine in a rat drug discrimination study (see Factor 2). In two human abuse potential studies, centanafadine produced subjective responses that indicate the drug has rewarding properties (see Factor 2). Accordingly, its mechanism of action and reinforcing properties share similarities with schedule II stimulants, like cocaine and methylphenidate, with known abuse potential. Both FDA and DEA concluded that centanafadine has an abuse potential lower than those of schedule II stimulants.

2. Scientific Evidence of Its Pharmacological Effects, if Known In Vitro Studies

Based on *in vitro* binding and functional reports, HHS noted that centanafadine acts as a triple reuptake inhibitor that targets norepinephrine, dopamine, and serotonin to achieve its CNS stimulant effects.

Binding Affinity and Functional Study: Centanafadine binds with high affinity to NET, SERT, and DAT, and inhibits the reuptake of these neurotransmitters. Conversely, its major metabolite, EB-10601, showed weak-to-no affinity for these three transporters, suggesting that it likely does not contribute to centanafadine's therapeutic efficacy. Neither compound showed significant activity at other CNS receptors measured.⁶

Intracerebral Microdialysis Study: Oral administration of centanafadine (3–30 mg/kg) in rats dose-dependently increased extracellular norepinephrine, dopamine, and serotonin in the prefrontal cortex, as well as dopamine

and serotonin in the ventral striatum. These microdialysis findings support the mechanism of action for centanafadine as a triple reuptake inhibitor at NET, DAT, and SERT.

Preclinical Behavioral Studies

Drug Discrimination: An HHS-reviewed drug discrimination study demonstrated that oral centanafadine fully generalizes to an amphetamine cue, indicating substantial potential for human abuse. In female rats trained to distinguish schedule II stimulant, amphetamine (0.3 mg/kg, intraperitoneal) from saline under a fixed-ratio (FR) 5 schedule, centanafadine achieved full generalization (76 percent) at the 10 mg/kg oral dose, producing a mean plasma concentration of 718 ng/mL, which is roughly half the human highest concentration (C_{max}) (1460 ng/mL) achieved at a dose of 200 mg twice daily. Similar to schedule II stimulant methylphenidate (83 percent generalization at 5 mg/kg oral dose) and schedule IV stimulant phentermine (93 percent generalization at 3 mg/kg oral dose), centanafadine mimics the interoceptive stimulus effects of amphetamine, strongly indicating an inherent abuse liability.⁷

Self-Administration: An HHS-reviewed intravenous self-administration study demonstrated that centanafadine possesses rewarding properties that sustain reinforcement, signaling an inherent risk of human abuse. In rats trained on a FR5 schedule to self-administer cocaine (0.36 mg/kg/injection, maintained at 19 injections per session) or undergo saline extinction (not greater than 5 injections per session), centanafadine sustained self-administration above saline levels across all doses tested. The two highest doses produced a degree of self-administration of 13 injections per session at the 0.03 mg/kg/injection dose and 15 injections/session from the 0.10 mg/kg/injection dose ($p < 0.001$ for both compared to saline). Schedule II methylphenidate and unscheduled bupropion similarly sustained cocaine-like self-administration at their highest doses, though bupropion data was excluded from the final assessment due to its uncontrolled regulatory status. While the rate of centanafadine self-administration remained statistically lower than cocaine (maintained at 19 injections per session) across all doses ($p < 0.001$), centanafadine's capacity to

⁵ NFLIS-Drug represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by federal, state and local forensic laboratories in the United States. While NFLIS-Drug data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See *Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV*, 76 FR 77330, 77332 (Dec. 12, 2011). NFLIS-Drug data were queried on July 20, 2026.

⁶ Department of Health and Human Services. (2026). Basis for the recommendation to control centanafadine and its salts in schedule III of the Controlled Substances Act. U.S. Department of Health and Human Services, July 17, 2026. Page 4.

⁷ Department of Health and Human Services. (2026). Basis for the recommendation to control centanafadine and its salts in schedule III of the Controlled Substances Act. U.S. Department of Health and Human Services, July 17, 2026. Page 5.

maintain active reinforcement mimics the profiles of schedule II stimulants, confirming its potential for abuse.⁸

Pharmacological and Behavioral Studies in Human

Human Abuse Potential (HAP) studies assess a drug's abuse liability by comparing a test drug to active controls and placebos. As described in HHS's scientific and medical evaluation, two HAP studies were conducted by the drug sponsor to assess the abuse potential of centanafadine in participants who were non-dependent, recreational drug users.

The first HAP study was a randomized, double-blind, placebo- and active-controlled, crossover trial that evaluated the oral abuse potential of immediate-release centanafadine (400 mg and 800 mg, representing 2 and 4 times the therapeutic levels) against placebo and active positive controls: immediate-release amphetamine (40 mg) and lisdexamfetamine (150 mg) in 36 healthy male, nondependent recreational stimulant users. Data from the study demonstrated that supratherapeutic doses of centanafadine produced positive subjective effects that were significantly greater than those by placebo and comparable to those by schedule II stimulants (amphetamine and lisdexamfetamine).

The second HAP study was a randomized, double-blind, placebo- and active-controlled, single-dose crossover trial evaluating the oral abuse potential of immediate-release centanafadine (200, 400, and 800 mg) against a schedule II positive control (15 and 30 mg immediate-release amphetamine) and placebo in 61 healthy, nondependent recreational stimulant users. Unlike the first study, which focused exclusively on supratherapeutic doses, this second trial evaluated both therapeutic and supratherapeutic ranges by testing doses roughly equivalent to the final marketing therapeutic strengths (210 and 280 mg) alongside doses that were approximately 2 and 4 times higher than the therapeutic doses. Throughout each session, subjective responses were tracked using Visual Analogue Scales (VAS) and the Addiction Research Center Inventory (ARCI) scales, which measured stimulant-specific effects on the Amphetamine subscale (0–11 range) and the Benzedrine subscale (0–13 range).

Subjective Visual Analog Scale Outcomes

Primary Liking and Reinforcement: Centanafadine produced responses just outside the placebo range that were statistically significantly lower than amphetamine, except when comparing 800 mg centanafadine to 15 mg amphetamine. For Overall Drug Liking, amphetamine demonstrated high scores that differed significantly from all centanafadine doses; meanwhile, centanafadine produced a dose-dependent shift toward drug disliking, with the 400-mg and 800-mg doses differing significantly from placebo. Similarly, on the "Take Drug Again" scale, amphetamine elicited a strong desire to take the drug again that was statistically significantly different than all centanafadine treatments.

Stimulant Profiles and Identification

ARCI-Amphetamine and ARCI-Benzedrine scales: Centanafadine and amphetamine generated stimulant-like responses above placebo, with 30 mg amphetamine producing the highest scores across both measures. ARCI-Amphetamine scores reached 5.9 and 7.7 for the 15 and 30-mg doses of amphetamine, respectively, compared to scores of 5.1, 4.8, and 4.9 from the 200-, 400-, and 800-mg doses of centanafadine, respectively, and score of 2.8 from placebo. On the ARCI-Benzedrine scale, the 15- and 30-mg doses of amphetamine produced scores of 8.3 and 9.6, respectively, which were slightly higher than the scores of 7.3, 6.8, and 6.5 from the 200-, 400-, and 800-mg doses of centanafadine, respectively, and score of 5.6 from placebo.

Drug Similarity: On the drug similarity question, centanafadine was categorized as a stimulant generally (either as amphetamine or cocaine), but it was more frequently identified as amphetamine than as cocaine; placebo was identified as any of the stimulants less than 10% of the time.

Adverse Events (AEs)

Euphoria and Stimulant Signs: As described in detail in HHS's review,⁹ oral administration of centanafadine exhibited classic stimulant-associated AEs. Both centanafadine and amphetamine produced comparable rates of euphoric mood, decreased appetite, anxiety, agitation, and bruxism (*i.e.*, teeth grinding or jaw clenching).

However, amphetamine produced higher rates of hypervigilance, whereas centanafadine was uniquely associated with disorientation at higher doses, dose-dependent tremor, and somnolence (*i.e.*, drowsiness), as well as certain other negative AEs, including nausea and vomiting.

Centanafadine demonstrated a clinical abuse potential profile distinct from schedule II stimulants (amphetamine and lisdexamfetamine), as its detectable stimulant-like activity at supratherapeutic doses (2 and 4 times the therapeutic dose) produced drug liking that was statistically greater than placebo but less than the positive control drug, amphetamine. Furthermore, centanafadine elicited a clear lack of willingness to take the drug again, contrasting sharply with the robust liking and desire for repeat self-administration of amphetamine. Ultimately, the reinforcing properties of centanafadine at high exposure levels are effectively restricted by negative user experiences, limiting its relative abuse liability. Overall data from the two HAP studies demonstrated that supratherapeutic doses of centanafadine produced negative subjective responses and AEs, which are likely to limit the abuse potential of the drug relative to the schedule II drugs, amphetamine and lisdexamfetamine.

Adverse Events in Clinical Safety and Efficacy Studies With Centanafadine

Combined safety data from 19 Phase 1 studies (872 centanafadine-treated and 66 placebo-treated healthy subjects) revealed a very low incidence of abuse-related and psychiatric AEs, with most incidents occurring in under 2 percent of participants across all formulation groups. Stimulant-associated AEs exceeding a 2 percent incidence were concentrated primarily in the highest-exposure group (>400 mg sustained release [SR]) or with specific formulations.

Psychiatric and Mood Effects: Euphoric mood occurred in only one subject (2.0 percent) receiving >400 mg SR (0.2–0.9 percent in lower doses; 0 percent in placebo). Altered mood appeared exclusively with other formulations (2.1 percent). Insomnia (4.1 percent) and hypervigilance (2.0 percent) were also highest in the >400 mg SR group.

Cardiovascular Effects: Tachycardia occurred in 4.1 percent of subjects receiving >400 mg SR (0–1.3 percent in lower doses; 0 percent in placebo).

Gastrointestinal and Appetite Effects: Decreased appetite was most prevalent in the >400 mg SR cohort (10.2 percent), followed by other formulations (2.1

⁸Department of Health and Human Services. (2026). Basis for the recommendation to control centanafadine and its salts in schedule III of the Controlled Substances Act. U.S. Department of Health and Human Services, July 17, 2026. Page 7.

⁹Department of Health and Human Services. (2026). Basis for the recommendation to control centanafadine and its salts in schedule III of the Controlled Substances Act. U.S. Department of Health and Human Services, July 17, 2026. Pages 16–17.

percent) and <329 mg extended-release (2.0 percent). Gastrointestinal symptoms peaked in the >400 mg SR group, led by nausea (14.3 percent), abdominal discomfort (8.2 percent), and diarrhea (10.2 percent).

Human Accidental Overdose and Diversion

Across 37 clinical trials evaluating centanafadine, HHS reported zero instances of drug overdose and suspected cases of drug diversion from one clinical site. In a multicenter, 52-week, open-label Phase 3 trial evaluating the long-term safety of centanafadine SR (400 mg total dose daily) in 662 adults with ADHD, three participants exhibited medication handling irregularities involving suspected or documented abuse or diversion, leading to their removal. Specifically, one participant was disqualified at Week 8 for suspected diversion after a second occurrence of lost or stolen medication, a second participant was removed after accelerating their intake to consume an entire 30-tablet supply within 9 days, and a third participant was discharged after failing a urine drug screen and subsequently claiming to have lost 10 tablets down a drain upon learning of their termination.

In summary, centanafadine is a new molecular entity that exhibits a pharmacological profile similar to that of cocaine (schedule II), functioning as a triple reuptake inhibitor of NET, DAT, and SERT. Preclinical drug discrimination studies in rats demonstrate that centanafadine produces interoceptive effects similarly to amphetamine (schedule II), matching the profiles of established stimulants like methylphenidate (schedule II) and phentermine (schedule IV). HAP studies indicate that centanafadine's subjective stimulant effects are generally less intense than those of amphetamine or lisdexamfetamine, leading to an overall clinical assessment of low misuse potential; however, the drug's administration remains associated with classic stimulant-type AEs. Consequently, based on a comprehensive review of *in vitro* testing, animal self-administration, drug discrimination, HAP studies, and clinical safety profiles, both HHS and DEA concluded that centanafadine possesses abuse potential and requires control under the CSA.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

Centanafadine, chemically known as (1R,5S)-1-(naphthalen-2-yl)-3-

azabicyclo[3.1.0]hexane, is a new molecular entity. Centanafadine drug products are formulated as proportionally similar, extended-release capsules in 140 mg, 210 mg, and 280 mg free base strengths (equivalent to 164.4 mg, 246.6 mg, and 328.8 mg hydrochloride salt, respectively). Each capsule utilizes a multi-bead delivery system distributed as 12.2 percent immediate-release, 43.9 percent delayed-release, and 43.9 percent sustained-release beads. According to HHS, chronic once-daily administration of centanafadine (140 mg to 280 mg) results in a slightly greater than dose-proportional increase in C_{max} and Area Under the Curve, with peak plasma concentrations occurring approximately 5 hours post-dose. Steady state is achieved by day 2 with minimal drug accumulation and a mean elimination half-life of 5.2 hours. The drug is primarily metabolized by monoamine oxidase A into an inactive primary lactam metabolite, with excretion occurring via urine (88 percent) and feces (7 percent). Notably, *in vitro* dissolution testing demonstrates a risk of alcohol-induced dose-dumping.

As discussed in the background section, centanafadine has a currently accepted medical use in treatment in the United States because it has been approved by FDA.

4. Its History and Current Pattern of Abuse

Centanafadine has no history of legal or illegal marketing globally, and current data do not reflect an actual real-world pattern of abuse. While distributed for clinical trials and research, evidence of diversion from legitimate channels remains minimal. For instance, a Phase 3 study evaluating centanafadine SR (400 mg daily) in 662 adults with ADHD reported only three subjects with medication handling irregularities involving suspected or known abuse or diversion (*see* Factor 2). Consequently, the assessment of abuse liability of centanafadine relies entirely on nonclinical and clinical studies, which collectively indicate a lower potential for abuse than schedule II stimulants, such as amphetamine, lisdexamfetamine, and methylphenidate. Consistent with the status of centanafadine as a new molecular entity, DEA's parallel search of NFLIS-Drug yielded zero records of law enforcement encounters.

In summary, pharmacological data on centanafadine show that it produces abuse-related effects and has an abuse potential lower than those of schedule II stimulants.

5. The Scope, Duration, and Significance of Abuse

Centanafadine has been not marketed in any country and remains unavailable in the United States, resulting in limited abuse data. Because nonclinical and clinical evaluations indicate that centanafadine possesses an abuse liability profile that overlaps with known schedule II stimulants, there is a risk of post-marketing diversion and abuse. DEA's comprehensive search of law enforcement data yielded zero domestic law enforcement encounters involving centanafadine. However, based on cumulative pharmacology data, centanafadine is anticipated to possess a post-marketing abuse potential that is less than those of schedule II stimulants, such as amphetamine, lisdexamfetamine, and methylphenidate.

6. What, if Any, Risk There Is to the Public Health

A drug's abuse potential is a key indicator of its overall risk to public health risk. HHS stated that, while centanafadine possesses an abuse potential comparable to those of schedule II stimulants (*e.g.*, cocaine, amphetamine, and methylphenidate), it is likely that centanafadine will exhibit a lesser abuse profile and present fewer public health risks than those of schedule II stimulants based on dependency data and negative AEs reported in studies. To evaluate public health risk associated with centanafadine, HHS analyzed clinical trial AEs, overdose data, and abuse potential studies and confirmed moderate signals that centanafadine poses some public health risks but to a lesser degree than those posed by schedule II stimulants.

In summary, data from nonclinical and clinical studies indicate that centanafadine's abuse potential and public health risks are comparable, but to a lesser degree, than to those of schedule II stimulants.

7. Its Psychic or Physiological Dependence Liability

Psychic (or psychological) dependence is a state similar to addiction and can be informed by animal self-administration studies, HAP studies and AE reports.

HHS cited investigations that demonstrate that while centanafadine generates clear rewarding properties in both preclinical and clinical studies, centanafadine concurrently elicits dose-dependent negative subjective effects in humans. Collectively, these findings show that it is likely that centanafadine

can produce psychological dependence, but likely to a lesser degree than with schedule II stimulants, such as amphetamine and cocaine.

Physical dependence develops from physiological adaptation to repeated drug use and manifests as withdrawal symptoms after abrupt drug discontinuation or reduction of a drug. According to HHS, experimental animal data evaluating chronic administration profiles for centanafadine are currently limited. Although the NDA applicant submitted two physical dependence studies in rats, HHS concluded that these evaluations were invalid for characterizing withdrawal potential, because the utilized dosing regimens failed to achieve systemic plasma concentrations matching therapeutic exposures in humans.

HHS reviewed withdrawal data from two Phase 3 clinical trials in adults with ADHD. Following abrupt discontinuation of centanafadine SR (200 mg or 400 mg daily), patients were monitored for 10 days using the Study Medication Withdrawal Questionnaire (SMWQ). SMWQ scores were indistinguishable between the active treatment and placebo groups at all time points. Based on these data, HHS concluded that centanafadine does not induce a withdrawal syndrome, indicating that chronic therapeutic administration followed by abrupt cessation does not produce physical dependence.

8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA

Centanafadine is not an immediate precursor of any controlled substance, as defined by 21 U.S.C. 802(23).

Conclusion: After considering the scientific and medical evaluation and scheduling recommendation provided by HHS, as well as DEA's own eight-factor analysis, DEA has determined that these facts and all relevant data constitute substantial evidence of potential for abuse of centanafadine. As such, DEA hereby schedules centanafadine as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V).¹⁰ After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Administrator

of DEA, pursuant to 21 U.S.C. 812(b) (3–), finds that:

(1) Centanafadine has a potential for abuse less than the drugs or other substances in schedules I and II.

Centanafadine is a novel triple reuptake inhibitor that targets NET, DAT, and SERT and is a CNS stimulant. While its mechanism of action shares similarities with those of schedule II stimulants, preclinical and clinical data demonstrate that centanafadine possesses an abuse potential lower than those of substances in schedules I and II. In animal self-administration and drug discrimination models, centanafadine produced reinforcing and interoceptive effects similar to known schedule II stimulants, including cocaine, amphetamine, and methylphenidate. Similarly, in two HAP studies, centanafadine elicited positive subjective responses that were significantly greater than those of placebo, closely approximating or falling slightly below those of amphetamine and lisdexamfetamine. However, centanafadine produced a dose-dependent increase in negative subjective responses and a higher prevalence of AEs like nausea from supratherapeutic doses. Overall, the evidence from nonclinical and clinical evaluations indicates that centanafadine possesses an abuse liability lower than those of schedule II controlled substances.

(2) Centanafadine has a currently accepted medical use in treatment in the United States.

Centanafadine was approved by FDA for the treatment of ADHD in adults and pediatric patients aged 6 years and older weighing at least 20 kg. Thus, centanafadine has a currently accepted medical use in treatment in the United States.

(3) Abuse of centanafadine may lead to moderate or low physical dependence or high psychological dependence.

According to HHS, therapeutic use of centanafadine did not produce a withdrawal syndrome in patients who were abruptly discontinued from the drug following chronic use. However, the ability of centanafadine to produce positive subjective responses at supratherapeutic doses suggests that centanafadine can produce psychic dependence, although this may be mediated by concurrent negative subjective responses and AEs. In contrast, schedule II drugs amphetamine and lisdexamfetamine produced positive responses without comparable negative responses. Overall, these data suggest that centanafadine has a dependence potential less than that of certain schedule II stimulants and may

lead to moderate or low physical dependence or high psychological dependence.

Based on these findings, the Administrator concludes that centanafadine and its salts warrant control in schedule III of the CSA.¹¹

Requirements for Handling Centanafadine

Centanafadine is subject to the CSA's schedule III regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distributing, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) centanafadine must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. These registration requirements, however, are not applicable to patients (end users) who possess centanafadine pursuant to a lawful prescription.

2. *Disposal of Stocks.* Any person unwilling or unable to obtain a DEA registration must surrender all quantities of currently held centanafadine, or may transfer all quantities of currently held centanafadine to a person registered with DEA. Centanafadine is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* Centanafadine is subject to schedule III–V security requirements for DEA registrants and must be handled and stored in accordance with 21 CFR 1301.71–1301.77, pursuant to 21 U.S.C. 821, 823, and 871(b). Non-practitioners handling centanafadine must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93. These requirements, however, are not applicable to patients (end users) who possess centanafadine pursuant to a lawful prescription.

4. *Labeling and Packaging.* All labels and packaging for commercial containers of centanafadine must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of centanafadine must have an initial

¹⁰ 21 U.S.C. 812(b).

¹¹ 21 U.S.C. 812(b)(3).

inventory of all stocks of controlled substances (including centanafadine) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who registers with DEA to handle centanafadine must take an initial inventory of all stocks of controlled substances (including centanafadine) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take inventory of all controlled substances (including centanafadine) on hand every two years, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. These requirements, however, are not applicable to patients (end users) who possess centanafadine pursuant to a lawful prescription.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for centanafadine, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for centanafadine, or products containing centanafadine, must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule III controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of centanafadine may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act, as applicable, and the CSA.

9. *Importation and Exportation.* All importation and exportation of centanafadine must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving centanafadine not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to

administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

The APA (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is (1) approved by HHS, under section 505(c) of the Federal Food Drug and Cosmetic Act, and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an IFR scheduling the drug within 90 days. As stated in the legal authority section, the 90-day time frame is the later of: (1) the date DEA receives HHS's scientific and medical evaluation and scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Additionally, subsection 811(j) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause.

Executive Orders 12866 and 14294

The Office of Management and Budget ("OMB") has determined that, although this rule is not economically significant under section (3)(f)(1) of Executive Order 12866, this rule is a "significant regulatory action" under the Order. OMB has therefore reviewed this rule.

DEA scheduling actions are not subject to E.O. 14294, Fighting Overcriminalization in Federal Regulations.

Executive Order 12988, Civil Justice Reform

This rulemaking meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship

between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Paperwork Reduction Act

This rule would require compliance with the following existing OMB collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–0010, 1117–0012, 1117–0014, 1117–0021, and 1117–0056. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, applies to rules that are subject to the notice-and-comment requirements the APA at 5 U.S.C. 553. The RFA's requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking. As noted in the above discussion regarding the applicability of the APA, DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this IFR.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this proposed action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year" Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this IFR to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.13:

■ a. Redesignate paragraphs (b)(3) through (5) as paragraphs (b)(4) through (6); and

■ b. Add a new paragraph (b)(3).
The addition reads as follows:

§ 1308.13 Schedule III.

* * * * *

(b) * * *

* * * * *	
(3) Centanafadine	1641

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Signing Authority

This document of the Drug Enforcement Administration was signed on October 28, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2026–22208 Filed 10–29–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket Number USCG–2026–0095]

RIN 1625–AA00

Safety Zone; S.S. UNITED STATES Dead Ship Tow, Sector Mobile Captain of the Port Zone, Mobile, AL

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary moving safety zone around the S.S. UNITED STATES and all vessels involved in its towage through the Mobile River Channel, Mobile Bay, and the Gulf of America. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the dead ship tow. Entry of persons and vessels into this zone is prohibited unless specifically authorized by the Captain of the Port (COTP), Sector Mobile.

DATES: This rule is effective from November 6, 2026 through November 16, 2026.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG–2026–0095.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact Lieutenant Zachary West, Waterways Management—Division, U.S. Coast Guard Sector Mobile; telephone (251) 382–8653, email SectorMobileWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION:**I. Table of Abbreviations**

CFR	Code of Federal Regulations
COTP	Captain of the Port
DHS	Department of Homeland Security
FR	Federal Register
NM	Nautical Mile
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background and Authority

The Coast Guard received notification that S.S. UNITED STATES, a former commercial ocean liner, will be moved, via dead ship tow, from its current location in Mobile, AL to a point in the Gulf of America where it will be sunk as an artificial reef. The entities involved in this operations have requested that the Coast Guard establish a safety zone around the S.S. UNITED STATES, and all vessels involved in its towage, as it is towed from its pier in Mobile, Alabama, through the Mobile River Channel, Mobile Bay, and into the Gulf of America. Hazards from the departure of the S.S. UNITED STATES include restricted maneuverability of tow, wake from passing traffic, and potential for significant vessel congestion. The Captain of the Port Sector Mobile (COTP) has determined that these potential hazards associated with towing the S.S. UNITED STATES are a safety concern for anyone within 100 yards of the towing evolution. Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel,

vessels, and the marine environment in the navigable waters within the vicinity of this dead-ship towing operation.

Because of these potential hazards, the Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest. The schedule for this towing operation was not finalized until October 20, 2026, and therefore the Coast Guard was unable to publish a Notice of Proposed Rulemaking for this safety zone prior to the dead-ship tow operation beginning as early as October 12, 2026. This safety zone must be established by November 6, 2026 to protect personnel, vessels, and the marine environment from the hazards associated with the operation. Therefore, we do not have enough time to solicit and respond to comments.

For the same reasons, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a temporary moving safety zone that will be in effect from November 6, 2026, through November 16, 2026. The safety zone will cover all navigable waters within 100 yards of the S.S. UNITED STATES and all vessels involved in the dead ship tow operation. While the rule will be effective 10 days, the zone will only be enforced during active dead ship tow operations for the transit of the S.S. UNITED STATES from the pier in Mobile, AL until it reaches the limit of the United States Territorial Sea, approximately 12 Nautical Miles (NM) offshore of Destin, FL. The date and time of the vessel's departure will depend on weather and sea conditions in the area. In advance of the vessel's departure, the COTP will issue a Broadcast Notice to Mariners via marine channel 16 (VHF–FM), as well as other public advisories, to inform the local maritime community of the exact dates(s) and times that the safety zone will be enforced. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or their designated representative.

IV. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses

based on a number of these statutes and Executive orders.

A. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to notice and comment. Because the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act's flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

B. Collection of Information

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

C. Federalism and Indian Tribal Governments

We have analyzed this rule under Executive Order 13132, Federalism, and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

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

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies that this rule will not result in an annual expenditure of \$100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment.

This rule is a safety zone. It is categorically excluded from further review under paragraph L60(a) of appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.A. Record of Environmental Consideration supporting this determination is available in the docket.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; DHS Delegation No. 00170.1, Revision No. 01.4.

■ 2. Add § 165.T08–0095 to read as follows:

§ 165.T08–0095 S.S. UNITED STATES Dead Ship Tow, Sector Mobile Captain of the Port Zone, Mobile, AL

(a) *Location.* The following area is a moving safety zone: All navigable waters within a 100-yard radius of the S.S. UNITED STATES and all vessels involved in the dead ship tow operation within the Sector Mobile Captain of the Port (COTP) Zone. The zone will become effective when the S.S. UNITED STATES departs the Modern American Recycling Services facility in Mobile, AL, and will move with the vessels until they reach the Territorial Sea boundary, approximately 12 Nautical Miles offshore of Destin, FL.

(b) *Definitions.* As used in this section, *designated representative* is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of the Captain of the Port Sector Mobile.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative on VHF–FM channel 16 or by telephone at (251) 266–5888. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section is effective from November 6, 2026 through November 16, 2026. During this period, the safety zone will be enforced only while the S.S. UNITED STATES and all towing vessels supporting its operation are transiting within the COTP Mobile zone. The COTP will issue a Broadcast Notice to Mariners via marine channel 16 (VHF–FM) to advise the public of the exact date(s) and times in advance of the enforcement periods.

M.O. Vega,

Captain, U.S. Coast Guard, Captain of the Port Sector Mobile.

[FR Doc. 2026–22249 Filed 10–29–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2026–0467]

RIN 1625–AA00

Safety Zone; M/T KALAHARI, Gulf of America, Pascagoula, MS

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the Gulf of America. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with the M/T KALAHARI that will be conducting repairs at anchorage due to both auxiliary boilers being out of service rendering the inert gas system inoperable. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Mobile, or their designated representative.

DATES: This rule is effective without actual notice from October 30, 2026 through December 27, 2026. For the purposes of enforcement, actual notice

will be used from October 28, 2026, through October 30, 2026.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG–2026–0467.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact LT Zachary West, Sector Mobile Waterways Management Division, U.S. Coast Guard; telephone (251) 382–8653, or email sectormobilewaterways@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
IGS Inert Gas System
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background and Authority

The Coast Guard received notification from the M/T KALAHARI that both the vessel's auxiliary boilers are out of service rendering the Inert Gas System (IGS) inoperable. To fix both the boilers and IGS system, the vessel must conduct repairs at anchorage, in the Gulf of America south of Pascagoula, MS. The IGS is a critical safety system on tank vessels, and the Captain of the Port (COTP) Mobile has determined that the inoperable IGS on the M/T KALAHARA presents an increased risk of fire or explosion. Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the marine environment within the navigable waters within the safety zone, until repairs can be completed on the vessel.

Because of these potential hazards, the Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard was notified of this issue on October 12, 2026, and we must establish this safety zone immediately to protect personnel, vessels, and the marine environment. Therefore, we do not have enough time to solicit and respond to comments.

For the same reason, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a temporary safety zone from October 28, 2026, through December 27, 2026. The safety zone will cover all navigable waters in the Pascagoula Anchorage, within 1,000 meters of the M/T KALAHARI, at approximate position 30°05.533' N, 088°24.958' W. Vessels and persons will not be allowed to enter the zone during this time, unless authorized by the Captain of the Port. The safety zone will be enforced upon the arrival of the MT Kalahari in the anchorage described above. Enforcement will be terminated when repair work on the M/T KALAHARI is completed. The COTP will announce the specific enforcement dates and times via Broadcast Notice to Mariners, or other public advisories.

IV. Regulatory Analyses

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

A. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to notice and comment. Because the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act's flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

B. Collection of Information

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

C. Federalism and Indian Tribal Governments

We have analyzed this rule under Executive Order 13132, Federalism, and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

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

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies that this rule will not result in an annual expenditure of \$100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment.

This rule is a safety zone. It is categorically excluded from further review under paragraph L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; DHS Delegation No. 00170.1, Revision No. 01.4.

■ 2. Add § 165.T08–0467 to read as follows:

§ 165.T08–0467 Safety Zone; M/T KALAHARI, Gulf of America, Pascagoula, MS

(a) *Location.* The following area is a safety zone: All navigable waters of the Pascagoula Anchorage from surface to bottom, encompassed by a 1,000-meter circle around the M/T KALAHARI, at approximate position 30°05.533' N, 088°24.958' W. These coordinates are based on the World Geodetic System (WGS 84)/North American Datum 83 (NAD 83).

(b) *Definitions.* As used in this section, *designated representative* is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of the Captain of the Port Mobile (COTP).

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative on VHF–FM channel 16 or by telephone at (251) 266–5888. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section is effective from October 28, 2026 until December 27, 2026. The safety zone will be enforced upon the arrival of the MT Kalahari in the anchorage described above. Enforcement will be terminated when repair work on the M/T KALAHARI is completed. The COTP will announce the specific enforcement dates and times via Broadcast Notice to Mariners, or other public advisories.

Michael O. Vega,

Captain, U.S. Coast Guard, Captain of the Port Sector Mobile.

[FR Doc. 2026–22269 Filed 10–29–26; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2026–0529; FRL–13642–01–OCSPJ]

Dimethyl Sulfoxide in Pesticide Formulations; Exemptions From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of dimethyl sulfoxide (CAS Reg. No. 67–68–5) when used as an inert ingredient (solvent/cosolvent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, in pesticide formulations applied to animals, and in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. Spring Regulatory Sciences on behalf of Gaylord Chemical Company, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of exemptions from the requirement of a tolerance. This regulation eliminates the need to establish maximum permissible levels for residues of dimethyl sulfoxide when used in accordance with the terms of those exemptions.

DATES: This regulation is effective October 30, 2026. Objections and requests for hearings must be received on or before December 29, 2026 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2026–0529, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is EPA's authority for taking this action?

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” FFDCA section 408(c)(2)(A)(ii) defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .” Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, “available information concerning the cumulative effects of a particular pesticide's residues” and “other substances that have a common mechanism of toxicity.”

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify the docket ID number EPA-HQ-OPP-2026-0529 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before December 29, 2026.

EPA's Administrative Law Judges Division (ALJD), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See "Order Urging Electronic Filing and Service," dated December 3, 2025, which can be found at <https://www.epa.gov/system/files/documents/2025-12/2025-12-03-order-urging-electronic-filing-and-service.pdf>. Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the ALJD electronically, a person should utilize the e-filing system at https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute. If you wish to include CBI in your request, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petition for Exemption

In the **Federal Register** of June 15, 2026 (91 FR 35936, FRL-13201-02-OCSP), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-12546) by Spring Regulatory Sciences (6620 Cypresswood Dr., Suite 250, Spring, TX 77379) on behalf of Gaylord Chemical Company, LLC (106 Galeria Boulevard, Slidell, LA 70458). The petition requested that EPA establish exemptions from the requirement of a tolerance for residues of dimethyl sulfoxide (CAS Reg. No. 67-68-5) when used as an inert ingredient (solvent/co-solvent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest under 40 CFR 180.910, in pesticide formulations applied to animals under 40 CFR 180.930, and in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(a). That document referenced a summary of the petition prepared by Spring Regulatory Sciences on behalf of Gaylord Chemical Company, LLC, which is available in the docket. There were no relevant comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide

chemical residues under reasonably foreseeable circumstances will pose no harm to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for dimethyl sulfoxide, including exposure resulting from the exemptions established by this action. EPA's assessment of exposures and risks associated with dimethyl sulfoxide follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by dimethyl sulfoxide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Dimethyl sulfoxide has low acute toxicity via the oral (lethal dose, LD₅₀ >7,920 mg/kg) and dermal (LD₅₀ >40,000 mg/kg) routes, and the inhalation (lethal concentration, LC₅₀ >1,600 mg/m³) route. It is a dermal and eye irritant. It is a skin sensitizer.

Overall systemic toxicity is low for dimethyl sulfoxide. The target organ of toxicity is the eye in repeated-dose oral and dermal toxicity studies in rats, dogs, and rabbits. Changes in the lens of the eyes such as refractive changes and composition are seen in animals above the limit dose of 1,000 mg/kg/day. Portal of entry effects (respiratory tract irritation) are observed in a subchronic

inhalation toxicity study at 2.783 mg/L (above the limit dose 1 mg/L) in rats. Maternal toxicity (reduced food consumption and body weight gain) is observed at 1,000 mg/kg/day in a developmental toxicity study in rabbits. No maternal or reproductive toxicity is seen in the reproduction/developmental toxicity screening test in rats at 1,000 mg/kg/day. Also, no developmental or offspring toxicity is seen in these studies; therefore, there is no concern for fetal susceptibility. The concern for carcinogenicity is low, based on cancer initiation/promotion studies and negative results in mutagenicity studies. No evidence of neurotoxicity or immunotoxicity is observed in the available studies.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the NOAEL and the LOAEL. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level, generally referred to as a population-adjusted dose or a reference dose, and a safe margin of exposure. For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program>.

The hazard profile of dimethyl sulfoxide is adequately defined. Overall, dimethyl sulfoxide is of low acute, subchronic, and developmental toxicity. Systemic toxicity is observed only at doses $\geq 1,100$ mg/kg/day. Since no toxicological endpoints of concern or PODs were identified, EPA conducted a qualitative risk assessment for dimethyl sulfoxide.

C. Exposure Assessment

1. Dietary Exposure From Food and Feed Uses

In evaluating dietary exposure to dimethyl sulfoxide, EPA considered exposure under the existing and proposed exemptions from the requirement of a tolerance. EPA assessed dietary exposures from dimethyl sulfoxide in food as follows.

Dietary exposure (food and drinking water) to dimethyl sulfoxide may occur following ingestion of foods with residues from use in accordance with these exemptions. However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

2. From Non-Dietary Exposure

The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, and tables).

Dimethyl sulfoxide may be present in pesticide and non-pesticide products that may be used in and around the home. However, a quantitative residential exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

3. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Based on the lack of toxicity in the available database, EPA has not found dimethyl sulfoxide to share a common mechanism of toxicity with any other substances, and dimethyl sulfoxide does not appear to produce a toxic metabolite produced by other substances. For the purposes of these tolerance exemptions, therefore, EPA has assumed that dimethyl sulfoxide does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act safety factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data are available to EPA support the choice of a different factor.

Based on an assessment of dimethyl sulfoxide, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children. Because there are no threshold effects associated with dimethyl sulfoxide, EPA conducted a qualitative assessment. As part of that assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to dimethyl sulfoxide residues.

F. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

G. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of dimethyl sulfoxide (CAS Reg. No. 67–68–5) when used as an inert ingredient (solvent/co-solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910, in pesticide formulations applied to animals under 40 CFR 180.930, and in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(a).

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance exemption under FFDCA section 408 are exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.*, because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

However, EPA's 2026 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . ." (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in the pesticide-specific review documents, located in the applicable docket at <https://www.regulations.gov>.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 26, 2026.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons stated in the preamble, the EPA amends 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, amend Table 1 to § 180.910 by adding, in alphabetical order, an entry for "Dimethyl sulfoxide (CAS Reg. No. 67–68–5)" to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.910

Inert ingredients	Limits	Uses
* * *	* * *	* * *
Dimethyl sulfoxide (CAS Reg. No. 67–68–5)	None	Solvent/Co-solvent.
* * *	* * *	* * *

■ 3. In § 180.930, amend Table 1 to § 180.930 by adding, in alphabetical order, an entry for “Dimethyl sulfoxide

(CAS Reg. No. 67–68–5)” to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.
* * * * *

TABLE 1 TO 180.930

Inert ingredients	Limits	Uses
* * * * *	* * * * *	* * * * *
Dimethyl sulfoxide (CAS Reg. No. 67–68–5)	None	Solvent/Co-solvent.

* * * * *

■ 4. In § 180.940, amend Table 1 to Paragraph (a) by adding, in alphabetical order, an entry for “Dimethyl sulfoxide” to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions)
* * * * *

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Inert ingredients	CAS Reg. No.	Limits
* * * * *	* * * * *	* * * * *
Dimethyl sulfoxide	67–68–5	Solvent/Co-solvent.
* * * * *	* * * * *	* * * * *

* * * * *

[FR Doc. 2026–22176 Filed 10–29–26; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 241203–0308; RTID 0648–XG162]

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfer From Rhode Island to North Carolina

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the State of Rhode Island is transferring a portion of their 2026 commercial bluefish quota to the State of North Carolina. This quota adjustment is necessary to comply with the Atlantic Bluefish Fishery Management Plan (FMP) quota transfer provisions. This announcement informs the public of the revised 2026 commercial bluefish quotas for Rhode Island and North Carolina.

DATES: Effective October 29, 2026, through December 31, 2026.

FOR FURTHER INFORMATION CONTACT: Matthew Rigdon, Fishery Management Specialist, (978) 281–9336.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.162, and the final 2026 allocations were published on February 19, 2026 (91 FR 7896).

The final rule implementing amendment 1 to the FMP, as published in the **Federal Register** on July 26, 2000 (65 FR 45844), provided a mechanism for transferring bluefish commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can request approval to transfer or combine bluefish commercial quota under § 648.162(e). The Regional Administrator is required to consider three criteria in the evaluation of requests for quota transfers or combinations: (1) the transfers would not preclude the overall annual quota from being fully harvested; (2) the transfers address an unforeseen variation or contingency in the fishery;

and (3) the transfers are consistent with the objectives of the FMP and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Regional Administrator has determined these criteria have been met for the transfers approved in this notification.

Rhode Island is transferring 100,000 pounds (lb) (45,359 kilograms (kg)) of Atlantic bluefish to North Carolina through mutual agreement of the states. This transfer was requested to ensure North Carolina would not exceed its 2026 state quota. The revised bluefish quotas for 2026 are: Rhode Island, 310,612 lb (140,891 kg); and North Carolina, 2,043,521 lb (926,926 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.162(e)(1)(i) through (iii), which was issued pursuant to section 304(b), and is exempted from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 28, 2026.

Shannon Bettridge,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–22217 Filed 10–29–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 679**

[Docket No. 260305–0067; RTID 0648–XG003]

Fisheries of the Exclusive Economic Zone off Alaska; Pollock in Statistical Area 630 in the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for pollock in Statistical Area 630 in the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the annual 2026 total allowable catch (TAC) of pollock in Statistical Area 630 in the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), October 28, 2026, through 2400 hours, A.l.t., December 31, 2026.

FOR FURTHER INFORMATION CONTACT: Abby Jahn, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared and recommended by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens

Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The annual 2026 TAC of pollock in Statistical Area 630 in the GOA is 37,936 metric tons (mt) as established by the final 2026 and 2027 harvest specifications for groundfish in the GOA (91 FR 11902, March 11, 2026).

The Regional Administrator, Alaska Region, NMFS (Regional Administrator) has determined that the annual 2026 TAC of pollock in Statistical Area 630 in the GOA has been or will be reached. Therefore, in accordance with § 679.20(d)(1)(i) and 679.20(d)(1)(ii)(B), the Regional Administrator is establishing a directed fishing allowance of 37,436 mt and is setting aside the remaining 500 mt as incidental catch because it is necessary to support other anticipated groundfish fisheries. The Regional Administrator finds that this directed fishing allowance has been or will be reached. Consequently, in accordance with § 679.20(d)(1)(iii), NMFS is prohibiting directed fishing for pollock in Statistical Area 630 in the GOA to prevent exceeding the annual apportionment of pollock TAC for this area.

While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data on pollock catch in a timely fashion and would delay the closure of directed fishing for pollock in Statistical Area 630 in the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data on pollock catch in Statistical Area 630 in the GOA only became available as of October 27, 2026.

There is good cause under 5 U.S.C. 553(d)(3) to establish an effective date less than 30 days after date of publication. This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 28, 2026.

Shannon Bettridge,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–22218 Filed 10–28–26; 4:15 pm]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 91, No. 209

Friday, October 30, 2026

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

APPRAISAL SUBCOMMITTEE OF THE FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS26–08]

Appraisal Subcommittee Notice of Cancellation of Open Session for Special Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of cancellation of open session.

Description: On October 23, 2026, the Appraisal Subcommittee (ASC) published a notice in the **Federal Register** at 91 FR 66833 regarding a Special Meeting scheduled for October 29, 2026, at 1:00 p.m., in accordance with 12 U.S.C. 3333(b). The Special Meeting was to begin with a closed session, immediately followed by an open session. This notice serves to announce the cancellation of the open session.

Natalie Lutz,
Attorney-Advisor.

[FR Doc. 2026–22204 Filed 10–29–26; 8:45 am]

BILLING CODE 6700–01–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Survey of Housing Starts, Sales, and Completions (SOC)

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication

of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on July 20, 2026 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Commerce.

Title: Survey of Housing Starts, Sales, and Completions (SOC).

OMB Control Number: 0607–0110.

Form Number(s): SOC–QI/SF.1; SOC–QI/MF.1.

Type of Request: Regular submission, Request for an Extension, without Change, of a Currently Approved Collection Change.

Number of Respondents: We sample 19,353 new buildings each year. This results in an estimated 177,702 interviews per year.

Average Hours per Response: 5 minutes.

Burden Hours: 14809.

Needs and Uses: The U.S. Census Bureau plans to request a revision and three-year extension of the current Office of Management and Budget (OMB) clearance of the Survey of Housing Starts, Sales and Completions, also known as the Survey of Construction (SOC). The SOC is co-sponsored by the U.S. Census Bureau and the U.S. Department of Housing and Urban Development (HUD). The SOC collects monthly data on new residential construction from a sample of owners or builders. The Census Bureau uses the Computer-Assisted Personal Interviewing (CAPI) electronic questionnaires SOC–QI/SF.1 and SOC–QI/MF.1 to collect data on start and completion dates of construction, physical characteristics of the structure (floor area, number of bathrooms, type of heating system, etc.), and if applicable, date of sale, sales price, and type of financing. Data collected through the SOC provide widely used measures of construction activity, including the economic indicators Housing Starts, Housing Completions, and New Residential Sales. The current clearance for this survey is scheduled to expire on March 31, 2027.

Beginning in January 2027, the SOC will no longer be covering a sample of

non-permit-issuing areas. Non-permit estimates have steadily decreased over time and now represent less than 1% of our single-family estimates, the cost and difficulty in collecting the data is no longer worth the benefit. Instead, SOC will note that the estimates for 2027 forward are based only on permit-issuing areas.

The Census Bureau uses the information collected in the SOC to publish estimates of the number of new residential housing units started, under construction, completed, and the number of new houses sold and for sale. The Census Bureau also publishes many financial and physical characteristics of new housing units. Government agencies use these statistics to evaluate economic policy, measure progress towards the national housing goal, make policy decisions, and formulate legislation. For example, the Board of Governors of the Federal Reserve System uses data from this survey to evaluate the effect of interest rates on housing sales and construction. The Bureau of Economic Analysis uses the data in developing Gross Domestic Product (GDP). The private sector uses the information for estimating the demand for building materials and the many products used in new housing and to schedule production, distribution, and sales efforts. The financial community uses the data to estimate the demand for short-term (construction loans) and long-term (mortgages) borrowing.

Frequency: Monthly.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, Sections 8(b), 131 and 182; Title 12 U.S.C., Sections 1701z–1 and 1701z–2g.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and

entering either the title of the collection or the OMB Control Number 0607–0110.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2026–22171 Filed 10–29–26; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; 2027 Commodity Flow Survey

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on May 20th, 2026, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Commerce.

Title: 2027 Commodity Flow Survey.
OMB Control Number: 0607–0932.

Form Number(s): There are no forms associated with the 2027 CFS. All collection will be done through Centurion electronic instruments.

Type of Request: Regular submission, Request for a Reinstatement, with Change, of a Previously Approved Collection.

Number of Respondents: 45,000 for the Pre-screener survey, 140,000 (each responding 4 times) during the 2027 survey cycle.

Average Hours per Response: 5 minutes (pre-screener survey), 1.5 hours (2027 survey cycle).

Burden Hours: 843,750.

Needs and Uses: The U.S. Census Bureau, in partnership with the Bureau of Transportation Statistics (BTS), Office of the Assistant Secretary for Research and Technology, U.S. Department of Transportation (DOT), requests Office of Management and Budget (OMB) approval to conduct the 2027 Commodity Flow Survey (CFS), a

component of the 2027 Economic Census, as it is the only comprehensive source of multi-modal, system-wide data on the volume and pattern of goods movement in the United States.

The CFS provides a crucial set of statistics on the value, weight, mode, and distance of commodities shipped by mining, manufacturing, wholesale, and selected retail and services establishments, as well as auxiliary establishments that support these industries. The Census Bureau will publish these shipment characteristics for the nation, census regions and divisions, states, and CFS defined geographic areas. As with the 2022 Commodity Flow Survey, this survey also identifies export, hazardous material, and temperature-controlled shipments.

BTS is mandated by Congress under Title 49 to collect economic data on transportation mode choice and goods movement. This information informs freight flows and is critical to understanding the use, performance, and condition of the nation's transportation system, as well as informing transportation policy and investment decisions. Data on the movement of freight are important for effective analyses of changes in regional and local economic development, safety issues, and environmental concerns. They also provide the private sector with valuable data needed for critical decision-making on a variety of issues including market trends, analysis, and segmentation. Each day, governments, businesses, and consumers make countless decisions about where to go, how to get there, what to ship and which transportation modes to use. Transportation constantly responds to external forces such as shifting markets, changing demographics, safety concerns, weather conditions, energy and environmental constraints, and national defense requirements. Good decisions require having the right information in the right form at the right time.

The CFS provides critical data to federal, state and local government agencies to make a wide range of transportation investment decisions for developing and maintaining an efficient transportation infrastructure that supports economic growth and competitiveness.

Transportation planners require the periodic benchmarks provided by a continuing CFS to evaluate and respond to ongoing geographic shifts in production and distribution centers, as well as policies such as “just in time delivery.”

The 2027 CFS will be split into 2 separate, but related surveys: the pre-screener survey and the main survey.

- The pre-screener survey is the first survey and is an electronic reporting sample survey of approximately 45,000 business establishments in selected retail industries, as well as auxiliary establishments. The pre-screener survey is used to determine if the establishment ships goods or not. If the respondent indicates that no shipments are made from the establishment, the business establishment will be removed from the main survey.

- The main survey is an electronic reporting sample survey of approximately 140,000 business establishments in the mining, manufacturing, wholesale, and selected retail and services industries, as well as auxiliary establishments that support these industries.

Frequency: The survey will be conducted quarterly over the course of one year.

Respondent's Obligation: Mandatory.

Legal Authority: As part of the 2027 Economic Census, the CFS information collection is authorized by law under Title 13, U.S.C., Sections 8(b), 131 and, 193. Title 13, U.S.C., Sections 224 and 225 require response. The BTS also has authority to collect these data based on its enabling legislation 49 U.S.C., Section 6302.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and entering either the title of the collection or the OMB Control Number 0607–0932.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2026–22169 Filed 10–29–26; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE**Office of the Secretary****Agency Information Collection Activities; Submission for OMB Review; Comment Request; Eligibility Questionnaire for HAVANA Act Payments**

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on January 27, 2026, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Office of the Secretary, Department of Commerce.

Title: Eligibility Questionnaire for HAVANA Act Payments.

OMB Control Number: 0690-0037.

Form Number(s): CD-350.

Type of Request: Regular submission, Extension of approved information collection.

Number of Respondents: 20.

Average Hours per Response: 1 hour (30 minutes claimant/30 minutes physician).

Burden Hours: 20.

Needs and Uses: An individual wishing to make a claim under the HAVANA Act IFR will fill out the "Patient Demographics" portion of the Eligibility Questionnaire (CD-350) and provide it to a physician currently certified with the American Board of Psychiatry and Neurology (ABPN), the American Osteopathic Board of Neurology and Psychiatry (AOBNP), the American Board of Physical Medicine and Rehabilitation (ABPMR) or the American Osteopathic Board of Physical Medicine and Rehabilitation (AOBPMR). The board-certified physician will complete the form after examining the individual and reviewing their records and will fax or email the completed form to the Department. The physician's findings will be instrumental in determining the individual's eligibility for payment under the HAVANA Act.

As noted in the IFR, the Department believes that many respondents to this information are already known to the

Department due to prior reporting. Nevertheless, the Department notes that this form, which will be available on www.commerce.gov/havana-act, can be completed by any Department covered employee, covered individual, or covered dependent as a way of beginning an application for a HAVANA Act payment.

Respondents to this information collection are individuals who believe they are eligible for payment under the HAVANA Act (Section I of the form) and physicians responsible for evaluating their symptoms and impairment (Section II of the form).

Affected Public: Individuals or Federal Government personnel.

Frequency: One-time payment.

Respondent's Obligation: Voluntary.

Legal Authority: HAVANA Act of 2021 (Pub. L. 117-46).

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function and entering either the title of the collection or the OMB Control Number 0690-0037.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary of Economic Affairs, Commerce Department.

[FR Doc. 2026-22210 Filed 10-29-26; 8:45 am]

BILLING CODE 3510-17-P

DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board**

[B-35-2026]

Foreign-Trade Zone (FTZ) 83; Authorization of Production Activity; Adtran, Inc.; (Telecommunications Equipment); Huntsville, Alabama

On March 26, 2026, Adtran Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 83G, in Huntsville, Alabama.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 16180, April 1,

2026). On October 27, 2026, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized on a limited basis, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14, and further subject to a two-year time limit on electrically erasable programmable, read-only memory integrated circuits and printed circuit boards as foreign-status components.

Dated: October 27, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026-22237 Filed 10-29-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board**

[B-29-2026]

Production Activity Not Authorized; Foreign-Trade Zone (FTZ) 116; Valero Energy Corporation on Behalf of The Premcor Refining Group, Inc.; (Renewable Fuels); Port Arthur, Texas

On March 10, 2026, Valero Energy Corporation submitted a notification of proposed production activity on behalf of its affiliate The Premcor Refining Group, Inc. to the FTZ Board for its facility within Subzone 116C, in Port Arthur, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 12341, March 13, 2026). On October 27, 2026, the applicant was notified of the FTZ Board's decision that further review of the activity is warranted. The production activity described in the notification was not authorized. If the applicant wishes to seek authorization for this activity, it will need to submit an application for production authority, pursuant to section 400.23.

Dated: October 27, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026-22236 Filed 10-29-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board****[B–25–2026]****Production Activity Not Authorized;
Foreign-Trade Zone (FTZ) 214;
Aprinova LLC; (Cosmetic Products);
Leland, North Carolina**

On February 26, 2026, Aprinova LLC submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 214, in Leland, North Carolina.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 10370, March 3, 2026). On October 27, 2026, the applicant was notified of the FTZ Board's decision that further review of the activity is warranted. The production activity described in the notification was not authorized. If the applicant wishes to seek authorization for this activity, it will need to submit an application for production authority, pursuant to section 400.23.

Dated: October 27, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22234 Filed 10–29–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board****[B–131–2026]****Foreign-Trade Zone (FTZ) 31,
Notification of Proposed Production
Activity; World Wide Technology;
(Networking Racks); Edwardsville,
Illinois**

The America's Central Port District, grantee of FTZ 31, submitted a notification of proposed production activity to the FTZ Board (the Board) on behalf of World Wide Technology (WWT) for WWT's facilities in Edwardsville, Illinois within FTZ 31. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on October 5, 2026.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/ component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under

FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz.

The proposed finished product is networking racks (duty free).

The proposed foreign-status materials/components include: hi-speed data networking switches, ethernet networking switches; network management appliances, direct-attach copper cable assemblies; and, optical transceiver modules (duty free).

The request indicates that certain materials/components are subject to duties under section 232 of the Trade Expansion Act of 1962 or section 301 of the Trade Act of 1974, depending on the country of origin. The applicable section 232 and section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is December 9, 2026.

A copy of the notification will be available for public inspection in the "Online FTZ Information System" section of the Board's website.

For further information, contact Brian Warnes at brian.warnes@trade.gov.

Dated: October 27, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22230 Filed 10–29–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board****[B–135–2026]****Foreign-Trade Zone (FTZ) 38,
Notification of Proposed Production
Activity; ElringKlinger South Carolina,
LLC; (Automotive Battery
Subassemblies); Easley, South
Carolina**

ElringKlinger South Carolina, LLC submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Easley, South Carolina within FTZ 38. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on September 24, 2026.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/ component(s) and specific finished product(s) described in the submitted

notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz.

The proposed finished products include: battery cell interconnection assembly; battery distribution and sensing assembly; and flexible printed circuit (duty rate ranges from duty-free to 3.4%).

The proposed foreign-status materials/components include: cleaning paste; plastic resin; insulating plastic film; plastic protective cover; steel bolts; steel screws; copper busbar; aluminum sheet; aluminum connector; plastic support used to secure busbar; plastic fastener for screws; flexible printed circuit; flexible electrical connector; and plastic carrier used to support busbar (duty rate ranges from duty-free to 8.5%).

The request indicates that certain materials/components are subject to duties under section 232 of the Trade Expansion Act of 1962 or section 301 of the Trade Act of 1974, depending on the country of origin. The applicable section 232 and section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is December 9, 2026.

A copy of the notification will be available for public inspection in the "Online FTZ Information System" section of the Board's website.

For further information, contact John Frye at John.Frye@trade.gov.

Dated: October 27, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22231 Filed 10–29–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board****[B–130–2026]****Foreign-Trade Zone (FTZ) 40,
Notification of Proposed Production
Activity; Atlantic Veal & Lamb, LLC;
(Meatpacking and Processing);
Creston and Sterling, Ohio**

The Cleveland Cuyahoga County Port Authority, grantee of FTZ 40, submitted

a notification of proposed production activity to the FTZ Board (the Board) on behalf of Atlantic Veal & Lamb, LLC for the company's facilities in Creston and Sterling, Ohio, within Subzone 40Q. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on September 30, 2026.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/ component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz.

The proposed finished products include: bovine products (chilled carcasses, half carcasses, and sectioned carcasses; chilled bone-in primal and subprimals; chilled boneless primal and subprimal cuts; cured, dried, or smoked meat; cured, dried, or smoked offal; tallow; fat; frozen carcasses, half carcasses, and sectioned carcasses; frozen bone-in primal and subprimals; frozen boneless primal and subprimal cuts; edible bones; frozen edible offal; frozen tongues; boneless, chilled veal trim and manufacturing beef; boneless, frozen veal trim and manufacturing beef; raw breaded or battered cutlets, chops, and portioned cuts; raw breaded or battered bone-in chops and racks; raw seasoned or marinated cuts, cutlets, and chops; raw seasoned or formulated ground patties; raw, ready to cook, formulated meatloaf and meatballs; cooked prepared dishes, including braised shanks, with or without sauce; ready to eat cured, smoked, and fully cooked; unformulated concentrated extract; bone broth, stock, and concentrated stock); sheep products (tallow; fat; edible bones; fresh lamb carcasses and half carcasses; fresh bone in lamb; fresh boneless lamb; frozen lamb carcasses and half carcasses; frozen bone in lamb; frozen boneless lamb; seasoned, breaded, or cooked; seasoned, breaded, or cooked lamb; bone broth, stock, and concentrated stock); raw, ready to cook, formulated bovine and pork meat; and, demi-glace, fond, sauce base, and soup base containing meat extract (duty rate ranges from duty-free to 6.4% and from 0.43¢/kg to 4.4¢/kg).

The proposed foreign-status materials/components include: bovine components (chilled carcasses, half carcasses, and sectioned carcasses; chilled bone-in primal and subprimals;

chilled boneless primal and subprimal cuts; cured, dried, or smoked meat; cured, dried, or smoked offal; tallow; fat; frozen carcasses, half carcasses, and sectioned carcasses; frozen bone-in primal and subprimals; frozen boneless primal and subprimal cuts; edible bones; frozen edible offal; frozen tongues; boneless, chilled veal trim and manufacturing beef; boneless, frozen veal trim and manufacturing beef); and sheep components (tallow; fat; edible bones; fresh lamb carcasses and half carcasses; fresh lamb bone in; fresh lamb boneless; frozen lamb carcasses and half carcasses; frozen lamb bone in, frozen lamb boneless) (duty rate ranges from duty-free to 2.3% and from 0.43¢/kg to 4.4¢/kg).

The request indicates that certain materials/components are subject to duties under section 301 of the Trade Act of 1974, depending on the country of origin. The applicable section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is December 9, 2026.

A copy of the notification will be available for public inspection in the "Online FTZ Information System" section of the Board's website.

For further information, contact Juanita Chen at juanita.chen@trade.gov.

Dated: October 27, 2026.

Colin Agostisi,
Executive Secretary.

[FR Doc. 2026-22238 Filed 10-29-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-28-2026]

Foreign-Trade Zone (FTZ) 46; Authorization of Production Activity; Patheon API, Inc.; (Pharmaceutical Products); Cincinnati, Ohio

On March 9, 2026, Patheon API, Inc., submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 46K, in Cincinnati, Ohio.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 12341, March 13, 2026). On October 27, 2026, the applicant was notified of the FTZ

Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: October 27, 2026.

Colin Agostisi,
Executive Secretary.

[FR Doc. 2026-22235 Filed 10-29-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-351-856]

Certain Aluminum Foil From Brazil: Final Results of Antidumping Duty Administrative Review; 2023-2024

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Companhia Brasileira de Alumínio and CBA Itapissuma Ltda. (collectively, CBA) made sales of certain aluminum foil (aluminum foil) from Brazil at prices below normal value (NV) during the period of review (POR) November 1, 2023, through October 31, 2024.

DATES: Applicable October 30, 2026.

FOR FURTHER INFORMATION CONTACT: Robert Hedberg, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-0955.

SUPPLEMENTARY INFORMATION:

Background

On May 7, 2026, Commerce published in the **Federal Register** the *Preliminary Results* of this review and invited interested parties to comment.¹ Commerce conducted this administrative review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act).

For a complete description of the events that followed the initiation of this review, see the Issues and Decision Memorandum.² The Issues and Decision

¹ See *Certain Aluminum Foil from Brazil: Preliminary Results of Antidumping Duty Administrative Review; 2023-2024*, 91 FR 24804 (December 13, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

² See Memorandum, "Issues and Decision Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order on Certain Aluminum Foil from Brazil; 2023-2024," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/frnotices>.

Scope of the Order³

The merchandise covered by scope of the *Order* is aluminum foil from Brazil. For a complete description of the scope of the *Order*, see the Issues and Decision Memorandum.⁴

Analysis of Comments Received

We addressed the issues raised by parties for these final results of review in the Issues and Decision Memorandum. A list of the issues that parties raised, to which we responded in the Issues and Decision Memorandum, is provided in the appendix to this notice.

Changes Since the Preliminary Results

Based on our analysis of the comments received from interested parties, we made certain changes to the *Preliminary Results*. For a discussion of these changes, see the Issues and Decision Memorandum.

Final Results of Administrative Review

We determine that the following weighted-average dumping margin exists for the period November 1, 2023, through October 31, 2024:

Exporter/producer	Weighted-average dumping margin (percent)
Companhia Brasileira de Alumínio/CBA Itapissuma ⁵	13.65

Disclosure

Commerce intends to disclose the calculations and analysis performed in

³ See *Certain Aluminum Foil from the Republic of Armenia, Brazil, the Sultanate of Oman, the Russian Federation, and the Republic of Turkey: Antidumping Duty Orders*, 86 FR 62790 (November 12, 2021) (*Order*).

⁴ See Issues and Decision Memorandum at 2.

⁵ Commerce preliminarily determined that Companhia Brasileira de Alumínio and CBA Itapissuma Ltda. are affiliated, within the meaning of sections 771(33)(E) and (G) of the Act, and should be treated as a single entity, in accordance with 19 CFR 351.401(f). See *Preliminary Results*, 91 FR at 24804. Commerce received no comments regarding this preliminary determination. Accordingly, Commerce continues to find that Companhia Brasileira de Alumínio and CBA

connection with the final results of this administrative review to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the publication date of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. For CBA, we calculated importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales and the total entered value of those sales in accordance with 19 CFR 351.212(b)(1). Where an importer-specific assessment rate is *de minimis* (i.e., less than 0.5 percent), the entries by that importer will be liquidated without regard to antidumping duties. For entries of subject merchandise during the POR produced by CBA for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.⁶

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (i.e., within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as provided by section 751(a)(2) of the Act: (1) the cash deposit rate for the companies subject to this review will be equal to the company-specific weighted-average dumping margin established in the final results of the review; (2) for merchandise exported

Itapissuma Ltda. are affiliated and continues to treat these companies as a single entity.

⁶ See *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

by producers or exporters not covered in this review but covered in a prior completed segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published in the completed segment for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the producer has been covered in a prior completed segment of this proceeding, then the cash deposit rate will be the rate established in the completed segment for the most recent period for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 13.93 percent, the all-others rate established in the less-than-fair-value investigation of this proceeding.⁷ These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order (APO)

This notice also serves as a reminder to parties subject to an APO of their responsibility concerning the destruction or return of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the destruction or return of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

⁷ See *Order*, 86 FR at 62791.

Dated: October 27, 2026.

Scot Fullerton,

*Acting Deputy Assistant Secretary for
Antidumping and Countervailing Duty
Operations.*

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Changes Since the *Preliminary Results*
- V. Discussion of the Issues
 - Comment 1: Whether to Treat CBA Aluminio and CBA Itapissuma as a Single Entity
 - Comment 2: Whether to Add Taxes Related to Billing Adjustments to the Gross Unit Price
 - Comment 3: Whether Insurance Expenses Were Properly Deducted from the Export Price
- VI. Recommendation

[FR Doc. 2026–22126 Filed 10–29–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–427–830]

Strontium Chromate From France: Final Results of Antidumping Duty Administrative Review; 2023–2024

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Société Nouvelle des Couleurs Zinciques (SNCZ) did not make sales of strontium chromate from France in the United States at less than normal value (NV) during the period of review (POR) November 1, 2023, through October 31, 2024.

DATES: Applicable October 30, 2026.

FOR FURTHER INFORMATION CONTACT: Jonathan Schueler or Rachel Accorsi, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9175 or (202) 482–3149, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 8, 2026, Commerce published the *Preliminary Results* of this administrative review in the **Federal Register**.¹ Between June 1 and 5, 2026,

¹ See *Strontium Chromate from France: Preliminary Results of Antidumping Duty Administrative Review; 2023–2024*, 91 FR 25339

Commerce conducted verification of SNCZ in Beauchamp, France.² On August 7, 2026, Commerce extended the deadline for the final results until October 28, 2026.³ On August 21, 2026, Commerce invited interested parties to comment on the *Preliminary Results* and SNCZ's Verification Report.⁴ No interested party submitted a case brief. Commerce conducted this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order⁵

The product covered by this *Order* is strontium chromate from France. For a complete description of the scope of the *Order*, see the *Preliminary Results* PDM.

Verification

As provided in section 782(i) of the Act, in June 2026, Commerce conducted on-site verification of the sales and cost data reported by SNCZ. We used standard verification procedures, including an examination of relevant accounting and sales records, and original source documentation provided by SNCZ.⁶

Changes Since the Preliminary Results

Commerce is implementing certain changes due to verification findings that have no impact on the dumping margin.⁷ As no parties submitted comments regarding the *Preliminary Results* or Commerce's verification findings, we made no further changes to the *Preliminary Results* and no decision memorandum accompanies this notice.

Final Results of Review

As a result of this review, we determine the following weighted-average dumping margin exists for the POR, November 1, 2023, through October 31, 2024:

(May 8, 2026) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, "Verification of the Sales and Cost Response of Société Nouvelle des Couleurs Zinciques in the Antidumping Administrative Review of Strontium Chromate from France," dated August 20, 2026 (SNCZ's Verification Report).

³ See Memorandum, "Extension of Deadline for Final Results of Antidumping Duty Administrative Review," dated August 7, 2026.

⁴ See Memorandum, "Establishment of the Briefing Schedule," dated August 21, 2026.

⁵ See *Strontium Chromate from Austria and France: Antidumping Duty Orders*, 84 FR 65349 (November 27, 2019) (*Order*).

⁶ See SNCZ's Verification Report.

⁷ See Memorandum, "Final Results Margin Calculation for Société Nouvelle des Couleurs Zinciques," dated concurrently with this notice.

Exporter or producer	Weighted-average dumping margin (percent)
Société Nouvelle des Couleurs Zinciques	0.00

Disclosure

Commerce intends to disclose to parties in this proceeding the calculations performed for these final results of review within five days of a public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final results in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. As there are no entered values on the record for SNCZ's sales, pursuant to 19 CFR 351.212(b)(1), we calculated importer-specific per-unit duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total quantity of those sales. To determine whether an importer-specific per-unit duty assessment rate is *de minimis*, we calculated an estimated entered value. If either SNCZ's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c), or an importer-specific assessment rate is zero or *de minimis*, we instruct CBP to liquidate the appropriate entries without regard to antidumping duties.⁸ Accordingly, because SNCZ's weighted-average dumping margin is zero percent, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Commerce's "reseller policy" will apply to entries of subject merchandise during the POR produced by the company included in these final results of review for which the reviewed company did not know that the merchandise it sold to the intermediary (e.g., a reseller, trading company, or exporter) was destined for the United States. In such instance, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for

⁸ See *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification*, 77 FR 8101, 8102 (February 14, 2012).

the intermediate company(ies) involved in the transaction.⁹

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for SNCZ will be equal to the weighted-average dumping margin established in the final results of this administrative review (*i.e.*, 0.00 percent); (2) for merchandise exported by a producer or exporter not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the producer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of the proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers and exporters will continue to be 32.16 percent *ad valorem*, the all-others rate established in the LTFV investigation.¹⁰ These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties

occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order (APO)

This notice also serves as a reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: October 26, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026-22233 Filed 10-29-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-557-822]

Utility Scale Wind Towers From Malaysia: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on utility scale wind towers (wind towers) from Malaysia would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the "Final Results of Sunset Review" section of this notice.

DATES: Applicable November 2, 2026.

FOR FURTHER INFORMATION CONTACT: Connor Field, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: 202-482-3997.

SUPPLEMENTARY INFORMATION:

Background

On August 4, 2021, Commerce published in the **Federal Register** the CVD order on wind towers from Malaysia.¹ On July 2, 2026, Commerce published the notice of initiation of the first sunset review of the *Order*, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.218(c).²

On July 17, 2026, Commerce received a notice of intent to participate in this review from the domestic interested party, within the deadline specified in 19 CFR 351.218(d)(1)(i).³ The domestic interested party claimed interested party status under sections 771(9)(C) and (F) of the Act as a U.S. producer and as a coalition consisting of a U.S. producer of the domestic like product.⁴

On August 3, 2026, Commerce received an adequate substantive response from the domestic interested party within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).⁵ Commerce did not receive a substantive response from either the Government of Malaysia or any other respondent interested party to this proceeding. On August 24, 2026, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.⁶ As a result, Commerce conducted an expedited (120-day) sunset review of the *Order*, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(B)(2) and (C)(2).

Scope of the Order

The products covered by the *Order* are utility scale wind towers. For a full description of the scope, see the Issues and Decision Memorandum.⁷

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of subsidization and the

¹ See *Utility Scale Wind Towers from Malaysia: Countervailing Duty Order*, 86 FR 41950 (August 4, 2021) (*Order*).

² See *Initiation of Five-Year (Sunset) Reviews*, 91 FR 40515, 40516 (July 2, 2026).

³ See Domestic Interested Party's Letter, "Notice of Intent to Participate in Sunset Review," dated July 17, 2026.

⁴ *Id.* at 2.

⁵ See Domestic Interested Party's Letter, "Substantive Response to Notice of Initiation," dated August 3, 2026.

⁶ See Commerce's Letter, "Sunset Reviews Initiated on July 2, 2026," dated August 24, 2026.

⁷ See Memorandum, "Issues and Decision Memorandum for the Final Results of the Expedited Sunset Review of the Countervailing Duty Order on Utility Scale Wind Towers from Malaysia," dated concurrently with this notice (Issues and Decision Memorandum).

⁹ For a full discussion of this practice, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

¹⁰ See *Order*, 84 FR at 65350.

countervailable subsidy rates likely to prevail if the *Order* were to be revoked, is contained in the accompanying Issues and Decision Memorandum.⁸ A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System, which is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/frnotices>.

Final Results of Sunset Review

Pursuant to sections 751(c) and 752(b) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to continuation or recurrence of countervailable subsidies at the following net countervailable subsidy rates:

Producers/exporters	Net countervailable subsidy rate (percent <i>ad valorem</i>)
CS Wind Malaysia Sdn Bhd	6.43
All Others	6.43

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act, and 19 CFR 351.221(c)(5)(ii).

Dated: October 28, 2026.
Scot Fullerton,
Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the *Order*
- IV. History of the *Order*
- V. Legal Framework
- VI. Discussion of the Issues
 - 1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
 - 2. Net Countervailable Subsidy Rates Likely to Prevail
 - 3. Nature of the Subsidies
- VII. Final Results of Sunset Review
- VIII. Recommendation

[FR Doc. 2026–22245 Filed 10–29–26; 8:45 am]
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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Coastal Zone Management Program Administration

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on June 17, 2026, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: Coastal Zone Management Program Administration.

OMB Control Number: 0648–0119.
Form Number(s): None.

Type of Review: Regular submission (revision and extension of a current information collection).

Number of Respondents: 34.

Average Hours per Response: Performance Reports, 2–40 hours depending on the report; assessment

and strategy documents, 260 hours; Section 306A questionnaire and documentation, 25 hours; amendments and routine program changes, 15 hours; CNP documentation, 15 hours; CZMA Performance Management System, 25 hours.

Total Annual Burden Hours: 7,961.

Needs and Uses: This request is for revision and extension of a currently approved information collection.

In 1972, in response to intense pressure on United States (U.S) coastal resources, and because of the importance of U.S. coastal areas, the U.S. Congress passed the Coastal Zone Management Act of 1972 (CZMA), 16 U.S.C. 1451 et. seq. The CZMA authorized a federal program to encourage coastal states and territories to develop comprehensive coastal management programs. The CZMA has been reauthorized on several occasions, most recently with the enactment of the Coastal Zone Protection Act of 1996. The program is administered by the Secretary of Commerce, who in turn has delegated this responsibility to the National Oceanic and Atmospheric Administration's (NOAA) National Ocean Services (NOS).

Coastal zone management grants provide funds to states and territories to: implement federally-approved coastal management programs; complete information for the Coastal Zone Management Program (CZMP) Performance Management System; develop multi-year program assessments and strategies to enhance their programs within priority areas under Section 309 of the CZMA; submit documentation as described in the CZMA Section 306A for specific construction, acquisition, and educational projects; submit requests to update their federally-approved programs through amendments or program changes; and develop and submit state coastal nonpoint pollution control programs (CNP) as required under Section 6217 of the Coastal Zone Act Reauthorization Amendments of 1990 (16 U.S.C. 1455b).

This collection of information is being revised as follows.

First, the *Office for Coastal Management Fiscal Year 2026 Performance Progress Report Guidelines Coastal Management Program Annual Awards (Sections 306, 306A, 309, and 310) and Projects of Special Merit* (Updated 2026) have been revised to include minor updates, formatting and copy edits and to provide clarification for reporting on competitive and multi-year awards, as well as additional guidance on financial reporting requirements. The updated guidance includes a short overview of the Federal

⁸ *Id.*

Funding Accountability and Transparency Act (FFATA) reporting requirements and requirements for reporting on real property acquired under the award.

Second, the *Section 309 Strategy & Assessment Program Guidance* has undergone minor updates to update the timeline for current submittals, and to ensure consistency with current NOAA/NOS priorities, as well as the CZM Program Strategic Plan.

Third, minor edits to clarify requirements and reference the new ServiceNow Performance Measure database have been made to the *Coastal Zone Management Act (CZMA) Performance Measurement System Coastal Management Program Guidance* (April 2011, updated June 2025).

Finally, the CZM Section 306A guidance has undergone minor updates to remove references to rescinded executive orders.

Affected Public: State, Local, or Tribal government.

Frequency: On occasion, depending on the collection instrument.

Respondent's Obligation: Required to Obtain or Retain Benefits.

Legal Authority: Coastal Zone Management Act (16 U.S.C. 1451, et seq).

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0119.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2026–22170 Filed 10–29–26; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; DOCX Submission Requirements

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

ACTION: Notice of information collection; request for comments.

SUMMARY: The United States Patent and Trademark Office (hereafter "USPTO" or "Agency") will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The USPTO invites comments on the information collection renewal of 0651–0089, which helps the USPTO assess the impact of its information collection requirements and minimize the reporting burden to the public. Public comments were previously requested via the **Federal Register** on April 27, 2026, during a 60-day comment period (91 FR 22526). This notice allows for an additional 30 days for public comments.

DATES: To ensure consideration, you must submit comments regarding this information collection on or before November 30, 2026.

ADDRESSES: Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website, <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function and entering either the title of the information collection or the OMB Control Number, 0651–0089. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT:

- This information collection request may be viewed at <https://www.reginfo.gov>. Follow the instructions to view the Department of Commerce, USPTO information collections currently under review by OMB.

- Email:** InformationCollection@uspto.gov. Include "0651–0089 information request" in the subject line of the message.

- Mail:** Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

- Telephone:** Raul Tamayo, Senior Legal Advisor, 571–272–7728.

SUPPLEMENTARY INFORMATION:

Title: DOCX Submission

Requirements.

OMB Control Number: 0651–0089.

Abstract: The fee set forth in 37 CFR 1.16(u) became effective January 17, 2024, and is due for any application filed under 35 U.S.C. 111 for an original patent—except design, plant, or provisional applications—where the specification, claims, and/or abstract do not conform to the USPTO requirements for submission in the DOCX format. Therefore, the fee is due for nonprovisional utility applications filed under 35 U.S.C. 111, including continuing applications, that are not filed in the DOCX format. See *Setting and Adjusting Patent Fees During Fiscal Year 2020*, 85 FR 46932 (August 3, 2020).¹

The USPTO continues to provide several resources to help applicants submit their applications in the DOCX format. The Patent Center and DOCX web pages contain many resources for applicants, such as FAQs and a training mode through which applicants may file test submissions to practice filing in DOCX.² The USPTO also provides a Patent Center User Guide³ and a DOCX Intake in Patent Center Quick Start Guide⁴ to assist applicants in navigating the Patent Center system. The USPTO also provides free training sessions and videos demonstrating how to file DOCX documents in Patent Center.⁵ For one-on-one assistance, the USPTO's Patent Center Help Desk provides step-by-step guidance for submitting applications to the USPTO.

The items in this information collection relate solely to the impacts of the § 1.16(u) non-DOCX filing surcharge fee on the filing of nonprovisional utility applications under 35 U.S.C. 111, including continuing applications. In particular, this information collection accounts for the § 1.16(u) non-DOCX filing surcharge fee itself, as well as an additional 30 minutes of time to

¹ <https://www.govinfo.gov/content/pkg/FR-2020-08-03/pdf/2020-16559.pdf>.

² <https://www.uspto.gov/patents/apply/patent-center>.

³ https://www.uspto.gov/sites/default/files/documents/Patent_Center_User_Guide_November_2023.pdf.

⁴ https://www.uspto.gov/sites/default/files/documents/DOCX_QSG_Final.pdf.

⁵ <https://www.uspto.gov/about-us/events/patents-docx-filing>.

accommodate (i) extra review that some respondents might undertake when filing in the DOCX format and (ii) submissions of the back-up applicant-generated PDF that some respondents will opt to submit.

The estimated volumes for the items in this information collection are based on the estimates for the corresponding nonprovisional utility applications filed under 35 U.S.C. 111, including continuing applications, that are covered under another OMB clearance 0651-0032 (Initial Patent Applications). Respondents for the items in this information collection will either take an extra 0.50 hours (30 minutes) to file their applications in DOCX format or they will pay the non-DOCX surcharge but will not do both.

Forms: None.

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Estimated Number of Annual Respondents: 364,999 respondents (including 27,156 respondents from filing fees).

Estimated Number of Annual Responses: 364,999 responses (including 27,156 responses from filing fees).

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately 30 minutes (0.50 hours) to complete. This includes the time to gather the necessary information, create the document, and submit the completed item to the USPTO.

Estimated Total Annual Respondent Burden Hours: 168,922 hours.

Estimated Total Annual Respondent Non-hourly Cost Burden: \$8,472,290.

Justin Isaac,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2026-22193 Filed 10-29-26; 8:45 am]

BILLING CODE 3510-16-P

CONSUMER FINANCIAL PROTECTION BUREAU

[Docket No. CFPB-2026-0025]

Agency Information Collection Activities: Comment Request

AGENCY: Consumer Financial Protection Bureau.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau or CFPB) requests the Office of Management and Budget's (OMB's) extension of the existing information collection titled "Electronic Fund Transfer Act (Regulation E)" approved under OMB Control Number 3170-0014.

DATES: Written comments are encouraged and must be received on or before December 29, 2026 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Email:* PRA_Comments@cfpb.gov. Include Docket No. CFPB-2026-0025 in the subject line of the email.

- *Mail/Hand Delivery/Courier:* Comment Intake, Consumer Financial Protection Bureau (Attention: PRA Office), 445 12th St. SW, Washington, DC 20024-2101. Because paper mail in the Washington, DC area and at the CFPB is subject to delay, commenters are encouraged to submit comments electronically.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to Anthony May, PRA Officer, at (202) 435-7278, or email: CFPB_PRA@cfpb.gov. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov. Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Electronic Fund Transfer Act (Regulation E).

OMB Control Number: 3170-0014.

Type of Review: Extension of a currently approved information collection.

Affected Public: Private sector.

Estimated Number of Respondents: 600,000.

Estimated Total Annual Burden Hours: 3,361,056.

Abstract: The Electronic Fund Transfer Act (EFTA), 15 U.S.C. 1693 *et seq.*, requires accurate disclosure of the costs, terms, and rights relating to

electronic fund transfer (EFT) services and remittance transfer services to consumers. Entities offering EFT services must provide consumers with full and accurate information regarding consumers' rights and responsibilities in connection with EFT services. These disclosures are intended to protect the rights of consumers using EFT services, such as automated teller machine (ATM) transfers, telephone bill-payment services, point-of-sale transfers at retail establishments, electronic check conversion, payroll cards, and preauthorized transfers from or to a consumer's account. EFTA also establishes error resolution procedures and limits consumer liability for unauthorized transfers in connection with EFT services. EFTA and Regulation E impose disclosure and other requirements on issuers and sellers of gift cards, gift certificates, and general-use prepaid cards. Further, EFTA and Regulation E establish a legal framework governing remittance transfers, including certain disclosure obligations, error resolution procedures, and cancellation rights.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB's approval. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2026-22227 Filed 10-29-26; 8:45 am]

BILLING CODE 4810-AM-P

CONSUMER FINANCIAL PROTECTION BUREAU

[Docket No. CFPB-2026-0026]

Agency Information Collection Activities: Comment Request

AGENCY: Consumer Financial Protection Bureau.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau or CFPB) is requesting to renew the Office of Management and Budget's (OMB's) approval for an existing collection, titled "Real Estate Settlement Procedures Act (Regulation X)" approved under OMB Control Number 3170-0016.

DATES: Written comments are encouraged and must be received on or before December 29, 2026 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Email:* PRA_Comments@cfpb.gov. Include Docket No. CFPB-2026-0026 in the subject line of the email.
- *Mail/Hand Delivery/Courier:* Comment Intake, Consumer Financial Protection Bureau (Attention: PRA Office), 445 12th St. SW, Washington, DC 20024-2101.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to Anthony May, PRA Officer, at (202) 435-7278, or email: CFPB_PRA@cfpb.gov. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov. Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Real Estate Settlement Procedures Act (Regulation X).

OMB Control Number: 3170-0016.

Type of Review: Extension of a currently approved collection.

Affected Public: Private sector.

Estimated Number of Respondents: 9,377.

Estimated Total Annual Burden Hours: 1,811,553.

Abstract: Regulation X, 12 CFR 1024.1 et seq., implements the Real Estate Settlement Procedures Act (RESPA). Regulation X contains information collections in the form of various

disclosure and recordkeeping requirements. The disclosures in this collection are required by the statute or implementing regulations. Consumers use the disclosures required by RESPA and Regulation X to inform their choice of settlement service providers, to review the final terms of a settlement, to understand whom to contact about questions concerning their mortgage loan, and to identify and to protect themselves against inaccurate or questionable loan servicing practices.

The information collections discussed in this supporting statement are required in Regulation X.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB's approval. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2026-22228 Filed 10-29-26; 8:45 am]

BILLING CODE 4810-AM-P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Comment Request; AmeriCorps Application Questions

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service (operating as AmeriCorps) is proposing to revise an information collection for AmeriCorps' grant application package.

DATES: Written comments must be submitted to the individual and office

listed in the **ADDRESSES** section by December 29, 2026.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) Electronically through www.regulations.gov (preferred method).

(2) By mail sent to: AmeriCorps, Attention: Katie Kane, AmeriCorps, 250 E Street SW, Washington, DC 20525.

(3) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (2) above, between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

Comments submitted in response to this notice may be made available to the public through [regulations.gov](http://www.regulations.gov). For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT:

Katie Kane, Office of Regional Operations, 202-606-6826, or by email at KKane@americorps.gov.

SUPPLEMENTARY INFORMATION:

Title of Collection: AmeriCorps Application Questions.

OMB Control Number: 3045-0187.

Type of Review: Revision.

Respondents/Affected Public:

Organizations, and State, local, or Tribal governments.

Total Estimated Number of Annual Responses: 13,200.

Total Estimated Number of Annual Burden Hours: 79,200.

Abstract: This information collection consists of generic application questions to which applicants for AmeriCorps funding respond. The application is completed electronically using the Agency's web-based grants management system or submitted via email. Revisions to the form including replacing the field for a DUNS number with a field for the UEI number; adding a question about whether the applicant is required to have a single audit in the fiscal year; adding affirmations that the applicant will complete all required

criminal history checks, comply with AmeriCorps branding requirements, provide any requested health care and liability coverage, and include any volunteer recognition activities; adding questions about how many documents are being submitted with the application; adding options under the narratives section for types of need, project management, and volunteer management; adding a category for “youth and young adults (14–21) in the target population list of options; adding options for “Characteristics and Priorities”; adding a field to enter or revise projected totals of other revenue funds, number of volunteers generated by AmeriCorps members, and percent of disadvantaged youth enrolled; adding options for type of service location and station type; replacing “Senior Corps” with “AmeriCorps Seniors” to reflect current terminology; and adding a field in the budget for Senior Demonstration Programs. The currently approved information collection is due to expire on January 31, 2027.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will

be available for public inspection on [regulations.gov](https://www.regulations.gov).

Erin McGrath,

Director, Office of Regional Operations.

[FR Doc. 2026–22216 Filed 10–29–26; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2026–0364; OMB Control Number 0704–0332]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement (DFARS) Appendix I

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice.

SUMMARY: The Defense Acquisition Regulations System has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by November 30, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

You may also submit comments, identified by docket number and title, by the following method: Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT: Mr. Reginald T. Lucas, 571–372–7574, or whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Appendix I; OMB Control Number 0704–0332.

Type of Request: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Number of Respondents: 96.

Responses per Respondent: 1.9, approximately.

Annual Responses: 180.

Average Burden per Response: 2.33 hours, approximately.

Annual Burden Hours: 420.

Needs and Uses: Section 831 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 1991 (Pub. L. 101–510, 10 U.S.C. 4902) required DoD to establish the DoD Pilot Mentor-Protégé Program, renamed the DoD Mentor-Protégé Program (the “Program”). Congress requires DoD to collect certain information from program participants in section 861, paragraph (b)(2), of Public Law 114–92. Thus, the need for this information collection is to comply with existing laws. DoD has incorporated these information collection requirements into the DFARS in section I–112 of Appendix I. Program participants agree to comply with these information collection requirements when they execute their mentor-protégé agreements, receiving the program's benefits in consideration.

This information is necessary to ensure that participants are fulfilling their obligations under the mentor-protégé agreements and furthering the purpose of the DoD Mentor-Protégé Program as required by section 18(d)(7) of the Small Business Act (15 U.S.C. 637(d)(7)). In accordance with 10 U.S.C. 4902, DoD uses the information to decide whether to approve continuation of the agreement. In addition, the information is necessary for program managers to direct developmental assistance to the most appropriate small business concerns and to ensure the program meets the Congressionally-mandated goal of enhancing the defense industrial base.

DoD Clearance Officer: Mr. Reginald T. Lucas. Requests for copies of the information collection proposal should be sent to Mr. Lucas at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Jennifer D. Johnson,

Alternate Federal Register Liaison Officer, Defense Acquisition Regulations System.

[FR Doc. 2026–22183 Filed 10–29–26; 8:45 am]

BILLING CODE 6001–FR–P

DELAWARE RIVER BASIN COMMISSION

Notice of Public Hearing and Business Meeting November 4, 2026 and December 3, 2026

Notice is hereby given that the Delaware River Basin Commission will hold a public hearing on Wednesday,

November 4, 2026. A business meeting will be held the following month on Thursday, December 3, 2026. Both the hearing and the business meeting are open to the public. The public hearing and the business meeting will be conducted virtually.

Public Hearing. The Commission will conduct the public hearing virtually on November 4, 2026, commencing at 1:30 p.m. Hearing items will include draft dockets for withdrawals, discharges, and other projects that could have a substantial effect on the basin's water resources. A list of the projects scheduled for hearing, including project descriptions, along with links to draft docket decisions and draft resolutions will be posted on the Commission's website, www.drbc.gov, in a long form of this notice at least ten days before the hearing date.

Written comments on matters scheduled for hearing on November 4, 2026 will be accepted through 5:00 p.m. on Monday, November 9, 2026.

The public is advised to check the Commission's website periodically during the ten days prior to the hearing date, as items scheduled for hearing may be postponed if additional time is needed to complete the Commission's review. Items also may be added up to ten days prior to the hearing date. In reviewing docket descriptions, the public is asked to be aware that the details of projects may change during the Commission's review, which is ongoing.

Business Meeting. The business meeting on December 3, 2026 will begin at 10:00 a.m. and will include: adoption of the Minutes of the Commission's September 2, 2026 business meeting; announcements of upcoming meetings and events; a report on hydrologic conditions; reports by the Executive Director and the Commission's General Counsel; and consideration of any items for which a hearing has been completed or is not required. The agenda is expected to include consideration of the resolutions and draft dockets for withdrawals, discharges, and other projects that are subjects of the public hearing on November 4, 2026.

After all scheduled business has been completed and as time allows, the business meeting will be followed by up to one hour of Open Public Comment, an opportunity to address the Commission off the record on any topic concerning management of the Basin's water resources outside the context of a duly noticed, on-the-record public hearing.

There will be no opportunity for additional public comment for the record at the December 3, 2026 business

meeting on items for which a hearing was completed on November 4, 2026 or a previous date. Commission consideration on November 4, 2026 of items for which the public hearing is closed may result in approval of the item as proposed, approval with changes, denial, or deferral. When the Commissioners defer an action, they may announce an additional period for written comment on the item, with or without an additional hearing date, or they may take additional time to consider the input they have already received without requesting further public input. Any deferred items will be considered for action at a public meeting of the Commission on a future date.

Advance Registration and Sign-Up for Oral Comment. Links for registration to attend the virtual public hearing and the business meeting will be posted at www.drbc.gov at least ten days before each meeting date. Registrants who wish to comment on the record during the public hearing on November 4, 2026 or to address the Commissioners informally during the Open Public Comment session following the meeting on December 3, 2026 as time allows, will be asked to so indicate when registering. The Commission's public hearing, business meeting, and Open Public Comment session will also be livestreamed on YouTube at https://www.youtube.com/@DRBC_1961. For assistance, please contact Ms. Kate Schmidt of the Commission staff, at kate.schmidt@drbc.gov.

Addresses for Written Comment. Written comment on items scheduled for hearing may be submitted through the Commission's web-based comment system, a link to which is provided at www.drbc.gov. Use of the web-based system ensures that all submissions are captured in a single location and their receipt is acknowledged. Exceptions to the use of this system are available based on need, by submitting your comment and written request to the attention of the Commission Secretary, DRBC, P.O. Box 7360, 25 Cooley Road, West Trenton, NJ 08628-0360. For assistance, please contact Kate Schmidt at kate.schmidt@drbc.gov.

Accommodation for Special Needs. Closed captioning will be available on both webinar and live-stream platforms. Those with limited internet access may listen and speak at virtual public meetings of the DRBC using any of several toll-free phone numbers that will be provided to all virtual meeting registrants.

Other individuals in need of an accommodation as provided for in the Americans with Disabilities Act who

wish to attend the virtual hearing or business meeting should contact the Commission Secretary directly at 609-477-7203 or through the Telecommunications Relay Services (TRS) at 711, to discuss how we can accommodate your needs.

Additional Information, Contacts. Additional public records relating to hearing items may be examined at the Commission's offices by appointment by contacting Donna Woolf, 609-477-7222. For other questions concerning hearing items, please contact David Kovach, Project Review Manager, at 609-477-7264.

Authority. Delaware River Basin Compact, Public Law 87-328, Approved December 27, 1961, 75 Statutes at Large, 688, sec. 14.4.

Dated: October 22, 2026.

Naomi Mendelsohn,

Commission Secretary and Assistant General Counsel.

[FR Doc. 2026-22253 Filed 10-29-26; 8:45 am]

BILLING CODE 6360-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2458-000]

Great Lakes Hydro America, LLC; Notice of Authorization for Continued Project Operation

The license for the Penobscot Mills Hydroelectric Project No. 2458 was issued for a period ending September 30, 2026.

Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year-to-year an annual license to the then licensee(s) under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b),

to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2458 is issued to Great Lakes Hydro America, LLC for a period effective October 1, 2026, through September 30, 2027, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first.

If issuance of a new license (or other disposition) does not take place on or before September 30, 2027, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that Great Lakes Hydro America, LLC is authorized to continue operation of the Penobscot Mills Hydroelectric Project under the terms and conditions of the prior license until the issuance of a subsequent license for the project or other disposition under the FPA, whichever comes first.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

(Authority: 18 CFR 2.1)

Dated: October 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-22200 Filed 10-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP27-3-000]

Double E Pipeline, LLC; Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Texas Mainline Compressor Station Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document that will discuss the environmental impacts of the Texas Mainline Compressor Station Project involving construction and operation of facilities by Double E Pipeline, LLC (Double E) in Loving County, Texas. The Commission will

use this environmental document in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the project. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. This gathering of public input is referred to as “scoping.” The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission’s NEPA process is described below in the *NEPA Process and Environmental Document* section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on November 27, 2026. Comments may be submitted in written form. Further details on how to submit comments are provided in the *Public Participation* section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all written comments during the preparation of the environmental document.

If you submitted comments on this project to the Commission before the opening of this docket on October 2, 2026, you will need to file those comments in Docket No. CP27-3-000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission’s current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about

the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the project, the Natural Gas Act conveys the right of eminent domain to the company. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law. The Commission does not subsequently grant, exercise, or oversee the exercise of that eminent domain authority. The courts have exclusive authority to handle eminent domain cases; the Commission has no jurisdiction over these matters.

Double E provided landowners with a fact sheet prepared by the FERC entitled “An Interstate Natural Gas Facility On My Land? What Do I Need To Know?” which addresses typically asked questions, including the use of eminent domain and how to participate in the Commission’s proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (www.ferc.gov) under the Natural Gas, Landowner Topics link.

Public Participation

There are three methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208-3676 or FercOnlineSupport@ferc.gov.

(1) You can file your comments electronically using the eComment feature, which is located on the Commission’s website (www.ferc.gov) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature, which is located on the Commission’s website (www.ferc.gov) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on “eRegister.” You will be asked to select the type of filing you are making; a comment on a particular project is considered a “Comment on a Filing”; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP27–3–000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Additionally, the Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Summary of the Proposed Project

Double E proposes to construct and operate a natural gas compressor station (“Mainline Compressor Station”) including two centrifugal compressor units driven by two natural gas-fired turbines totaling approximately 54,000 horsepower, associated piping, valves, controls, coolers, conditioning equipment, and other appurtenant facilities; two approximately 250-foot-long, 42-inch-diameter pipelines connecting the station to Double E’s existing Double E Pipeline; and an associated permanent access road. The Texas Mainline Compressor Station Project would create approximately 800,000 dekatherms per day of firm transportation capacity on Double E’s existing pipeline system from receipt points to gas processing complexes in the Permian and Delaware Basins and the Waha Market Hub.

The general location of the project facilities is shown in appendix 1.¹

¹ The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at www.ferc.gov using the link called “eLibrary.” For instructions on connecting to eLibrary, refer to the last page of this notice. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll free, (888) 208–3676 or TTY (202) 502–8659.

Land Requirements for Construction

Construction of the proposed facilities would disturb about 17.87 acres of land for the aboveground facilities and the pipeline. Following construction, Double E would maintain about 15.80 acres for permanent operation of the project’s facilities, and the remaining acreage would be restored and revert to former uses.

NEPA Process and the Environmental Document

Any environmental document issued by the Commission will discuss impacts that could occur as a result of the construction and operation of the proposed project under the relevant general resource areas:

- geology and soils;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- socioeconomic;
- land use;
- air quality and noise; and
- reliability and safety.

Commission staff will also evaluate reasonable alternatives to the proposed project or portions of the project and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Following this scoping period, Commission staff will determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff’s independent analysis of the issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its decision regarding the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/ Notice of Schedule* will be issued, which will open up an additional comment period. Staff will then prepare a draft EIS which will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS and revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the

public record through eLibrary² and the Commission’s natural gas environmental documents web page (<https://www.ferc.gov/industries-data/natural-gas/environmental-environmental-documents>). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate in the preparation of the environmental document.³ Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the *Public Participation* section of this notice.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation’s implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project’s potential effects on historic properties.⁴ The environmental document for this project will document findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; Native American Tribes; environmental and public interest groups; other interested parties; and regional libraries, newspapers, and media outlets. This list also includes all affected landowners (as defined in the Commission’s regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the

² For instructions on connecting to eLibrary, refer to the last page of this notice.

³ Cooperating agency responsibilities are addressed in Section 107(a)(3) of NEPA (42 U.S.C. 4336(a)(3)).

⁴ The Advisory Council on Historic Preservation’s regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

project and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to GasProjectAddressChange@ferc.gov stating your request. You must include the docket number CP27–3–000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

OR

(2) Return the attached “Mailing List Update Form” (appendix 2).

Additional Information

Additional information about the project is available from the FERC website at www.ferc.gov using the eLibrary link. Click on the eLibrary link, click on “General Search” and enter the docket number in the “Docket Number” field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission’s calendar located at <https://www.ferc.gov/news-events/events> along with other related information.

(Authority: 18 CFR 2.1)

Dated: October 27, 2026.
Debbie-Anne A. Reese,
Secretary.
[FR Doc. 2026–22201 Filed 10–29–26; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR27–5–000.
Applicants: Pecan Pipeline Company.
Description: § 284.123(g) Rate Filing: Application to Revise Statement of Operating Conditions to be effective 1/1/2027.
Filed Date: 10/26/26.
Accession Number: 20261026–5128.
Comment Date: 5 p.m. ET 11/16/26.
§ 284.123(g) Protest: 5 p.m. ET 12/28/26.

Docket Numbers: RP27–64–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Differing MDQ Capacity Filing to be effective 11/27/2026.
Filed Date: 10/27/26.
Accession Number: 20261027–5051.
Comment Date: 5 p.m. ET 11/9/26.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission’s Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission’s eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/>

[docs-filing/efiling/filing-req.pdf](#). For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: October 27, 2026.
Carlos D. Clay,
Deputy Secretary.
[FR Doc. 2026–22190 Filed 10–29–26; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1494–438]

Grand River Dam Authority; Notice of Revised Procedural Schedule

This notice revises the Federal Energy Regulatory Commission’s (Commission) schedule for processing the relicense application for the Pensacola Hydroelectric Project No. 1494, which was filed by Grand River Dam Authority (GRDA) on May 30, 2023. On June 5, 2023, Commission staff issued a notice of application tendered for filing, which included an initial processing schedule.

On September 3, 2026, GRDA filed a Draft Contaminated Sediment Transport Study Report (Draft Report) and requested comments by November 2, 2026.¹ On October 13 and October 14, 2026, the City of Miami and the Miami Tribe of Oklahoma (joined by the Ottawa Tribe of Oklahoma, and Seneca Cayuga Nation; collectively, the Tribes), respectively, requested a 30-day extension of time for parties to submit comments on GRDA’s Draft Report.² Commission staff granted the requests on October 26, 2026, and also granted GRDA’s October 14, 2026 request for a 30-day extension to file a final contaminated sediment transport study report.

By this notice, Commission staff is updating the procedural schedule. The revised schedule is shown below. Further revisions to the schedule may be made as appropriate.

Milestone	Target date
Submit comments on the Draft Report	December 2, 2026.

¹ Commission staff issued a study plan modification determination on September 23, 2025, requiring GRDA to conduct a desktop study of contaminated sediment transport, provide a 30-day comment period for a draft report, and file a final report by April 21, 2026. GRDA subsequently filed

requests for 180-day and 45-day extensions to file a final report, which staff granted on December 12, 2025, and August 28, 2026, respectively. Staff’s December 12, 2025, response also provided a 30-day extension of the draft report comment period, making it 60 days.

² On October 20, 2026, the Eastern Shawnee Tribe of Oklahoma filed a letter of support for the City of Miami and the Tribes request for a 30-day extension of time.

Milestone	Target date
Submit final report to the Commission, including documentation of consultation with Oklahoma Department of Environmental Quality (Oklahoma DEQ), the City of Miami, the Tribes, and other affected stakeholders, copies of comments and recommendations, and specific descriptions of how comments from Oklahoma DEQ, the City of Miami, the Tribes, and other stakeholders were accommodated in the report.	January 31, 2027.
Issue Notice of Acceptance and Ready for Environmental Analysis	March 17, 2027.

Any questions regarding this notice may be directed to Erin Kimsey by email at erin.kimsey@ferc.gov or by telephone at (202) 502-8621.

(Authority: 18 CFR 2.1)

Dated: October 26, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-22134 Filed 10-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11617-003]

Niagara Mohawk Power Corporation; Notice of Intent To File License Application, Filing of Pre-Application Document, Approving Use of the Traditional Licensing Process

a. *Type of Filing:* Notice of Intent to File License Application and Request to Use the Traditional Licensing Process.

b. *Project No.:* 11617-003.

c. *Date Filed:* September 2, 2026.

d. *Submitted By:* Niagara Mohawk Power Corporation.

e. *Name of Project:* Varick-High Dam #21 Transmission Line Project.

f. *Location:* City of Oswego, Oswego County, New York.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. *Potential Applicant Contact:* Meredith Mathias, 300 Erie Boulevard West, Syracuse, NY 13202; telephone at (518) 521-8700; email at meredith.mathias@nationalgrid.com.

i. *FERC Contact:* Nicholas Ettema, Project Coordinator, Great Lakes Branch, Division of Hydropower Licensing; telephone at (312) 596-4447; email at nicholas.ettema@ferc.gov.

j. Niagara Mohawk filed its request to use the Traditional Licensing Process on September 2, 2026. Niagara Mohawk provided public notice of its request on August 27, 2026. In a letter dated October 26, 2026, the Director of the Division of Hydropower Licensing approved Niagara Mohawk's request to use the Traditional Licensing Process.

k. With this notice, we are initiating informal consultation with the U.S. Fish and Wildlife Service under section 7 of the Endangered Species Act and the

joint agency regulations thereunder at 50 CFR, Part 402. We are also initiating consultation with the New York State Historic Preservation Officer, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating Niagara Mohawk as the Commission's non-federal representative for carrying out informal consultation pursuant to section 7 of the Endangered Species Act and consultation pursuant to section 106 of the National Historic Preservation Act.

m. Niagara Mohawk filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD may be viewed on the Commission's website (<http://www.ferc.gov>), using the "eLibrary" link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY).

Register online at <https://ferconline.ferc.gov/FERCOOnline.aspx> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. The licensee states its unequivocal intent to submit an application for a new license for Project No. 11617-003. Pursuant to 18 CFR 16.8, 16.9, and 16.10 each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by October 31, 2029.

p. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

(Authority: 18 CFR 2.1)

Dated: October 26, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-22137 Filed 10-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10198-000]

City of Pelican, AK; Notice of Authorization for Continued Project Operation

The license for the Pelican Hydroelectric Project No. 10198 was issued for a period ending September 16, 2026.

Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year-to-year an annual license to the then licensee(s) under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 10198 is issued to the City of Pelican, AK for a period effective September 17, 2026, through September 16, 2027, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first.

If issuance of a new license (or other disposition) does not take place on or before October 16, 2027, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that the City of Pelican, AK is authorized to continue operation of the Pelican Hydroelectric Project under the terms and conditions of the prior license until the issuance of a subsequent license for the project or other disposition under the FPA, whichever comes first.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or *OPP@ferc.gov*.

(Authority: 18 CFR 2.1.)

Dated: October 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-22198 Filed 10-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2572-000]

Great Lakes Hydro America, LLC; Notice of Authorization for Continued Project Operation

The license for the Ripogenus Hydroelectric Project No. 2572 was issued for a period ending September 30, 2026.

Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year-to-year an annual license to the then licensee(s) under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires,

until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2572 is issued to Great Lakes Hydro America, LLC for a period effective October 1, 2026, through September 30, 2027, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first.

If issuance of a new license (or other disposition) does not take place on or before September 30, 2027, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that the Great Lakes Hydro America, LLC is authorized to continue operation of the Ripogenus Hydroelectric Project under the terms and conditions of the prior license until the issuance of a subsequent license for the project or other disposition under the FPA, whichever comes first.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or *OPP@ferc.gov*.

(Authority: 18 CFR 2.1)

Dated: October 27, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-22199 Filed 10-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EF26-4-000]

Southeastern Power Administration; Notice of Filing

Take notice that on September 17, 2026, Southeastern Power Administration submitted a tariff filing per 300.1: Rate Order No. SEPA-69—Jim Woodruff to be effective October 1, 2026.

Any person desiring to intervene or to protest this filing must file in

accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or *OPP@ferc.gov*.

Comment Date: 5:00 p.m. Eastern Time on November 16, 2026.

Dated: October 26, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-22140 Filed 10-29-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP27-8-000]

Enable Mississippi River Transmission, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on October 16, 2026, Enable Mississippi River Transmission, LLC (EMRT), 1300 Main Street, Houston, Texas 77002, filed in the above referenced docket, a prior notice request pursuant to sections 157.205 and 157.213(b) of the Commission's regulations under the Natural Gas Act (NGA), and EMRT's blanket certificate issued in Docket No. CP82-489-000, for authorization to convert an existing

observation well to a salt water disposal well at the St. Jacob Storage Field in Madison County, Illinois (NS-12 Well Conversion Project). EMRT states the project will have no impact on the St. Jacob Storage Field's certificated physical parameters, including total inventory, reservoir pressure, reservoir and buffer boundaries, and certificated capacity. The estimated cost for the project is \$200,000, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.reference.room@ferc.gov.

Any questions concerning this request should be directed to Irma Jarrett, Senior Manager of Certificates, Enable Mississippi River Transmission, LLC, 1300 Main Street, P.O. Box 4967, Houston, Texas 77210-4967, by phone at (713) 989-7679, or by email at irma.jarrett@energytransfer.com.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5 p.m. Eastern Time on December 28, 2026. How to file protests, motions to intervene, and comments is explained below.

For public inquiries and assistance with making filings such as interventions, comments, or requests for

rehearing, contact the Office of Public Participation (OPP) at (202) 502-6595 or OPP@ferc.gov.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,¹ any person² or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,³ and must be submitted by the protest deadline, which is 5:00 p.m. Eastern Time on December 28, 2026. Filings that do not meet requirements of 18 CFR 157.205(e)(2)⁴ will not be considered protests by the Commission.⁵ A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁶ and the regulations under the NGA⁷ by the intervention deadline for the project, which is 5 p.m. Eastern Time on December 28, 2026. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an

impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to/intervene.asp>.

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before 5 p.m. Eastern Time on December 28, 2026. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP27-8-000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Protest", "Intervention", or "Comment on a Filing"; or⁸

(2) You can file a paper copy of your submission by mailing it to the address

¹ 18 CFR 157.205.

² Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

³ 18 CFR 157.205(e).

⁴ 18 CFR 157.205(e)(2).

⁵ *Cheniere Creole Trail Pipeline, L.P.*, 195 FERC ¶ 61,208, at P 8 n.16 (2026).

⁶ 18 CFR 385.214.

⁷ 18 CFR 157.10.

⁸ Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

below. Your submission must reference the Project docket number CP27–8–000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other method: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail at: Irma Jarrett, Senior Manager of Certificates, Enable Mississippi River Transmission, LLC, 1300 Main Street, P.O. Box 4967, Houston, Texas 77210–4967, or by email (with a link to the document) at irma.jarrett@energytransfer.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from OPP at (202) 502–6595 or on the FERC website at www.ferc.gov using the “eLibrary” link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

(Authority: 18 CFR 2.1)

Dated: October 26, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026–22141 Filed 10–29–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following Exempt Wholesale Generator filings:

Docket Numbers: EG27–26–000.

Applicants: Edged Microgrid Dallas LLC.

Description: Edged Microgrid Dallas LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 10/26/26.

Accession Number: 20261026–5166.

Comment Date: 5 p.m. ET 11/16/26.

Take notice that the Commission received the following Electric Rate filings:

Docket Numbers: ER26–3443–001.

Applicants: Dolet Hills Solar, LLC.

Description: Tariff Amendment: Response to Deficiency Letter and Revised Market-Based Rate Tariff to be effective 8/21/2026.

Filed Date: 10/26/26.

Accession Number: 20261026–5143.

Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: ER26–3667–001.

Applicants: Ameren Transmission Company of Illinois.

Description: Tariff Amendment: Request to Defer Action to be effective 12/31/9998.

Filed Date: 10/27/26.

Accession Number: 20261027–5110.

Comment Date: 5 p.m. ET 11/17/26.

Docket Numbers: ER27–274–000.

Applicants: Northwest Power Pool.

Description: § 205(d) Rate Filing: Tariff Changes to Establish Transition Deficiency Charge Deferral Mechanism to be effective 12/26/2026.

Filed Date: 10/26/26.

Accession Number: 20261026–5153.

Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: ER27–275–000.

Applicants: Commonwealth Edison Company.

Description: Tariff Amendment: Cancellation of TSA with Red Energy (October 2026) to be effective 10/27/2026.

Filed Date: 10/26/26.

Accession Number: 20261026–5155.

Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: ER27–276–000.

Applicants: Citizens S-Line Transmission LLC.

Description: § 205(d) Rate Filing: Annual Operating Cost True-Up Adjustment Informational to be effective 1/1/2027.

Filed Date: 10/27/26.

Accession Number: 20261027–5006.

Comment Date: 5 p.m. ET 11/17/26.

Docket Numbers: ER27–277–000.

Applicants: Citizens Sycamore-Penasquitos Transmission LLC.

Description: § 205(d) Rate Filing: Annual Operating Cost True-Up Adjustment Informational to be effective 1/1/2027.

Filed Date: 10/27/26.

Accession Number: 20261027–5007.

Comment Date: 5 p.m. ET 11/17/26.

Docket Numbers: ER27–278–000.

Applicants: Citizens Sunrise Transmission LLC.

Description: § 205(d) Rate Filing: Annual Operating Cost True-Up Adjustment Informational to be effective 1/1/2027.

Filed Date: 10/27/26.

Accession Number: 20261027–5008.

Comment Date: 5 p.m. ET 11/17/26.

Docket Numbers: ER27–279–000.

Applicants: Alligator Creek Solar, LLC.

Description: Initial Rate Filing: Petition for Order Accepting MBR Tariff and Waiver Request to be effective 11/16/2026.

Filed Date: 10/27/26.

Accession Number: 20261027–5028.

Comment Date: 5 p.m. ET 11/17/26.

Docket Numbers: ER27–280–000.

Applicants: Two Blues Solar LLC.

Description: Initial Rate Filing: Petition for Order Accepting MBR Tariff and Waiver Request to be effective 11/16/2026.

Filed Date: 10/27/26.

Accession Number: 20261027–5029.

Comment Date: 5 p.m. ET 11/17/26.

Docket Numbers: ER27–281–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: DEA, SA No. 7993 between PJM and Kammer Juniata Transmission, LLC to be effective 10/2/2026.

Filed Date: 10/27/26.

Accession Number: 20261027–5038.

Comment Date: 5 p.m. ET 11/17/26.

Docket Numbers: ER27–282–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: TO SA 284: EA for CCSF San Francisco Airport to be effective 10/28/2026.

Filed Date: 10/27/26.

Accession Number: 20261027–5068.

Comment Date: 5 p.m. ET 11/17/26.

Docket Numbers: ER27–283–000.

Applicants: Piney Woods Solar, LLC.

Description: § 205(d) Rate Filing: Application for Market-Based Rate Authority to be effective 12/15/2026.

Filed Date: 10/27/26.

Accession Number: 20261027–5077.

Comment Date: 5 p.m. ET 11/17/26.

Docket Numbers: ER27–284–000.
Applicants: Louisville Gas and Electric Company.
Description: § 205(d) Rate Filing: Filing of Rate Schedule FERC No. 157 and FERC No. 185 to be effective 12/31/9998.
Filed Date: 10/27/26.
Accession Number: 20261027–5079.
Comment Date: 5 p.m. ET 11/17/26.
Docket Numbers: ER27–285–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: Gem Sub BA Service Agreement (R.S. No. 814) to be effective 12/31/9998.
Filed Date: 10/27/26.
Accession Number: 20261027–5081.
Comment Date: 5 p.m. ET 11/17/26.
Docket Numbers: ER27–286–000.
Applicants: Louisville Gas and Electric Company.
Description: § 205(d) Rate Filing: Filing of Notice of Succession for Borderline Agreement to be effective 12/31/9998.
Filed Date: 10/27/26.
Accession Number: 20261027–5083.
Comment Date: 5 p.m. ET 11/17/26.
Docket Numbers: ER27–287–000.
Applicants: Clearlight Energy Sanger LLC.
Description: Tariff Amendment: Notice of Cancellation of Market-Based Rate Tariff to be effective 12/31/9998.
Filed Date: 10/27/26.
Accession Number: 20261027–5089.
Comment Date: 5 p.m. ET 11/17/26.
Docket Numbers: ER27–288–000.
Applicants: Energia Sierra Juarez U.S. Transmission, LLC, Energia Sierra Juarez U.S. Transmission, LLC.
Description: § 205(d) Rate Filing: Energia Sierra Juarez U.S. Transmission, LLC submits tariff filing per 35.13(a)(2)(iii): Filing of Third Amended and Restated Facilities Agreement to be effective 12/27/2026.
Filed Date: 10/27/26.
Accession Number: 20261027–5096.
Comment Date: 5 p.m. ET 11/17/26.
Docket Numbers: ER27–289–000.
Applicants: New England Hydro Transmission Electric Company.
Description: § 205(d) Rate Filing: Request for Approval of Updated Depreciation Rates to be effective 1/1/2027.
Filed Date: 10/27/26.
Accession Number: 20261027–5112.
Comment Date: 5 p.m. ET 11/17/26.
 The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.
 Any person desiring to intervene, to protest, or to answer a complaint in any

of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: October 27, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–22189 Filed 10–29–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF26–10–000]

Longboard TerminalCo, LLC; Notice of Scoping Period Requesting Comments on Environmental Issues for the Planned Longboard LNG Project, and Notice of Public Scoping Sessions

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document that will discuss the environmental impacts of the Longboard LNG Project involving construction and operation of facilities by Longboard TerminalCo, LLC (Longboard LNG) in Honolulu County, Hawai'i. The Commission will use this environmental document in its decision-making process to determine whether the project is in the public interest.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the project. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of an authorization. This

gathering of public input is referred to as “scoping.” The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission's NEPA process is described below in the *NEPA Process and Environmental Document* section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on November 27, 2026. Comments may be submitted in written or oral form. Further details on how to submit comments are provided in the *Public Participation* section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all written or oral comments during the preparation of the environmental document.

If you submitted comments on this project to the Commission before the opening of this docket on May 15, 2026, you will need to file those comments in Docket No. PF26–10–000 to ensure they are considered.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this planned project and encourage them to comment on their areas of concern.

A fact sheet prepared by the FERC entitled “An Interstate Natural Gas Facility On My Land? What Do I Need To Know?” addresses typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (www.ferc.gov) under the Natural Gas, Landowner Topics link.

Public Participation

There are four methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to

assist you at (866) 208–3676 or FercOnlineSupport@ferc.gov.

(1) You can file your comments electronically using the eComment feature, which is located on the Commission’s website (www.ferc.gov) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature, which is located on the Commission’s website (www.ferc.gov) under the link to FERC Online. With

eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on “eRegister.” You will be asked to select the type of filing you are making; a comment on a particular project is considered a “Comment on a Filing”;

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (PF26–10–000) on your letter. Submissions sent via the United States Postal Service must be

addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852; or

(4) In lieu of sending written comments, the Commission invites you to attend one of the public scoping sessions its staff will conduct in the project area, scheduled as follows:

Date and time	Location
Wednesday, November 18, 2026, 5:00 p.m.–7:00 p.m.	Imin International Conference Center, 1777 East-West Road, Honolulu, HI 96848, 808–944–7159.
Thursday, November 19, 2026, 5:00 p.m.–7:00 p.m.	Kroc Center Hawai’i, 91–3257 Kualaka’i Parkway, Ewa Beach, HI 96706, 808–682–5505.

The primary goal of these scoping sessions is to have you identify the specific environmental issues and concerns that should be considered in the environmental document. The sessions are not public hearings to solicit discussions. They present an opportunity for attendees to provide oral rather than written input on the environmental review that FERC staff will conduct. Individual oral comments will be taken on a one-on-one basis with a court reporter. This format is designed to receive the maximum amount of oral comments in a convenient way during the timeframe allotted.

Each scoping session is scheduled from 5:00 p.m. to 7:00 p.m. Hawai’i Standard Time. You may arrive at any time after 5:00 p.m. There will not be a formal presentation by Commission staff when the session opens. If you wish to speak, the Commission staff will hand out numbers in the order of your arrival. Comments will be taken until 7:00 p.m. However, if no additional numbers have been handed out and all individuals who wish to provide comments have had an opportunity to do so, staff may conclude the session at 6:30 p.m. Please see appendix 1 for additional information on the session format and conduct.¹

Your scoping comments will be recorded by a court reporter (with FERC staff or representative present) and become part of the public record for this

¹ The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at www.ferc.gov using the link called “eLibrary.” For instructions on connecting to eLibrary, refer to the last page of this notice. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll free, (866) 208–3676 or TTY (202) 502–8659.

proceeding. Transcripts will be publicly available on FERC’s eLibrary system (see the last page of this notice for instructions on using eLibrary). If a significant number of people are interested in providing oral comments in the one-on-one settings, a time limit of 3 minutes may be implemented for each commentor.

It is important to note that the Commission provides equal consideration to all comments received, whether filed in written form or provided orally at a scoping session. Although there will not be a formal presentation, Commission staff will be available throughout the scoping session to answer your questions about the environmental review process. Representatives from Longboard LNG will also be present to answer project-specific questions.

Additionally, the Commission offers a free service called eSubscription, which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Summary of the Planned Project

Longboard LNG plans to construct and operate a liquefied natural gas

(LNG) import terminal and related natural gas facilities in state waters offshore Kalaeloa (Barbers Point), and onshore near Campbell Industrial Park, on O’ahu, Hawai’i.

FERC jurisdictional facilities include:

- a single point mooring system;
- an approximately 3-mile-long, 16-inch-diameter subsea natural gas pipeline;
- an approximately 2-acre onshore receiving facility connecting the subsea pipeline to onshore pipelines; and
- other appurtenant and ancillary facilities.

Longboard LNG plans to use horizontal directional drilling to install the nearshore portion of the subsea pipeline beneath the shoreline and seabed, extending from the onshore receiving facility to an offshore exit point approximately 0.8 mile from shore, to minimize disturbance to coastal areas and sensitive marine habitats. A non-jurisdictional, internationally flagged, waterborne Floating Storage and Regasification Unit (FSRU), leased under a long-term time charter, would accept LNG carriers making deliveries via ship-to-ship transfer. The FSRU would be subject to regulation by the United States Coast Guard and would not be part of the LNG terminal facilities subject to the Commission’s jurisdiction under section 3 of the Natural Gas Act.

The general location of the project facilities is shown in appendix 2.

Land Requirements for Construction

Construction of the planned facilities would disturb about 270 acres of land and seabed for the planned facilities. Following construction, Longboard LNG would maintain about 27.3 acres for

permanent operation of the project's facilities; the remaining acreage would be restored.

NEPA Process and the Environmental Document

Any environmental document issued by Commission staff will discuss impacts that could occur as a result of the construction and operation of the jurisdictional components of the planned project under the relevant general resource areas:

- geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- socioeconomic;
- land use;
- visual;
- air quality and noise; and
- reliability and safety.

Commission staff have already identified several issues that deserve attention based on a preliminary review of the planned facilities and the environmental information provided by Longboard LNG. This preliminary list of issues may change based on your comments and our analysis:

- marine and oceanographic conditions;
- marine transportation; and
- facility construction and effects on water resources and marine species.

Commission staff will also evaluate reasonable alternatives to the planned project or portions of the project and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Although no formal application has been filed, Commission staff have already initiated a NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the Commission receives an application. As part of the pre-filing review, Commission staff will contact federal and state agencies to discuss their involvement in the scoping process and the preparation of the environmental document.

If a formal application is filed, Commission staff will then determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff's

independent analysis of the environmental issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its determination on the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/ Notice of Schedule* will be issued once an application is filed, which will open an additional public comment period. Staff will then prepare a draft EIS that will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS, and revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the public record through eLibrary² and the Commission's natural gas environmental documents web page (<https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents>). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to this project to formally cooperate in the preparation of the environmental document.³ Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the *Public Participation* section of this notice. Currently, the United States Coast Guard and United States Environmental Protection Agency have expressed their intention to participate as cooperating agencies in the preparation of the environmental document.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Native Hawaiian organizations, and the public

on the project's potential effects on historic properties.⁴ The environmental document for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; Native Hawaiian organizations; environmental and public interest groups; other interested parties; and local libraries and media outlets. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the planned project.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

- (1) Send an email to GasProjectAddressChange@ferc.gov stating your request. You must include the docket number PF26–10–000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

OR

- (2) Return the attached "Mailing List Update Form" (appendix 3).

Becoming an Intervenor

Once Longboard LNG files its application with the Commission, you may want to become an "intervenor" which is an official party to the Commission's proceeding. Only intervenors have the right to seek

² For instructions on connecting to eLibrary, refer to the last page of this notice.

³ Cooperating agency responsibilities are addressed in section 107(a)(3) of NEPA (42 U.S. Code 4336(a)(3)).

⁴ The Advisory Council on Historic Preservation regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

rehearing of the Commission’s decision and be heard by the courts if they choose to appeal the Commission’s final ruling. An intervenor formally participates in the proceeding by filing a request to intervene pursuant to Rule 214 of the Commission’s Rules of Practice and Procedures (18 CFR 385.214). Motions to intervene are more fully described at <https://www.ferc.gov/how-intervene>. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the project, after which the Commission will issue a public notice that establishes an intervention deadline.

Additional Information

Additional information about the project is available on the FERC website (www.ferc.gov) using the eLibrary link. Click on the eLibrary link, click on “General Search” and enter the docket number in the “Docket Number” field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission’s calendar located at <https://www.ferc.gov/news-events/events> along with other related information.

(Authority: 18 CFR 2.1)

Dated: October 26, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026–22161 Filed 10–29–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory
Commission

[Project No. 4644–017]

GR Catalyst Two, LLC; Notice of
Revised Procedural Schedule

Take notice that the schedule for processing the Dahowa Hydroelectric Project No. 4644 final license application has been updated. Subsequent revisions to the schedule may be made as appropriate.

Milestone	Target date
Issue Acceptance Letter	March 2027.

Milestone	Target date
Issue Scoping Notice for Comments.	April 2027.
Issue Notice of Ready for Environmental Analysis.	May 2027.

(Authority: 18 CFR 2.1)

Dated: October 26, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026–22163 Filed 10–29–26; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION
AGENCY

[EPA–HQ–OAR–2026–8350, EPA–HQ–OAR–2007–1196; FRL–13631–01–OAR]

Additions to the Clean Air Act Section
111, 112, and 129 Applicability
Determination Dashboard and to the
List of Broadly Applicable Alternative
Test Methods

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This document announces the availability of applicability determinations, regulatory interpretations, alternative monitoring, and other determinations made by the Environmental Protection Agency (EPA) from June 2025 to July 2026. The EPA made these applicability determinations, regulatory interpretations, alternative monitoring, and other determinations in response to inquiries concerning compliance with the Clean Air Act (CAA) stationary source program, specifically the New Source Performance Standards (NSPS); the National Emission Standards for Hazardous Air Pollutants (NESHAP); and the Emission Guidelines and Federal Plan Requirements for existing sources. The EPA posted the decisions on the CAA Section 111, 112, and 129 Applicability Determination Dashboard (ADD). This document also announces six broadly applicable alternative test method approval decisions that the EPA made in 2022, 2024, and 2025. These broadly applicable alternative test methods were approved in support of the NSPS and the NESHAP.

FOR FURTHER INFORMATION CONTACT: For questions about the ADD, broadly applicable alternative test methods, or this document, contact RADIMMO@epa.gov. This email address is for inquiries on all Regulatory Applicability Determinations, Interpretations, Alternative Methods, Monitoring, and Other requests (RADIMMO).

We post an electronic copy of each document on the ADD, which is available on the internet at: <https://www.epa.gov/complying-air-emissions-standards-stationary-sources/epa-determinations-compliance-and>. An electronic copy of each alternative test method approval document is available at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods>.

SUPPLEMENTARY INFORMATION:

I. Applicability Determinations,
Regulatory Interpretations, and
Alternative Monitoring, and Other
Requests

The General Provisions of the NSPS in 40 CFR 60.5 and the General Provisions of the NESHAP in 40 CFR 61.06 allow a source owner or operator to request a determination of whether certain intended actions constitute the commencement of construction, reconstruction, or modification. The General Provisions in 40 CFR part 60 also apply to Federal and EPA-approved state plans for existing sources in 40 CFR ¹. The EPA’s written responses to source or facility-specific inquiries on provisions in 40 CFR parts 60, 61 and 62 are commonly referred to as applicability determinations. Although the NESHAP (40 CFR part 63) regulations contain no specific regulatory provision providing that sources may request applicability determinations, the EPA also responds to written inquiries regarding applicability for the 40 CFR part 63 regulations.

The General Provisions in 40 CFR parts 60 and 63 allow sources to seek permission to use monitoring or recordkeeping that is different from the promulgated requirements.² The EPA’s written responses to these inquiries are commonly referred to as alternative monitoring decisions.

The EPA responds to written inquiries about the broad range of regulatory requirements in 40 CFR parts 60 through 63 as they pertain a whole source category, e.g., petroleum refineries, printing and coating operations.³ These inquiries may concern the type of source subject to the regulation, or the applicable testing, monitoring, recordkeeping, or reporting requirements required by the regulation. The EPA’s written responses to these

¹ See 40 CFR 62.02(b)(2).

² See 40 CFR 60.13(i), 61.14(g), 63.8(b)(1), 63.8(f), and 63.10(f).

³ Source category refers to a collection of stationary sources or equipment at stationary sources that are grouped together because they share similar processes, operations, or emissions characteristics.

inquiries are commonly referred to as regulatory interpretations.

The EPA posts our responses to questions about compliance determination, alternative monitoring or recordkeeping, and regulatory determination on the CAA Section 111, 112, and 129 Applicability Determination Dashboard (ADD). The ADD is a data system, accessed via the internet, containing all determinations signed after May 2019. The letters and

memoranda on the ADD may be located by facility name, affected subpart, or by response date and is searchable by string word searches.

The EPA previously posted EPA-issued NSPS and NESHAP applicability determinations, alternative monitoring decisions, and regulatory interpretations to the Applicability Determination Index (ADI). All previously issued responses (those signed before June 2019) are posted on the ADI data system

available on the internet at: <https://cfpub.epa.gov/adi/>.

This document comprises a list of 39 such documents added to the ADD on September 22, 2026. Table 1 of this document lists the title of each letter or memorandum. Complete copies of these documents may be obtained from the ADD on the internet at: <https://www.epa.gov/compliance/resources-and-guidance-documents-compliance-assistance>.

TABLE 1—APPLICABILITY DETERMINATIONS, REGULATORY INTERPRETATIONS, ALTERNATIVE MONITORING, AND OTHER DETERMINATIONS

Facility name	Title	Affected subpart	Date of response
Imperial Zinc Corporation	Applicability Determination for Zinc Alloy Processing Facility.	40 CFR Part 63, Subpart TTTTTT	2025–06–30
City of Amarillo MSW Landfill	Corrective Action Plan for Landfill Gas Collection and Control System.	40 CFR Part 62, Subpart OOO; 40 CFR Part 63, Subpart AAAA.	2025–07–18
Cheniere Energy Sabine Pass	Alternative Monitoring Plan for Stationary Turbines.	40 CFR Part 63, Subpart YYYY	2025–07–31
Cheniere Energy Corpus Christi Liquefaction.	Alternative Monitoring Plan for Stationary Turbines.	40 CFR Part 63, Subpart YYYY	2025–07–31
Alyeska Pipeline Service Company	Regulatory Interpretation for Reciprocating Internal Combustion Engines (RICE).	40 CFR Part 63, Subpart ZZZZ; 40 CFR Part 60, Subpart IIII.	2025–08–07
Eastman Chemical Company Longview Facility.	Alternative Monitoring for Rotary Kiln Incinerator (RKI) Unassisted Backup Flare.	40 CFR Part 63, Subpart XX; 40 CFR Part 63, Subpart CC.	2025–08–12
Hyliion, Inc.	Regulatory Interpretation for Generator Technology.	40 CFR Part 60, Subpart IIII; 40 CFR Part 60, Subpart JJJJ.	2025–09–11
Heartland Corn Products	Alternative Monitoring for Stationary Gas Turbines.	40 CFR Part 63, Subpart YYYY	2025–09–09
MSU Simon Power Plant	Alternative Monitoring for Stationary Gas Turbines.	40 CFR Part 63, Subpart YYYY	2025–09–17
Spokane Northside Landfill	Alternative Test Method for Condensate Trap Sampling at Landfill.	40 CFR Part 60, Subpart Cc	2025–09–18
Potrero Hills Landfill	Alternative Temperature for Landfill Gas Extraction Wells.	40 CFR Part 62, Subpart OOO; 40 CFR Part 63, Subpart AAAA.	2025–09–17
El Sobrante Landfill	Alternative Temperature for Landfill Gas Extraction Wells.	40 CFR Part 62, Subpart OOO; 40 CFR Part 63, Subpart AAAA.	2025–09–30
RYAM/Rayonier Performance Fibers—RPF Fernandina Beach Plant.	Alternative Monitoring for Dry Electrostatic Precipitator and Wet Scrubber.	40 CFR Part 63, Subpart DDDDD	2025–10–03
TradeBe Environmental Services	Alternative Monitoring for Thermal Oxidizer Units.	40 Part 60, Subpart J; 40 CFR Part 60, Subpart Ja.	2025–10–06
International Paper—Bogalusa Mill	Alternative Monitoring for Closed-Vent Systems and Pulping Process Condensate Closed-Collection Systems.	40 CFR Part 63, Subpart S	2025–10–06
Specialty Granules LLC Annapolis Plant	Applicability Determination for Rotary Dryer.	40 CFR Part 60, Subpart UUU	2025–10–14
City of High Point—Eastside Wastewater Treatment Plant.	Alternative Monitoring for Sorbent Polymer Composite Material Absorber.	40 CFR Part 60, Subpart MMMM	2025–11–03
TC Energy Columbia Gulf Transmission—Rayne Compressor Station.	Alternative Monitoring Plan for Stationary Turbines.	40 CFR Part 63, Subpart YYYY	2025–11–14
TC Energy Columbia Gulf Transmission—Delhi Compressor Station.	Alternative Monitoring Plan for Stationary Turbines.	40 CFR Part 63, Subpart YYYY	2025–11–14
LBWL Delta Energy Park	Request for Operating Limits/Monitoring Petitions for Stationary Gas Turbines.	40 CFR Part 63, Subpart YYYY	2025–12–17
Tesoro Kenai Refinery	Performance Test Extension for Cogeneration Turbines.	40 CFR Part 60, Subpart KKKK	2026–01–27
ME Global	Applicability Determination for Electric Arc Furnaces.	40 CFR Part 63, Subpart A; 40 CFR Part 63, Subpart ZZZZ.	2026–04–02
IKO—Maxville Plant	Performance Test Waiver for Storage Vessels at an Asphalt Shingle Manufacturing Facility.	40 CFR Part 60, Subpart Kc	2026–04–02
Rubble Reprocessing, LLC	Alternative Monitoring Parameters for an Air Pollution Control Device.	40 CFR Part 60, Subpart CCCC	2026–04–23
Imperial Zinc Corporation	Applicability Determination for Zinc Alloy Processing Facility.	40 CFR Part 63, Subpart TTTTTT	2026–04–29

TABLE 1—APPLICABILITY DETERMINATIONS, REGULATORY INTERPRETATIONS, ALTERNATIVE MONITORING, AND OTHER DETERMINATIONS—Continued

Facility name	Title	Affected subpart	Date of response
Loess Hills Regional Landfill—Malvern IA.	Alternative Temperature for Landfill Gas Extraction Wells.	40 CFR Part 62, Subpart OOO; 40 CFR Part 63, Subpart AAAA.	2026–05–01
ConocoPhillips Alaska, Inc.	Performance Test Waiver for Solid Waste Incinerator.	40 CFR Part 61, Subpart E	2026–05–05
Honda Development and Manufacturing of America.	Applicability Determination for an Iron and Steel Foundry.	40 CFR Part 63, Subpart ZZZZ	2026–05–09
Golden Valley Electric Association	Alternative Test Date for Coal-Fired Boilers.	40 CFR Part 63, Subpart UUUUU	2026–05–21
UniSea, Inc.	Performance Test Extension for Boilers	40 CFR Part 63, Subpart JJJJ	2026–06–02
OQ Chemical	Applicability Determination for Fence Line Monitoring Requirements.	40 CFR Part 63, Subpart F; 40 CFR Part 63, Subpart H.	2026–06–10
Clearwater Paper—Augusta Mill	Alternative Test Method for Measuring Methanol Vent Gas Concentrations.	40 CFR Part 63, Subpart S	2026–06–21
East Kentucky Power Cooperative	Regulatory Interpretation for the Operation of Stationary Emergency Engines.	40 CFR Part 63, Subpart ZZZZ	2026–06–24
NRG Energy	Regulatory Interpretation for the Operation of Stationary Emergency Engines.	40 CFR Part 63, Subpart ZZZZ	2026–06–24
Mid-Valley Landfill	Alternative Temperature for Landfill Gas Extraction Wells.	40 CFR Part 62, Subpart OOO; 40 CFR Part 63, Subpart AAAA.	2026–07–07
Los Reales Landfill	Alternative Temperature for Landfill Gas Extraction Wells.	40 CFR Part 63, Subpart AAAA	2026–07–07
South Carolina Department of Environmental Services.	Regulatory Interpretation for Waste Burning Kiln Emission Limitations.	40 CFR Part 60, Subpart CCCC; 40 CFR Part 60, Subpart DDDD.	2026–07–15
H&T Recharge (Panasonic Energy)	Alternative Monitoring for Halogenated Solvent Cleaning.	40 CFR Part 63, Subpart T	2026–07–15
Gulf Coast Growth Ventures	Alternative Monitoring for a Monoethylene Glycol Unit.	40 CFR Part 63, Subpart G	2026–07–16

II. Broadly Applicable Alternative Test Method

A. Background

This document identifies four broadly applicable alternative test methods the EPA approved between January 1, 2025, and December 31, 2025. Two additional broadly applicable alternative test methods are identified in this notice, one from 2022 and one from 2024, which were inadvertently omitted from the previous annual notices. See Table 2 of this document for the summary of these broadly applicable alternative test methods. Source owners and operators may voluntarily use these broadly applicable alternative test methods in lieu of otherwise required test methods or related testing procedures. Use of these broadly applicable alternative test methods is not intended to and should not change the applicable emission standards.

The Administrator has the authority to approve the use of alternative test methods for compliance with requirements under 40 CFR parts 59, 60, 61, 63, and 65.⁴ The criteria for approval and procedures for submission and

review of broadly applicable alternative test methods are explained in 72 FR 4257 (January 30, 2007), which is available at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods>. As explained in the 2007 notice, we will announce approvals for broadly applicable alternative test methods at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods> as they are issued. We will also publish a notice in the **Federal Register** that summarizes the previous year's approvals.

We review numerous source-specific requests for alternatives and modifications to test methods and procedures. Based on these reviews, we sometimes find that test method modifications or alternatives would be equally valid and appropriate to apply to other sources within a particular class, category, or subcategory. Therefore, where either a method modification or an alternative method is clearly broadly applicable to a class, category, or subcategory of sources, we will approve its use for all appropriate sources and situations. When appropriate, approval of broadly applicable test methods is both equitable and efficient.

Use of approved alternative test methods is not mandatory but rather permissive. Sources are not required to employ such a method but may choose to do so in appropriate circumstances. However, as specified in 40 CFR 63.7(f)(5), a source owner or operator electing to use an alternative method for 40 CFR part 63 standards must continue to use the alternative method until otherwise authorized. Source owners or operators should, therefore, review the specific broadly applicable alternative method approval decision at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods> before electing to employ any alternative method. Source owners or operators choosing to use a broadly applicable alternative should also notify their regulatory agency prior to using the alternative.

B. Approved Alternative Test Methods and Modifications to Test Methods

Table 2 of this notice summarizes the following information for the six broadly applicable alternative test methods: the alternative method designation number; date of approval letter; test methods affected; sources allowed to use the alternative; and method modifications or alternative methods allowed. For more detailed

⁴ This authority is found in 40 CFR 60.8(b)(3), 61.13(h)(1)(ii), and 63.7(e)(2)(ii). Additional and similar authority can be found in 40 CFR 59.104(f) and 65.158(a)(2).

information, please refer to the complete copies of these approval documents available at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods>.

The EPA will revisit approvals of alternative test methods in response to written requests or objections indicating that a particular approved alternative

test method either should not be broadly applicable or that its use is not appropriate or should be limited in some way. Any objection to a broadly applicable alternative test method, as well as the resolution of that objection, will be announced at <https://www.epa.gov/emc/broadly-applicable->

approved-alternative-test-methods and in a subsequent **Federal Register** notice. If we decide to retract a broadly applicable test method, we will likely consider the need for an appropriate transition period for users either to request case-by-case approval or to transition to an approved method.

TABLE 2—BROADLY APPLICABLE ALTERNATIVE TEST METHODS AND MODIFICATIONS TO TEST METHODS ^a

Alternative method designation No.	Date of approval letter	Test method(s) affected	Sources allowed to use the alternative method	Method modifications and alternatives you may use
ALT-152-A	August 13, 2024.	EPA Method 9— <i>Visual Determination of the Opacity of Emissions from Stationary Sources</i> (40 CFR Part 60, Appendix A-4).	All sources subject to training and certification requirements in section 3.2 of EPA Method 9.	As an alternative to section 3.2 of EPA Method 9—training for certification procedures required for opacity observers—you may use Compliance Assurance Associates, Inc. virtual reality headset-based alternative method for conducting Method 9 EPA training and certification as described in ALT-152.
ALT-152-B	September 29, 2025.	Method 9— <i>Visual Determination of the Opacity of Emissions from Stationary Sources</i> (40 CFR Part 60, Appendix A-4).	All sources subject to training and certification requirements in section 3.2 of EPA Method 9.	As an alternative to section 3.2 of EPA Method 9—training for certification procedures required for opacity observers—you may use VR Smoke School, LLC virtual reality headset-based alternative method for conducting Method 9 EPA training and certification as described in ALT-152.
ALT-158	March 27, 2025.	Method 21—Determination of volatile organic compound leaks (40 CFR Part 60, Appendix A-7) Determination of Volatile Organic Compound and Greenhouse Gas Leaks Using Optical Gas Imaging (OGI) (40 CFR Part 60, Appendix K).	Sources subject to Standards of Performance for Crude Oil and Natural Gas Facilities for Which Construction, Modification or Reconstruction Commenced After December 6, 2022 (40 CFR 60.5398b in 40 CFR Part 60, Subpart OOOOb).	As an alternative to OGI or EPA Method 21, you may use the Xplorobot Laser Gas Imager and associated protocol when conducting follow-up actions as described in 40 CFR 60.5398b(b)(5)(iv) and for verification of repairs in 40 CFR 60.5397b(h) and 60.5416b(b).
ALT-159	June 25, 2025	EPA Method 18—Measurement of gaseous organic compound emissions by gas chromatography (40 CFR Part 60, Appendix A-6).	Sources subject to Standards of Performance for Stationary Spark Ignition Internal Combustion Engines (40 CFR Part 60, Subpart JJJJ).	As an alternative to EPA Method 18, you may use EPA Method 320 to measure methane and ethane for the purpose of excluding those compounds from the total VOC measurement measured by EPA Method 25A as required by 40 CFR 60.4244 and Table 2 of 40 CFR Part 60 Subpart JJJJ. EPA Method 320—Measurement of Vapor Phase Organic and Inorganic Emissions by Extractive Fourier Transform Infrared (FTIR) Spectroscopy (40 CFR Part 63, Appendix A).

TABLE 2—BROADLY APPLICABLE ALTERNATIVE TEST METHODS AND MODIFICATIONS TO TEST METHODS ^a—Continued

Alternative method designation No.	Date of approval letter	Test method(s) affected	Sources allowed to use the alternative method	Method modifications and alternatives you may use
ALT 160	July 27, 2022	SW-846 Method 8270D: Semivolatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS) (https://archive.epa.gov/epa/hw-sw846/sw-846-test-method-8270d-semivolatile-organic-compounds-gas-chromatographymass-spectrometry.html). SW-846 Method 8015C: Nonhalogenated Organics by Gas Chromatography (https://www.epa.gov/hw-sw846/sw-846-test-method-8015c-nonhalogenated-organics-gas-chromatography).	Sources subject to National Emission Standards for Hazardous Air Pollutant Emissions for Polyvinyl Chloride and Copolymers Production (40 CFR Part 63, Subpart HHHHHHH).	As alternatives to SW-846 Methods 8270D and 8015C, you may use the updated method SW-846 Method 8270E for analysis of semivolatile organic compounds (SVOC) in stripped resin and wastewater samples, and SW-846 Method 8015D for the analysis of alcohol compounds in stripped resin and wastewater samples. The approval letter includes several caveats which must be adhered to when using this alternative method. SW-846 Method 8270D: Semivolatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS) (https://www.epa.gov/hw-sw846/sw-846-test-method-8270e-semivolatile-organic-compounds-gas-chromatographymass). SW-846 Method 8015C: Nonhalogenated Organics by Gas Chromatography (https://www.epa.gov/esam/epa-method-8015d-sw-846-nonhalogenated-organics-using-gcfid).
ALT-162	September 10, 2025.	EPA Method 25B with the option to exclude methane and ethane content measurements using EPA Method 18. EPA Method 25B—Determination of total gaseous organic concentration using a nondispersive infrared analyzer (40 CFR Part 60, Appendix A-7). EPA Method 18—Measurement of gaseous organic compound emissions by gas chromatography (40 CFR Part 60, Appendix A-6).	Sources subject to bulk gasoline terminal and gasoline distribution NSPS and NESHAP regulations, specified below. Standards of Performance for Bulk Gasoline Terminals (40 CFR Part 60, Subpart XX). Standards of Performance for Bulk Gasoline Terminals that Commenced Construction, Modification, or Reconstruction After June 10, 2022 (40 CFR Part 60, Subpart XXa).	As an alternative to using EPA Method 25B, with the option to use EPA Method 18, you may use the Infrared Industries IR-208 and IR-8400DC instruments with non-dispersive infrared light absorption (NDIR) gas analyzers with methane compensation Model IR-8400DC to conduct emission monitoring and Model IR-208 to conduct performance testing and to serve as the reference method measurement device for relative accuracy testing (RATA) to measure total nonmethane gaseous organic compound (TNMOC) emissions. The letter of approval includes several caveats which must be adhered to when using this alternative method.

TABLE 2—BROADLY APPLICABLE ALTERNATIVE TEST METHODS AND MODIFICATIONS TO TEST METHODS ^a—Continued

Alternative method designation No.	Date of approval letter	Test method(s) affected	Sources allowed to use the alternative method	Method modifications and alternatives you may use
.....			National Emission Standards for Gasoline Distribution Facilities (Bulk Gasoline Terminals and Pipeline Breakout Stations) (40 CFR Part 63, Subpart R). National Emission Standards for Hazardous Air Pollutants for Source Category: Gasoline Distribution Bulk Terminals, Bulk Plants, and Pipeline Facilities (40 CFR Part 63, Subpart BBBBBB).	

^aSource owners or operators should review the specific broadly applicable alternative method approval letter at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods> before electing to employ any alternative test method.

Panagiotis Tsirigotis,
Director, Office of Clean Air Programs.
[FR Doc. 2026–22164 Filed 10–29–26; 8:45 am]
BILLING CODE 6569–60–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OPRM–FAD–246]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–993–3272 or <https://www.epa.gov/nepa>.
Weekly receipt of Environmental Impact Statements (EIS)
Filed October 19, 2026 10 a.m. EST
Through October 26, 2026 10 a.m. EST
Pursuant to CEQ Guidance on 42 U.S.C. 4332.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: <https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search>.

EIS No. 20260136, Final, NRCS, OR,
Medford Irrigation District Joint System Canal Modernization Project, Review Period Ends: 11/30/2026, Contact: Gary Diridoni 503–414–3092.
EIS No. 20260137, Final, NRC, KY,
Global Laser Enrichment, LLC, License Application for the Paducah

Laser Enrichment Facility, Contact: Amy Minor 817–200–1454.

Dated: October 26, 2026.

Nancy Abrams,
Deputy Director, Federal Activities Division.
[FR Doc. 2026–22202 Filed 10–29–26; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2013–0119; FRL–13678–01–OAR]

Agency Information Collection Activities; Proposed Information Collection Request; Comment Request; Motor Vehicle and Engine Compliance Program Fees (Renewal), EPA ICR 2080.09, OMB Control No. 2060–0545

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), “Motor Vehicle and Engine Compliance Program Fees (Renewal)” (EPA ICR No. 2080.09, OMB Control No. 2060–0545) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a

proposed extension of the ICR, which is currently approved through July 31, 2027. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before December 29, 2026.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2013–0119, to EPA online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Noah Goldberg, Implementation, Analysis, and Compliance Division, Diesel Engine Compliance Branch, Environmental Protection Agency, 2000 Traverwood, Ann Arbor, MI 48105; telephone number: (734) 214–4772; email address: goldberg.noah@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through July 31,

2027. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

This notice allows 60 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate forms of information technology. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: As required by the Clean Air Act, EPA has regulations establishing emission standards and other requirements for various classes of vehicles, engines, and evaporative emission components. These regulations require that compliance be demonstrated prior to EPA granting a "Certificate of Conformity". EPA charges fees for administering this certification program. In 2004, then in 2008 the fees program was expanded to include nonroad categories of vehicles and engines, such as several categories of marine engines, locomotives, non-road recreational vehicles, many nonroad compression-ignition and spark-ignition engines and evaporative emission components. Manufacturers and importers of covered vehicles, engines and components are required to

pay the applicable certification fees prior to their certification applications being reviewed by the Agency. Under section 208 of the Clean Air Act (42 U.S.C. 7542(c)) all information, other than trade secret processes or methods, must be publicly available. Information about fee payments is treated as confidential information prior to certification.

Form Numbers: 3520-29.

Respondents/affected entities:

Manufacturers or importers of passenger cars, motorcycles, light trucks, heavy duty truck engines, nonroad vehicles or engines, and evaporative emissions components are required to receive a certificate of conformity from EPA prior to selling or introducing these products into commerce in the U.S.

Respondent's obligation to respond:

Required to obtain or retain a benefit (40 CFR part 1027).

Estimated number of respondents:

633 (total).

Frequency of response: An average of approximately eight responses per respondent per year.

Total estimated burden: 1058 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$96,118 (per year), includes \$15,179 annualized capital or operation and maintenance costs.

Changes in Estimates: There is an increase of 36 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to the greater number of responses in the number of certificates and, therefore, the number of fees paid from year to year. The estimate of the costs associated with the fees program have increased from \$77,444 to \$96,118 due to wage estimate increases, as well as an average higher pay grade for cert reps. The average increased due to employee progression, as well as attrition.

Byron Bunker,

Director, Implementation, Analysis and Compliance Division.

[FR Doc. 2026-22209 Filed 10-29-26; 8:45 am]

BILLING CODE 6568-60-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank

or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than November 16, 2026. *A. Federal Reserve Bank of Minneapolis* (Mark Nagle, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291. Comments can also be sent electronically to MA@mpls.frb.org:

1. *The MOR GST Trust and the MOR Non-GST Trust, Michael O. Regan as trustee, all of Grant, Minnesota; the 2026 COR Irrevocable Trust, Casey O. Regan as trustee, both of Maplewood, Minnesota; the 2026 MMW Irrevocable Trust, Meghan M. Weyland as trustee, both of Louisville, Kentucky; the 2026 GOR Irrevocable Trust, Garrett O. Regan as trustee, both of Lakeville, Minnesota; the 2026 AJM Irrevocable Trust, Angela J. Mattingly and Michael C. Mattingly as co-trustees, all of Louisville, Kentucky; the KJR GST Trust and the KJR Non-GST Trust, Kelly J. Regan, all of Prescott, Wisconsin, and Katie J. Nath, North St. Paul, Minnesota, as co-trustees; the SOR-MDR GST Trust and the SOR-MDR Non-GST Trust, Sean O. Regan as trustee, all of White Bear Lake, Minnesota; the KJN GST Trust, the KJN Non-GST Trust, the DOR GST Trust, the DOR Non-GST Trust, Katie J. Nath as*

trustee, all of North St. Paul, Minnesota; the POR Non-GST Trust, Patrick O. Regan as trustee, both of Hastings, Minnesota; and the CMR GST Trust and the CMR Non-GST Trust, Katie J. Nath, all of North St. Paul, Minnesota, and Colleen M. Regan, Madrid, Spain, as co-trustees; to join the Regan Family Control Group, a group acting in concert, to acquire voting shares of PB Bancshares Inc., ("PBBI"), and thereby indirectly retain voting shares of Premier Bank, both of Maplewood, Minnesota. Michael O. Regan, Patrick O. Regan, Kelly J. Regan, Colleen M. Regan, Sean O. Regan, and Katie J. Nath are members of the Regan Family Control Group and were each previously permitted by the Federal Reserve System to acquire voting shares of PBBI in their individual capacities.

2. Zachary Watson, Fargo, North Dakota, and Christopher Watson, Scottsdale, Arizona; to join the Watson Family Control Group, a group acting in concert, to retain voting shares of Security State Bank Holding Company, Fargo, and thereby indirectly retain voting shares of Bank Forward, both of Fargo, North Dakota. B. Federal Reserve Bank of San Francisco (Keith Dudley, Vice President) 101 Market Street, San Francisco, California 94105-1579. Comments can also be sent electronically to *SF.Supervision.Comments.Applications@sf.frb.org*:

1. The Scott M. Browning Legacy Trust, Sally W. Browning and Robert Tanzer Wallace Browning as trustees, all of Salt Lake City, Utah; to join the Browning Family Control Group, a group acting in concert, to retain voting shares of First Utah Bancorporation, and thereby indirectly retain voting shares of First Utah Bank, both of Salt Lake City, Utah. Sally W. Browning is a member of the Browning Family Group and was previously permitted by the Federal Reserve System to acquire and retain voting shares of First Utah Bancorporation.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026-22205 Filed 10-29-26; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Advisory Committee on Immunization Practices

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is seeking nominations for membership on the Advisory Committee on Immunization Practices (ACIP). The ACIP consists of up to 19 experts that collectively represent a balanced range of scientific, clinical, and public health expertise relevant to the Committee's mission, including person(s) knowledgeable about consumer perspectives and/or social and community aspects of immunization programs.

DATES: Nominations for membership on the ACIP must be received no later than December 31, 2026. Submissions received after this time will not be considered for the current membership cycle.

ADDRESSES: All nomination forms and additional required documents should be emailed to *ACIP@cdc.gov* with the subject line: "ACIP Nomination Application". The ACIP nomination form and instructions can be found at <https://www.cdc.gov/acip/apply-for-membership/index.html>.

FOR FURTHER INFORMATION CONTACT: ACIP Secretariat, Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21-12, Atlanta, Georgia 30329-4027. Email: *ACIP@cdc.gov*.

SUPPLEMENTARY INFORMATION: The Advisory Committee on Immunization Practices (ACIP) is charged with advising the Director, Centers for Disease Control and Prevention (CDC), regarding the use of vaccines and related immunobiologic agents for the prevention and control of vaccine-preventable diseases in the United States, including identifying areas where additional data or evaluation would inform future recommendations regarding such vaccines and immunizations. In addition, under 42 U.S.C. 1396s, the Committee is mandated to establish and periodically

review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines.

Nominations are sought for individuals who have the expertise and qualifications necessary to contribute to the accomplishment of the objective of the ACIP. Nominees will be selected to represent a balanced range of scientific, clinical, and public health expertise relevant to the Committee's mission, including person(s) knowledgeable about consumer perspectives and/or social and community aspects of immunization programs. Federal employees will not be considered for membership. Members may be invited to serve for up to four-year terms. Selection of members is based on candidates' qualifications to contribute to the accomplishment of ACIP objectives.

Department of Health and Human Services (HHS) policy stipulates that committee membership be balanced in terms of points of view represented and the committee's function. Appointments shall be made free from discrimination on the basis of race, color, religion, sex, national origin, age, disability, or other protected status, consistent with applicable law and Departmental policy. Nominees cannot be full-time employees of the U.S. Government. Preference is given to U.S. citizens; nominations from non-U.S. citizens are handled on a case-by-case basis. Current participation on Federal workgroups or prior experience serving on a Federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning of and annually during their terms. The Centers for Disease Control and Prevention (CDC) reviews potential candidates for ACIP membership and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of their term, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year.

Candidates should email the following materials to *ACIP@cdc.gov* with the subject line: "ACIP Nomination Application".

- ACIP Nomination Form, which can be found at <https://www.cdc.gov/acip/apply-for-membership/index.html>.

- Current curriculum vitae (CV), including complete contact information (telephone numbers, mailing address, email address). CVs should include candidates' education, training, board certification and career history and list main areas of employment or other relevant activity and public appointments, if any. CVs should also include details of any relevant academic or professional qualifications.

- At least one letter of recommendation from person(s) not employed by HHS. Candidates may also submit letter(s) from current HHS employees if they wish (excluding CDC employees), but at least one letter must be submitted by a person not employed by an HHS agency (*i.e.*, National Institutes of Health, Food and Drug Administration).

Nominations may be submitted by the candidate or by the person/organization recommending the candidate.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2026-22185 Filed 10-29-26; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Amended Order Requirement for Attestation by All Persons Arriving in the United States From Any Foreign Country Via Transportation by Aircraft and Controlled Free Pratique for Airlines and Other Aircraft Operators Confirming That Such Persons Have Not Been in the Democratic Republic of the Congo in the Past 21 Days

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of Agency Order.

SUMMARY: The Centers for Disease Control and Prevention (CDC), a component of the Department of Health and Human Services (HHS), announces the issuance of an Amended Order under Sections 361, 365, 368, and 369 of the Public Health Service Act, and associated implementing regulations, prohibiting the boarding of any person who is not otherwise subject to an exemption on any aircraft destined to the United States from a foreign country unless the person presents a signed attestation confirming the person has not been present in the Democratic Republic of the Congo (DRC) during the 21 days prior to boarding a flight to the United States. This Amended Order was issued on October 28, 2026, to become effective at 11:59 p.m. Eastern Standard Time (EST) on November 3, 2026, and shall remain in effect through 11:59 p.m. EST on December 18, 2026. This Amended Order may be amended or rescinded prior to that time at the discretion of the Secretary or his designee.

DATES: This action will take effect November 3, 2026, at 11:59 p.m. EST. For individuals intending to travel to the United States by air, the Order will apply to flights departing at or after 11:59 p.m. EST on November 3, 2026.

FOR FURTHER INFORMATION CONTACT: Mina Zadeh, Acting Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS V18-2, Atlanta, GA 30329. Phone: 404-639-7000. Email: cdcregulations@cdc.gov.

SUPPLEMENTARY INFORMATION: On October 22, 2026, the Assistant Secretary for Health (ASH), HHS, signed an Order prohibiting the boarding of any passenger on any aircraft destined to the United States from a foreign country unless the passenger presents a signed attestation in paper or digital format confirming that the person has not been present in the Democratic Republic of the Congo (DRC) during the 21 days prior to boarding a flight to the United States. On October 28 the ASH signed an Amended Order making minor changes, *e.g.*, changing “passenger” to “person,” to clarify that crew members are also subject to this requirement. This includes any flight arriving in the United States, including cargo flights, regardless of whether the United States is its final destination or the flight is connecting through the United States en route to another country. The airline or aircraft operator must retain a copy of the completed version of the signed attestation for at least 42 days after the person’s flight departs for the United States from a foreign country and

provide the attestation to the U.S. Government upon request.

This Amended Order is effective for a period of 45 days. This Amended Order may be amended further or rescinded prior to that time at the discretion of the Secretary or his designee. Any amendment or extension of this Amended Order will be based on the current outbreak metrics, including case counts, geographic spread, community-transmission indicators, and containment capacity in affected countries.

Pursuant to 42 U.S.C. 268, the U.S. customs officers and U.S. Coast Guard officers will assist in implementation of this Amended Order. Other federal departments and agencies, including the U.S. Department of Homeland Security and the U.S. Department of Transportation, may also cooperate and assist with implementation of this Amended Order consistent with their own legal authorities.

This Amended Order shall be enforceable through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 270, 271; and 42 CFR 71.2. Pursuant to 42 U.S.C. 271, CDC may request the U.S. Department of Justice seek to prosecute individuals who knowingly and willfully submit false attestations in violation of 18 U.S.C. 1001.

This Amended Order is not a rule within the meaning of the Administrative Procedure Act (“APA”) but rather is an action taken under the existing authority of 42 U.S.C. 264(a) and 42 CFR 71.20, 71.31(b), and 71.32(b), which were promulgated in accordance with the APA after full notice and comment rulemaking and a delayed effective date. Separately, HHS/CDC issued a Paperwork Reduction Act (PRA) notice related to the required attestation form. The PRA notice provides an opportunity for public comment through www.regulations.gov using docket CDC-2026-1750.-

A copy of the Amended Order is provided below and a copy of the signed Amended Order can be found at <https://www.cdc.gov/port-health/legal-authorities/attestation-order.html>.

Centers for Disease Control and Prevention (CDC)

Department of Health and Human Services (HHS)

Notice and Amended Order Under Sections 361, 365, 368, & 369 of the Public Health Service Act (42 U.S.C. 264, 268, 270, & 271) and 42 Code of Federal Regulations 71.20, 71.31(b), & 71.32(b)

Requirement for Attestation by All Persons Arriving in the United States From Any Foreign Country via Transportation by Aircraft and Controlled Free Pratique for Airlines and Other Aircraft Operators Confirming That Such Persons Have Not Been in the Democratic Republic of the Congo in the Past 21 Days

Summary

Pursuant to 42 CFR 71.20, 71.31(b), and 71.32(b), and as set forth in greater detail below, this Notice and Order prohibit the boarding of any person who is not otherwise subject to an exemption on any aircraft destined to the United States from a foreign country unless the person presents:

- A signed attestation in paper or digital format confirming that the person has not been present in the Democratic Republic of the Congo (DRC) during the 21 days prior to boarding a flight to the United States.

This includes any flight arriving in the United States, regardless of whether the United States is its final destination or the flight is connecting through the United States en route to another country. This Order does not apply to overflights that do not land at any airport in the United States.

Further, pursuant to 42 CFR 71.31(b) and as set forth in greater detail below, this Notice and Order operates as a controlled free pratique requiring an airline or other aircraft operator with an aircraft arriving into the United States to confirm to the U.S. Government that every person onboard the aircraft has completed and signed an attestation confirming that the person has not been in the DRC during the 21 days prior to boarding the flight to the United States as a condition of the airline or aircraft operator being granted permission to enter a U.S. port of entry, disembark persons, and begin operations with respect to arriving at a U.S. airport.

A parent or other authorized representative may complete and sign the required attestation on behalf of a person under 18 years of age. An authorized representative may also act on behalf of any person who is in their traveling party or any person who is unable to act on their own behalf (*e.g.*,

by reason of age, or physical or mental impairment). An airline or aircraft operator employee or agent may assist with data entry or submission at the direction of the person or authorized representative.

The person must provide the airline or aircraft operator with a paper or digital copy of the completed attestation reflecting that the person has not been present in the DRC in the past 21 days prior to boarding a flight to the United States. The airline or aircraft operator must retain the paper or digital copy of each person's completed and signed attestation for at least 42 days after the person's flight departs for the United States from a foreign country and provide the attestation to the U.S. Government upon request.

CDC encourages airlines and aircraft operators to incorporate the attestation into paperless check-in processes. An airline or aircraft operator may use a third party (including a third-party digital application) to provide translations. However, an airline or aircraft operator has sole legal responsibility to ensure the accuracy of any translation and to comply with all other obligations under this Order. An airline or aircraft operator is responsible for any failure to comply with its responsibilities as set forth in this Order, including for actions of a third party used to help effectuate its compliance with this Order. As between the airline or aircraft operator and the U.S. Government, the airline or aircraft operator remains responsible for compliance with this Order regardless of the involvement of any third party.

Pursuant to 42 U.S.C. 268, customs officers and U.S. Coast Guard officers will assist in the implementation of this Order. Other federal departments and agencies, including the U.S. Department of Homeland Security and the U.S. Department of Transportation, may also cooperate and assist with implementation of this Order consistent with their own legal authorities.

The U.S. Department of Justice may seek to prosecute individuals who knowingly and willfully submit false attestations in violation of 18 U.S.C. 1001.

Relationship to Other Orders

This Order operates in addition to, and does not supersede, modify, or replace, other CDC orders currently in effect concerning Ebola disease caused by the Bundibugyo virus, including the Order Suspending the Right to Introduce Certain Persons from Countries Where a Quarantinable Communicable Disease Exists issued pursuant to 42 U.S.C. 265, 268 and 42

CFR 71.40, as most recently continued. Nothing in this Order limits the authority of CDC, the Department of State, the Department of Homeland Security, the Department of Transportation, or any other federal department or agency to take additional measures under their own separate legal authority.

Statement of Intent

This Order shall be interpreted and implemented to achieve the following paramount objectives:

- Preservation of human life;
- Preventing the introduction, transmission, and spread of the Ebola virus into the United States; and
- Preserving the health and safety of crew members, passengers, airport personnel, and communities.

Definitions

21 days for purposes of the individual attestation means a 21-day waiting period based on calendar days. Day 0 is the day the individual departed the DRC. Day 1 is the first full calendar day the individual is outside the DRC. A person who was present in the DRC may board a flight to the United States on day 22.

Aircraft shall have the same definition as under 49 U.S.C. 40102(a)(6).

"Aircraft" includes, but is not limited to, commercial, general aviation, cargo, and private aircraft destined for the United States from a foreign country.

Aircraft Operator means an individual or organization causing or authorizing the operation of an aircraft.

Airline shall have the same definition as under 42 CFR 71.1(b).

Attest/Attestation means completion and signature of the attestation in Attachment A. Such attestation may be completed and signed in paper or digital form, including through electronic signature. The attestation is a statement, writing, entry, or other representation made under 18 U.S.C. 1001.

Authorized representative means a parent, guardian, travel companion, adult member of a person in the same traveling party or person authorized by the person required to complete and submit an attestation on the person's behalf. An airline or aircraft operator employee or agent who assists with data entry or submission at the direction of the person or authorized representative does not, solely by providing such assistance, become the authorized representative or provide the attestation on the person's behalf.

Foreign country means anywhere that is not a state, territory, or possession of the United States.

Person(s) means any of the persons (including passengers, air crew, or conveyance operators) on any aircraft destined for the United States from a foreign country. This includes crewmembers on official duty assigned by the airline or aircraft operator, including for activities that involve operation of aircraft or the positioning of crew not operating the aircraft (*e.g.*, on “deadhead” status).

Present/Presence in the DRC means any physical presence, including entering or traveling through the country by air (excluding overflights), land, or sea. Presence also includes connecting through an airport in the DRC, even if the person did not disembark the plane or leave the airport.

United States has the same definition as “United States” in 42 CFR 71.1(b), meaning “the 50 States, District of Columbia, and the territories (also known as possessions) of the United States, including American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.”

Exemptions

The following are exempt from the requirements of this Order:

- Aircraft operators transporting passengers with Ebola disease pursuant to U.S. Government authorization and in accordance with CDC guidance.
- Individuals for whom the CDC has issued an exemption based on humanitarian or other important government considerations, *e.g.*, emergency medical evacuations. Additional conditions may be placed on individuals granted such exemptions, including but not limited to, observing precautions during travel, providing consent to post-arrival monitoring, and/or self-quarantine after arrival in the United States, as may be directed by federal, state, territorial, tribal or local public health authorities to reduce the risk of disease transmission.

Background

A. Ebola Disease

Viral hemorrhagic fever refers to a group of severe illnesses caused by certain viruses that damage the body's blood vessels and affect the ability of the blood to clot properly. Viral hemorrhagic fevers include diseases such as Ebola, Marburg, and Lassa fever.

Bundibugyo virus disease (BVD) is a severe and often fatal illness caused by one of the viruses in the Ebola family. Ebola disease outbreaks occur mainly in parts of sub-Saharan Africa and can spread rapidly in communities with limited healthcare resources. Ebola

disease caused by the Bundibugyo virus is a rare form of Ebola first identified during an outbreak in Bundibugyo District, Uganda, in 2007. BVD is one of several species within the orthoebolavirus family and causes symptoms similar to other forms of Ebola, including fever, weakness, vomiting, diarrhea, and, in severe cases, hemorrhagic complications and organ failure. The disease spreads through direct contact with infected bodily fluids or contaminated materials.

The incubation period for BVD is typically between 2 and 21 days, with most people developing symptoms within 4 to 10 days after exposure. During this incubation period, infected individuals do not spread BVD until symptoms begin.

Screening for BVD focuses on identifying symptoms and possible exposure history, such as recent travel to affected areas or contact with infected individuals. Patients with suspected BVD are evaluated for symptoms including fever, weakness, vomiting, diarrhea, and bleeding, and laboratory confirmation is performed using specialized tests such as PCR (polymerase chain reaction) to detect the virus in blood and other body fluid samples. Health authorities also use temperature checks and contact tracing to identify suspected cases, and quarantine and isolation procedures, as applicable, to prevent transmission.

There are currently no widely approved vaccines or specific antiviral treatments for BVD. Treatment mainly consists of supportive care, including intravenous fluids, electrolyte replacement, oxygen support, pain and fever management, and treatment of secondary infections. Early medical care significantly improves survival chances. Robust public health measures such as early detection, rapid isolation, strong infection prevention measures (*i.e.*, use of personal protective equipment [PPE]), and monitoring of contacts are critical to controlling outbreaks and reducing deaths. Clinical trials of monoclonal antibodies and of an existing vaccine approved for use to prevent disease caused by the Ebola Zaire virus are presently underway in the DRC.^{1 2} However, experts expect it will be

¹ World Health Organization. *Patient enrolment begins in a scientific trial to identify the first effective treatments for Bundibugyo virus disease*, <https://www.who.int/news/item/02-07-2026-patient-enrolment-begins-in-a-scientific-trial-to-identify-the-first-effective-treatments-for-bundibugyo-virus-disease> (last accessed October 13, 2026).

² United Nations. *Ebola vaccine research programme begins in DR Congo*, <https://news.un.org/en/story/2026/09/1168381> (last accessed October 13, 2026).

several months before these therapeutics are potentially available for wider use.

B. Ongoing Bundibugyo Virus Disease Outbreak

The confirmed ongoing outbreak of BVD in the DRC continues to escalate in intensity. The outbreak remains centered in eastern DRC's Ituri Province, although cases have been identified in North Kivu, South Kivu, Haut-Uélé, Bas-Uélé, Tshopo, North Ubangi, and South Ubangi provinces. This geographic expansion is concerning, particularly given that response efforts are still not at the scale required for outbreak containment. As of October 18, 2026, the DRC reports 9,455 confirmed cases and 4,561 deaths in 66 health zones across eight provinces.

The World Health Organization has reported substantial under-ascertainment of cases and persistent challenges with contact tracing. As of its most recent assessment, only approximately 20 percent of BVD cases were identified through follow-up of listed contacts, and approximately 40 percent were ultimately linked to a known chain of transmission, indicating substantial undetected transmission.³ Surveillance challenges persist in the most heavily affected areas, with conflict and insecurity, weak health infrastructure, and relatively porous borders in the region complicating containment efforts. Although contact tracing efforts are underway, they remain insufficient and the daily follow-up necessary to rapidly detect symptomatic individuals and ensure their prompt isolation has not been achieved.

Persons who have unknowingly been infected with BVD may travel before becoming symptomatic. Such travelers may spread the virus beyond DRC and ultimately reach the United States. The DRC is connected to the global aviation network through a series of regional and international transit hubs that provide pathways into the United States. These international transportation corridors support continuous movement of travelers between Central and East Africa and major U.S. metropolitan centers, increasing the likelihood that persons exposed to Ebola disease could enter the United States before symptoms become apparent. Complex multi-leg

³ Second meeting of the IHR Emergency Committee on the epidemic of Ebola Bundibugyo virus disease in the Democratic Republic of the Congo—Meeting report <https://www.who.int/news/item/28-08-2026-second-meeting-of-the-ihremergency-committee-on-the-epidemic-of-ebola-bundibugyo-virus-disease-in-the-democratic-republic-of-the-congo---meeting-report> (last accessed October 13, 2026).

itineraries and the rapid pace of international travel create substantial challenges for identifying potentially infected persons before arrival.

The risk of BVD introduction into the United States is heightened by the virus's incubation period, which can extend up to 21 days, allowing infected persons to travel internationally while asymptomatic and therefore unlikely to be detected through routine symptom-based screening measures. The current outbreak has demonstrated this risk: for example, a physician infected while providing patient care in the DRC traveled internationally before becoming ill and was diagnosed only after arriving in France.⁴ That case required extensive public health coordination, including federal, state, and local government efforts to identify, notify, and monitor potentially exposed U.S. citizens, demonstrating that a single infected traveler can impose significant cross-border public health response demands even without onward transmission occurring within the United States. Additionally, on October 6, 2026, the Kenya Ministry of Health announced the country's first BVD case and death in an individual who had traveled from DRC to Uganda, flown from Kampala to Nairobi on October 2, and was hospitalized before dying on October 5, 2026.⁵ By October 19, 2026, Kenya had announced another seven cases had been confirmed in previously identified close contacts, reaching a total of eight BVD cases in Kenya, including the initial case that resulted in a death.⁶ The interconnected nature of global air travel presents a credible pathway for BVD importation into the United States, underscoring the importance of aggressive surveillance, traveler monitoring, airport public health screening, healthcare preparedness, and rapid containment capabilities.

The ongoing outbreak has also demonstrated that substantial U.S. public health resources may be required to respond to an Ebola exposure or infection in any U.S. citizen. On July 10,

2026, CDC announced that an additional U.S. citizen working for a humanitarian organization in the DRC had tested positive for BVD.⁷ The individual, who was not involved in direct patient care,⁸ prompted an extensive U.S. public health response. CDC, in coordination with the humanitarian organization, initiated contact tracing, exposure risk assessments, and monitoring activities to identify high-risk contacts and evaluate potential exposures among humanitarian personnel who had recently returned to, or are planning to return to, the United States. The Department of State arranged medical evacuation outside of the DRC for treatment. This incident demonstrates that even when an infected U.S. citizen remains overseas, the outbreak can require substantial U.S. public health resources to identify, assess, and monitor potentially exposed individuals associated with international humanitarian operations.

Persons utilizing air transit pathways originating in the DRC include U.S. and non-U.S. citizens, regional migrants, foreign contract workers, humanitarian personnel, business travelers, crew members students, refugees, and third-country nationals moving through international aviation hubs in Africa, the Middle East, and Europe. Many travelers entering U.S.-bound itineraries from these pathways may do so under temporary visas, refugee or asylum processing mechanisms, international organizational travel, or multi-country itineraries that obscure their original point of departure. As a result, public health screening and border security systems face heightened operational complexity in identifying travelers with recent exposure histories linked to Ebola-affected regions, particularly when travelers transit through multiple jurisdictions prior to arrival at major U.S. metropolitan airports.

CDC has issued Travel Health Notices (THN) for affected countries and regions. Currently, there is a Level 4 THN for Ituri and Nord-Kivu Provinces of DRC (avoid all travel); a Level 3 THN for Haut-Uélé and Tshopo Provinces of DRC (reconsider nonessential travel); a Level 2 THN (practice enhanced precautions) for the remainder of the DRC and Uganda; and a Level 1 THN

(practice usual precautions) for Nairobi, Kenya.⁹ CDC modeling indicates that, absent rapid and sustained public health interventions, the outbreak could become one of the largest Ebola epidemics ever recorded.¹⁰ The analysis further demonstrates that early identification of cases, contact tracing, isolation, and treatment of symptomatic persons, community engagement, and safe burial practices are critical to reducing transmission and mitigating outbreak growth.¹¹ CDC has concluded that the current outbreak is already the largest known outbreak of BVD and that large-scale, temporary public health measures are necessary to prevent further international spread of the disease and to reduce the risk of introduction of infected persons into the United States.¹² Commensurate with the deterioration of the epidemiological situation in the DRC, CDC escalated its response to the outbreak to a Level 1, the highest level within the agency's Graduated Response Framework.¹³

CDC has determined that the risk profile presented by the DRC is materially distinct from that of other affected countries. The DRC remains the epicenter of the outbreak, with an estimated 80 percent of newly confirmed cases in Ituri Province not linked to known contacts, indicating substantial undetected community transmission. Contact tracing, surveillance, and containment capacity in the DRC are impaired by conflict, insecurity, weak health infrastructure, and porous borders. CDC has therefore determined that a categorical temporary measure directed at travelers with recent presence in the DRC is appropriately tailored to the elevated importation risk presented by that country. CDC will continue to monitor conditions in the DRC and other affected countries and may modify the scope of this Order accordingly.

Statement of Good Cause Under the Administrative Procedure Act

This Order is not a rule within the meaning of the Administrative Procedure Act ("APA") but rather is an action taken under the existing authority of 42 U.S.C. 264(a) and 42 CFR 71.20, 71.31(b), and 71.32(b), which were promulgated in accordance with

⁴ World Health Organization, *WHO Director-General's opening remarks at the media briefing—24 June 2026*, available at <https://www.who.int/news-room/speeches/item/who-director-general-s-opening-remarks-at-the-media-briefing---24-june-2026> (last accessed October 13, 2026).

⁵ World Health Organization, *Kenya confirms first imported Bundibugyo virus disease case; WHO supports control efforts*, <https://www.afro.who.int/countries/kenya/news/kenya-confirms-first-imported-bundibugyo-virus-disease-case-who-supports-control-efforts> (last accessed October 13, 2026).

⁶ Ebola cases in Kenya rise to 8 after another person tests positive, <https://apnews.com/article/kenya-ebola-congo-uganda-0b23b5ff00d39345037f2d298e92e24f> (last accessed October 19, 2026).

⁷ CDC, *CDC Statement on Ebola Outbreak in the Democratic Republic of Congo and Uganda: 7/10/26*, <https://www.cdc.gov/media/releases/2026/cdc-ebola-outbreak-in-democratic-republic-of-congo-and-uganda.html> (last accessed October 13, 2026).

⁸ Walsh, D. and Yoon, J., *U.S. Citizen Tests Positive for Ebola in Democratic Republic of Congo*, https://www.nytimes.com/2026/07/11/world/africa/dr-congo-ebola-american-us-citizen.html?unlocked_article_code=1.w1A.A4kv.spNPZlf8jap6&smid=url-share (last accessed October 13, 2026).

⁹ CDC Travel Health Notices, <https://wwwnc.cdc.gov/travel/notices>.

¹⁰ Mooring EQ, Koval WT, Routledge I, et al. *Modeled Scenario Projections for the Ebola Disease Outbreak Caused by Bundibugyo Virus, 2026*. MMWR Morb Mortal Wkly Rep 2026;75:285–289. DOI: <http://dx.doi.org/10.15585/mmwr.mm7522e1>.

¹¹ *Id.*

¹² *Id.*

¹³ CDC, Internal Decision Memo, June 26, 2026.

the APA after full notice and comment rulemaking and a delayed effective date. If this Order qualifies as a new rule under the APA, notice and comment and a delayed effective date are not required because there is good cause to dispense with prior public notice and comment and a delay in effective date. See 5 U.S.C. 553(b)(B), (d)(3).

Based on the foregoing, I have determined that Ebola disease caused by the Bundibugyo virus, a highly transmissible quarantinable communicable disease designated as such by Executive Order 13295, as amended, is confirmed present in the DRC. I have also determined that Ebola disease if introduced into the United States would constitute a public health emergency. I have considered other alternatives, including reliance on airport-based public health screening, voluntary questioning, and expansion of the existing federal public health travel restrictions process, and have determined that these alternatives, standing alone or in combination, would not adequately address the identified risk given the disease's incubation period of up to 21 days, the substantial proportion of asymptomatic transmission-window travel, and the demonstrated capacity of a single infected person to consume substantial U.S. public health resources. Finally, I determine that requiring persons arriving in the United States via transportation by aircraft to submit an attestation confirming that they have not been present in the DRC during the 21 days prior to boarding a flight to the United States, combined with a conditioning of controlled free pratique on airline or aircraft operator confirmation of such attestations, is a necessary public health measure to protect the public health and prevent the introduction, transmission, and spread of Ebola disease into the United States. In making these determinations I have considered the prevalence of Ebola disease in the DRC, that country's limited ability to screen for the disease and engage in other mitigation measures, and the potential for spread in the United States. Accordingly, I find that any delay in issuing this Order beyond the minimum necessary for operationally feasible implementation would be contrary to the public's health in the United States and therefore the public's interest.

Any delay in the effective date, would be impracticable and contrary to the public interest for the additional reason that the outbreak in the DRC continues to expand, the 21-day incubation period of Ebola disease means that each additional day of pre-effective delay

materially increases the risk that infected persons will board flights bound for the United States while asymptomatic, and public notice of a forthcoming attestation requirement could prompt individuals presently in the DRC to accelerate their travel to the United States before the requirement takes effect, defeating the purpose of this Order.

If any provision of this Order, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, persons, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

Pursuant to 5 U.S.C. 553(b)(B), and for the reasons stated above, I hereby conclude that notice-and-comment rulemaking would defeat the purpose of the Order and endanger the public health, and is, therefore, impracticable and contrary to the public interest. For the same reasons, I have determined, consistent with 5 U.S.C. 553(d)(3), that there is good cause to make this Order effective immediately following the minimum delay necessary for the Order's implementation to be operationally feasible.

Action

For the reasons outlined above, I hereby determine that persons covered by this Order are at risk of transmitting Ebola disease and requiring persons to attest that they have not been present in the DRC during the 21 days prior to boarding a flight to the United States is needed as a public health measure to protect the health of other travelers and U.S. communities.

This Order shall remain in effect until rescinded or modified based on specific public health or other considerations, or until December 18, 2026, whichever occurs first. Any amendment or extension of this Order will be based on a review of then-current outbreak metrics, including case counts, geographic spread, community-transmission indicators, and containment capacity in affected countries.

1. Requirements for Airlines & Other Aircraft Operators

This Order conditions the grant of controlled free pratique on the airline and aircraft operator compliance measures specified below. This Order does not regulate landing rights, airspace access, or aircraft certification, which remain within the jurisdiction of the Department of Transportation, the Federal Aviation Administration, and

other agencies exercising their respective legal authorities.

Any airline or other aircraft operator with persons who are not otherwise exempt from the requirements of this Order boarding a flight to the United States from a foreign country, shall:

A. Confirm to the U.S. Government, at or before the time of boarding, that all persons boarding or onboard the aircraft have completed and signed an attestation in paper or digital format confirming that they have not been present in the Democratic Republic of the Congo (DRC) during the 21 days preceding their boarding a flight to the United States. For purposes of this requirement, "confirm" means that the airline or aircraft operator has reviewed the completed attestation from each covered person prior to boarding and has determined, based on the face of the attestation, that the attestation is complete and signed; and

B. Not board any person who has failed to complete and present such an attestation.

C. Retain a paper or digital copy each person's completed and signed attestation for at least 42 days after the person's flight departs for the United States from a foreign country and provide the attestation to the U.S. Government on request.

Any airline or other aircraft operator that fails to comply with section 1, "Requirements for Airlines & Other Aircraft Operators," may be subject to criminal penalties under, *inter alia*, 42 U.S.C. 270 and 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571 (providing for fines of up to \$100,000 for individuals and \$200,000 for organizations, and/or imprisonment of up to one year). CDC anticipates that separate compliance mechanisms may be established by the Transportation Security Administration pursuant to its own statutory authorities.

Any airline or other aircraft operator that fails to provide the U.S. Government the confirmation of completed attestations of all persons as outlined above will not receive controlled free pratique to enter a U.S. port of entry, disembark passengers, and begin operation with respect to arriving at an airport in the United States.

2. Requirements for Persons Traveling Via Transportation by Aircraft Who Are Not Otherwise Exempt

A. Complete and sign the attestation under penalty of law as provided by 18 U.S.C. 1001 which provides criminal penalties for knowingly and willfully submitting false statements to the U.S. government; and

B. Provide for confirmation the completed and signed attestation to the airline or other aircraft operator confirming that they have not been present in the Democratic Republic of the Congo (DRC) during the 21 days preceding their boarding a flight to the United States.

The required attestation text is attached to this Order as Attachment A. Unless otherwise permitted by law, a parent or other authorized representative may present the required documentation on behalf of a person required to submit such an attestation.

Any person who fails to provide this attestation, or submits false or misleading information, may face a delay of travel, denial of boarding, or denial of boarding on future travel.

Any person who fails to comply with the requirements of section 2, “Requirements for Persons Traveling via Transportation by Aircraft,” may be subject to criminal penalties under, *inter alia*, 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571. Willfully giving false or misleading information to the government may result in criminal penalties under, *inter alia*, 18 U.S.C. 1001. This Order shall be enforceable through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 270, 271; and 42 CFR 71.2. The U.S. Department of Justice in its discretion may prosecute any individual who knowingly and willfully submits a false statement in violation of 18 U.S.C. 1001.

Effective Date

This Order takes effect at 11:59 p.m. Eastern Standard Time on November 3, 2026. For individuals intending to travel to the United States by air, the Order will apply to flights departing at or after 11:59 p.m. Eastern Standard Time on November 3, 2026.

In testimony whereof, the Assistant Secretary for Health, U.S. Department of Health and Human Services, has hereunto set his hand at _____, this October 28, 2026.

Dated:

Brian Christine,
*Assistant Secretary for Health (ASH) and
Head of the United States Public Health
Service (USPHS) Commissioned Corps,
Department of Health and Human Services.*

Authority

The authority for this order is Sections 361, 365, 368, and 369 of the

Public Health Service Act (42 U.S.C. 264, 268, 270, and 271), as amended.

Brian Christine,

*Assistant Secretary for Health (ASH) and
Head of the United States Public Health
Service (USPHS) Commissioned Corps,
Department of Health and Human Services.*

[FR Doc. 2026–22211 Filed 10–29–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2560]

Essential Drug Delivery Performance Characteristics for Devices Intended To Deliver Drugs and Biological Products; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled “Essential Drug Delivery Performance Characteristics for Devices Intended to Deliver Drugs and Biological Products.” This revised draft guidance revises and replaces the draft guidance entitled “Essential Drug Delivery Outputs Intended to Deliver Drugs and Biological Products” announced in the **Federal Register** on July 1, 2024 (89 FR 54470). In accordance with its mission of protecting, promoting, and advancing public health, this guidance addresses key aspects of drug delivery performance information for devices, and combination products that include device constituent parts, intended for delivery of a human drug, including a biological product (herein referred to as *drug delivery devices*). This guidance provides recommendations for development and organization of device drug-delivery performance information and data to improve the consistency of this information in applications and to facilitate transparency and predictability in development and regulatory review. The guidance is intended to facilitate and streamline development and lifecycle management of drug delivery devices.

DATES: Submit either electronic or written comments on the revised draft guidance by January 28, 2027 to ensure that the Agency considers your comment on this revised draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2024–D–2560 for “Essential Drug Delivery Performance Characteristics for Devices Intended to Deliver Drugs and Biological Products.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two

copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the revised draft guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia Love, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993, 301-796-8930, patricia.love@fda.hhs.gov or combination@fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled "Essential Drug Delivery Performance Characteristics for Devices Intended to Deliver Drugs and Biological Products." This revised draft guidance revises and replaces the draft guidance entitled "Essential Drug Delivery Outputs Intended to Deliver Drugs and Biological Products" announced on July 1, 2024 (89 FR 54470). This guidance provides updates to clarify content on testing and controlling device drug-delivery performance and to align with the revised Quality Management System Regulation, 21 CFR part 820.

The guidance describes FDA's recommendations related to information that is essential for establishing and assessing drug delivery performance for drug delivery devices. Device drug-delivery performance information is intended to demonstrate that the device drug-delivery function consistently performs as intended. The guidance focuses on recommendations for the information and data to submit in investigational, marketing, and post-market change applications.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on "Essential Drug Delivery Performance Characteristics for Devices Intended to Deliver Drugs and Biological Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 for investigational new drug applications have been approved under OMB control number 0910-0014 and the collections

of information in 21 CFR part 812 for investigational device exemptions have been approved under OMB control number 0910-0078. The collections of information in 21 CFR part 314 for new drug applications and abbreviated new drug applications, including the collections of information contained in the guidance for industry entitled "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products" have been approved under OMB control number 0910-0001. The collections of information in 21 CFR parts 601 and 610 for biologics license applications have been approved under 0910-0338. The collections of information in section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) have been approved under 0910-0718. The collections of information in 21 CFR part 814 for premarket approval applications have been approved under 0910-0231. The collections of information in section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), 21 CFR part 807, subpart E for premarket notifications, have been approved under OMB control number 0910-0120. The collections of information in 21 CFR 860, subpart D for De Novo classifications have been approved under OMB control number 0910-0844. The collections of information in 21 CFR part 211 for current good manufacturing practice for finished pharmaceuticals have been approved under OMB control number 0910-0139. The collections of information in 21 CFR part 820 for the quality management system regulation have been approved under OMB control number 0910-0073. The collections of information for meetings and controlled correspondence related to generic drug development have been approved under OMB control number 0910-0727. The collections of information in the guidance for industry and FDA staff entitled "Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with the Food and Drug Administration Staff" have been approved under OMB control number 0910-0756.

III. Electronic Access

Persons with access to the internet may obtain the revised draft guidance at <https://www.fda.gov/combination-products/guidance-regulatory-information/combination-products-guidance-documents>, <https://www.fda.gov/regulatory-information/>

search-fda-guidance-documents or <https://www.regulations.gov>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22203 Filed 10–29–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1998–P–0083 (formerly 76N–0377); DESI 7661]

Drugs for Human Use; Drug Efficacy Study Implementation: Estrogen-Androgen Fixed-Combination Drug Products; Third Extension of Effective Date of Final Resolution of Drug Efficacy Study Implementation 7661

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; third extension of effective date.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the effective date of the notice published in the **Federal Register** on May 27, 2026, titled **Drugs for Human Use; Drug Efficacy Study Implementation: Estrogen-Androgen Fixed-Combination Drug Products; Syntest D.S. and Syntest H.S. Tablets; Withdrawal of Hearing Requests; Final Resolution of Drug Efficacy Study Implementation 7661** (91 FR. 31462) (the “May 2026 Notice”), as previously extended by the notice published in the **Federal Register** on August 27, 2026 (91 FR 55348), by an additional 6 months. The effective date of the May 2026 Notice, as previously extended to November 4, 2026, is hereby further extended to May 4, 2027. This further extension is necessary to allow FDA sufficient time to consider issues raised by interested parties.

DATES: The effective date of the May 27, 2026, notice (91 FR 31462), as previously extended, is further extended to May 4, 2027.

ADDRESSES: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500 between 9 a.m. and 4 p.m., Monday

through Friday. Publicly available submissions may be seen in the docket.

The most relevant background documents regarding this matter are available in the docket. However, additional background documents are available upon request (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT:

Amber McKinley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5172, Silver Spring, MD 20993–0002, 301–796–0061, Amber.McKinley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On May 27, 2026, FDA published a notice in the **Federal Register** (91 FR 31462) announcing the final resolution of Drug Efficacy Study Implementation (DESI) 7661 for estrogen-androgen fixed-combination drug products. The May 2026 Notice concluded that all outstanding hearing requests for estrogen-androgen fixed-combination drug products under Docket FDA–1998–P–0083 had been withdrawn, and that such products lack substantial evidence of effectiveness for the treatment of moderate to severe vasomotor symptoms associated with the menopause in patients not improved by estrogen alone. The May 2026 Notice stated that shipment in interstate commerce of any drug product identified in the docket, or any identical, related, or similar (IRS) product, that is not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) would be unlawful as of June 26, 2026.

FDA subsequently extended the effective date of the May 2026 Notice to September 24, 2026, and then to November 4, 2026, to allow the Agency sufficient time to consider issues raised by interested parties following publication of the May 2026 Notice. See 91 FR 38717 and 91 FR 55348.

II. Third Extension of Effective Date

FDA has determined that additional time is needed to fully consider the issues raised by interested parties. Accordingly, FDA is extending the effective date of the May 2026 Notice by an additional six months, from November 4, 2026, to May 4, 2027. See 21 CFR 314.200(h).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22175 Filed 10–29–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: AIDS Drug Assistance Program—Transformation: Optimization and Best Practices in the Evolving Health Care Landscape, OMB No. 0906–XXXX—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than December 29, 2026.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 443–9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: AIDS Drug Assistance Program—Transformation: Optimization and Best Practices in the Evolving Health Care Landscape, OMB No. 0906–XXXX—New.

Abstract: HRSA’s HIV/AIDS Bureau administers the Ryan White HIV/AIDS Program, including the AIDS Drug Assistance Program (ADAP). ADAPs help low-income people with HIV access therapeutics to treat HIV/AIDS or prevent the serious deterioration of health arising from HIV/AIDS, including measures for the prevention and

treatment of opportunistic infections and health care coverage assistance. As health care coverage environments, treatment options, and program financing mechanisms continue to evolve, ADAPs face increasing operational complexity related to eligibility determination; client enrollment and retention; health care coverage navigation; pharmacy management; rebate administration; and data infrastructure. HRSA currently lacks comprehensive, national-level information about how ADAPs manage these operational functions and address emerging challenges.

To address these information gaps, HRSA developed the ADAP Transformation: Optimization and Best Practices in the Evolving Health Care Landscape study. Through this effort, HRSA will collect program-level information from ADAPs nationwide through a web-based survey, qualitative interviews with a purposeful sample of ADAP staff, and virtual listening sessions with the broader ADAP community. The study will identify operational best practices, barriers, and opportunities for technical assistance to strengthen ADAP capacity and support

access to HIV care and treatment services. No client-level information, personally identifiable information, or protected health information will be collected.

Need and Proposed Use of the Information: The proposed information collection will provide HRSA with systematic information on operational and administrative practices across ADAPs nationwide. Survey, interview, and listening session data will help HRSA identify effective strategies for managing eligibility processes; client enrollment and recertification; health care coverage continuity; pharmacy operations; rebate management; cost-containment efforts; and data systems modernization.

Findings will support the development of tailored technical assistance, tools, guidance, and dissemination activities designed to strengthen ADAP operations. Results will also inform HRSA program planning and future data collection efforts. Study findings will be reported only in aggregate or de-identified form and will not be used for compliance monitoring or funding decisions.

Likely Respondents: Respondents will consist of staff from state and territorial

ADAPs, including program administrators, eligibility and enrollment staff, pharmacy and benefits coordinators, financial and rebate management staff, data systems personnel, and other staff responsible for ADAP operations. HRSA will also invite ADAP staff to participate in virtual listening sessions focused on validating and contextualizing study findings.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Quantitative Survey	54	1	54	0.5	27
Qualitative Interview	54	1	54	1.5	81
Listening Sessions	177	1	177	1.5	265.5
Total	285		285		373.5

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,
Director, Executive Secretariat.
[FR Doc. 2026–22220 Filed 10–29–26; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. HHS–OASH–2026–0496]
RIN 0910–ZD94

Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances

AGENCY: Office of the Secretary, Department of Health and Human Services.
ACTION: Notice of availability.

SUMMARY: The Secretary of the Department of Health and Human Services (HHS) is announcing the availability of an “Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances.” This document describes the Secretary of HHS’s enforcement policy regarding the use of

certain peptide bulk drug substances in compounding pursuant to section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) while the list of bulk drug substances that can be used in compounding under section 503A of the FD&C Act (the 503A bulks list) is developed through rulemaking.

DATES: This announcement is published in the **Federal Register** as of October 30, 2026.

ADDRESSES: Written comments can be submitted until 2 weeks after date of publication in the **Federal Register** via *regulations.gov* on Docket No. HHS–OASH–2026–0496

FOR FURTHER INFORMATION CONTACT: Victoria Marshall, Office of the Assistant Secretary for Health, 200 Independence Avenue SW, Washington, DC, 202–690–7694, *OASH-RFI@hhs.gov*

SUPPLEMENTARY INFORMATION:

I. Background

HHS is announcing the availability of a draft "Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances." This document describes the HHS Secretary's enforcement policy regarding the use of certain peptide bulk drug substances in compounding pursuant to section 503A of the FD&C Act while the list of bulk drug substances that can be used in compounding under section 503A of the FD&C Act (the 503A bulks list) is developed through rulemaking (21 U.S.C. 353a).

Compounding is generally a practice in which a licensed pharmacist, a licensed physician or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Compounded drugs are not FDA-approved, which means FDA does not review their safety, effectiveness, or quality before they are marketed. Although compounded drugs can serve an important medical need for certain patients, they also may pose risks to patients. However, based on the Pharmacy Compounding Advisory Committee meetings and data regarding utilization of peptides, HHS believes that there is significant interest in the use of these peptides in compounding given the lack of availability of approved products. Therefore, to expand and improve patient access, HHS does not intend to take enforcement action against a State-licensed pharmacy, Federal facility, or licensed physician compounding a drug product using a peptide bulk drug substance found in Appendix A. FDA's future rulemakings may propose adding some or all of these peptides to the 503A bulks list based on the available evidence.

HHS may revisit application of this interim policy (in whole or in part) if, among other things, a safety signal or product quality issue arises with a compounded drug product within the scope of this policy. The draft Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances does not establish any rights for any person and is not binding on HHS or the public.

II. Paperwork Reduction Act of 1995

This policy contains no collection of information. Therefore, clearance by the Office of Management and Budget under

the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required.

III. Electronic Access

Persons with access to the internet may obtain the document at <https://www.hhs.gov/sites/default/files/hhs-503a-peptide-enforcement-discretion-policy-appendix-b.pdf>, or <https://www.regulations.gov>. Use the HHS website listed in the previous sentence to find the most current version of the policy.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–22192 Filed 10–28–26; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>.

Name of Committee: National Advisory Board on Medical Rehabilitation Research
Date: December 6–7, 2027.

Time: December 06, 2027, 10:00 a.m. to 3:00 p.m.

Agenda: NICHD Director's Report, NCMRR Director's report; Election of a new Board Chair-Elect; Scientific Talk on Rehabilitation Research topic.

Address: Eunice Kennedy Shriver National Institute of Child, Health and Human Development, National Institutes of Health, 6710 B Rockledge Drive, Bethesda, MD 20817.

Meeting Format: In Person and Virtual Meeting.

Time: December 07, 2027, 10:00 a.m. to 2:00 p.m.

Agenda: Update on NIH policy issues; Discussion of Research support and Training; Scientific Talk; Planning for Next NABMRR Meeting.

Address: Eunice Kennedy Shriver National Institute of Child, Health and Human Development, National Institutes of Health,

6710 B Rockledge Drive, Bethesda, MD 20817.

Meeting Format: In Person and Virtual Meeting.

Contact Person: Joseph Bonner, Ph.D., National Center for Medical Rehabilitation Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710 B Rockledge Drive, Bethesda, MD 20817, (301) 827–8303, joe.bonner@nih.gov.

Registration is not required to attend this meeting.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Persons listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at <https://security.nih.gov/visitors/Pages/visitor-campus-access.aspx> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <https://www.nichd.nih.gov/about/advisory/nabmrr>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: October 27, 2026.

Margaret N. Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-22195 Filed 10-29-26; 8:45 am]

BILLING CODE 4167-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: May 12, 2027.

Open: May 12, 2027, 8:30 a.m. to 12:00 p.m.

Agenda: Council Business.

Open: May 12, 2027, 1:00 p.m. to 2:30 p.m.

Agenda: KUH, DEM, DDN Open session.

Closed: May 12, 2027, 1:00 p.m. to 2:30 p.m.

Agenda: DEM, DDN, KUH Closed session to review and evaluate grant applications.

Closed: May 12, 2027, 3:45 p.m. to 4:00 p.m.

Agenda: Reports of Subcommittees and Consideration of Applications.

Address: Shady Grove Conference Center, National Institutes of Health, 9609 Medical Center Drive, Rockville, MD 20850.

Meeting Format: In Person and Virtual Meeting.

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594-4757, malikk@niddk.nih.gov.

In the interest of security, NIH has procedures at <https://security.nih.gov/visitors/Pages/visitor-campus-access.aspx> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council>, where an agenda and any additional information for the meeting will be posted when available.

Dated: October 26, 2026.

Margaret N. Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-22196 Filed 10-29-26; 8:45 am]

BILLING CODE 4167-05-P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2026-0694]

Notice of Order Regarding Exclusion and Removal of Acronis Products From Federal Civilian Executive Branch Information Technology Systems and Procurements

AGENCY: Department of Homeland Security (DHS).

ACTION: Notice of order.

SUMMARY: The Department of Homeland Security is publishing notice of the Secretary of Homeland Security's issuance of an order excluding Acronis AG and all affiliated entities, as well as any covered articles directly or indirectly supplied by them (Acronis covered articles) from federal civilian agency procurements; and, removing all Acronis covered articles from civilian agency information technology systems.

FOR FURTHER INFORMATION CONTACT:

FASCSA Order Implementation Team
CISA Cybersecurity Division,
fascsa.orders@cisa.dhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted by the Federal Acquisition Supply Chain Security Act of 2018, 41 U.S.C. 1321-1328, and implementing regulations at 41 CFR 201-1, following review of the Federal Acquisition Security Council Recommendation and affiliated evidence, the Secretary of Homeland Security has ordered: (1) exclusion of information technology products developed by Acronis, Inc., Acronis SCS, and affiliated entities as defined in 48 CFR 2.101, from federal civilian executive branch procurements; and (2) to remove said information technology products from federal civilian executive branch information technology systems.

A copy of the signed order is contained in the accompanying Appendix and can be found at <https://www.regulations.gov> by searching for DHS Docket Number DHS-2026-0694.

Kateland R. Jackson,

Principal Deputy General Counsel, U.S. Department of Homeland Security.

BILLING CODE 9111-LF-P

Appendix

Exclusion and Removal Order #2026-02**Federal Acquisition Supply Chain Security Act Exclusion and Removal of Acronis Products and Services from Federal Civilian Executive Branch Information Technology Systems**

Original Release Date: July 31, 2026

Applies to: Federal Civilian Executive Branch Agencies except for their national security systems and secure compartmented information systems

FROM: Markwayne Mullin 
Secretary, United States Department of Homeland Security

CC: Russell Vought
Director, Office of Management and Budget

The Federal Acquisition Supply Chain Security Act of 2018, 41 U.S.C. §§ 1321-1328, and implementing regulations at 41 C.F.R. part 201-1, authorize the Department of Homeland Security Secretary to issue exclusion and/or removal orders for purposes of safeguarding federal civilian information systems. Recommendations of the Council shall be reviewed by the Secretary of Homeland Security, who may issue exclusion and removal orders based upon such recommendations, to the extent not covered by the Department of Defense or the Intelligence Community. 41 U.S.C. §1323 (c)(5)(A). Section 201-1.304 of the Federal Acquisition Supply Chain Security Act Final Rule states that executive agencies shall comply with exclusion and removal orders issued pursuant to § 201-1.303.

Background:

Information and communications technology and services are essential to the proper functioning of U.S. government information systems. To better coordinate the scale of supply chain risks faced by government agencies, the Federal Acquisition Supply Chain Security Act of 2018 established the Federal Acquisition Security Council, an executive branch interagency council consisting of officials from the Office of Management and Budget, General Services Administration, Department of Homeland Security (DHS), Office of the Director of National Intelligence, Department of Justice, Department of Defense, and Department of Commerce. The Council is responsible for managing supply chain risk at the federal level by recommending the exclusion of products or services from federal procurement opportunities and removal from federal information technology systems that have been determined to pose a significant risk to the federal enterprise.

Per the statute and the implementing regulations, the Secretary of Homeland Security has the authority to issue exclusion or removal orders applicable to Federal civilian executive agency information systems, with the exception of those specifically under the purview of the Department of Defense and the Office of the Director of National Intelligence.

Summary of Risks from Source:

Acronis, AG (hereinafter Acronis), a foreign, privately-owned company with U.S. subsidiaries, provides data protection, data backup, secure file sharing, and disaster recovery solutions (on premises and via the cloud). Acronis's cyber and backup tools have privileged or root access to customer security systems and present significant risk to the U.S. government information systems.

Scope:

This Exclusion and Removal Order directs Federal Civilian Executive Branch agencies¹ to: (1) exclude Acronis AG and all affiliated entities,² as well as any covered articles³ directly or indirectly supplied by them (Acronis covered articles), from agency procurement actions; and (2) remove any Acronis covered articles from agency information systems.⁴

Required Actions:

All Federal Civilian Executive Branch agencies are required to:

1. **Exclude** Acronis covered articles from all ongoing and future procurements effective immediately after issuance of this Order, to include agency-approved products lists, service provider equipment lists, e-commerce markets, and other similar functions that facilitate the procurement of information technology hardware, software, and services.
2. **Remove** Acronis covered articles from all agency information systems within 180 calendar days of the issuance of the Order, or seek an Exception, as described below.

Exceptions:

Executive agencies may submit to the issuing official a request to be excepted from the order's provisions, in accordance with 41 C.F.R. § 201-1.304(b).⁵ The requesting agency may ask to be excepted from some or all of the order's requirements. The agency may ask, for example, that

¹ The Secretary of Homeland Security's authority to issue exclusion and removal orders is applicable to federal civilian executive branch agencies, to the extent not covered by the authority of the Secretary of Defense and Director of National Intelligence, as defined by 41 U.S.C. § 1323(5)(A)(ii) or (iii).

(ii) The Secretary of Defense, for exclusion and removal orders applicable to the Department of Defense and national security systems other than sensitive compartmented information systems.

(iii) The Director of National Intelligence, for exclusion and removal orders applicable to the intelligence community and sensitive compartmented information systems, to the extent not covered by clause (ii).

² For purposes of this Order, an individual or business is an "affiliated entity" or "affiliate" of Acronis AG if, directly or indirectly, either one controls or can control the other; or a third party controls or can control both. See 48 C.F.R. § 2.101 (definition of "affiliates").

³ As used in this order, "covered article" has the meaning given in 41 U.S.C. § 4713(k)(2).

⁴ Consistent with the Federal Information Security Modernization Act, this order applies to all Federal Information Systems, including information systems used or operated by an agency or by a contractor of an agency or other organization on behalf of an agency. See 41 U.S.C. § 3354(1)(1)(A)(ii).

⁵ The Federal Acquisition Regulation uses the term "waiver" instead of "exceptions", but for the purpose of this order, these terms are considered to be the same. See FAR 52.204-30, Federal Acquisition Supply Chain Security Act Orders—Prohibition.

the order not apply to the agency, to specific actions of the agency, or to actions of the agency for a period of time before compliance with the order is practicable.

Executive agency requests for exceptions must be **submitted in writing within 60 days** of the issuance of this order and include all necessary information for the issuing official to review and evaluate it, including:

1. Identification of the applicable exclusion order or removal order;
2. A description of the exception sought, including, if limited to only a portion of the order, a description of the order provisions from which an exception is sought;
3. The name or a description sufficient to identify the covered article or the product or service provided by a source that is subject to the order from which an exception is sought;
4. Compelling justification for why an exception should be granted, such as the impact of the order on the agency's ability to fulfill its mission-critical functions, or considerations related to the national interest, including national security reviews, national security investigations, or national security agreements; and
5. Any alternative mitigations to be undertaken to reduce the risks addressed by the exclusion or removal order.

DHS will review requests for exceptions and provide a written approval or disapproval. Please submit any exception requests to FASCSA.Orders@cisa.dhs.gov.

Interim Cybersecurity Measures:

During the period between the issuance of this order and full removal of covered articles from agency systems, federal agencies are encouraged to take steps to address risk to their systems, such as monitoring the flow of traffic in and out of the agency, implementing enhanced logging and controls on data exfiltration for the relevant systems, and detecting and flagging anomalous activity.

Actions by DHS and its Cybersecurity and Infrastructure Security Agency (CISA):

1. CISA may provide technical assistance to agencies that are without internal capabilities sufficient to comply with this Order.
2. DHS will review requests for exceptions and provide a written approval or disapproval.
3. The Secretary of Homeland Security will review this order as required by the Federal Acquisition Supply Chain Security Act within one year and annually thereafter.

Additional Information:

Contact FASCSA.Orders@cisa.dhs.gov for additional information, assistance, and reporting.

[FR Doc. 2026-22215 Filed 10-28-26; 4:15 pm]

BILLING CODE 9111-LF-C

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-NEW]

Agency Information Collection Activities; New Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until November 30, 2026.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at <http://www.regulations.gov> under e-Docket ID number USCIS-2026-0463. All submissions received must include the OMB Control Number 1615-NEW in the body of the letter, the agency name and Docket ID USCIS-2026-0463.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, telephone number (240) 721-3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at <http://www.uscis.gov>, or call the USCIS Contact Center at 800-375-5283 (TTY 800-767-1833).

SUPPLEMENTARY INFORMATION:

Comments

USCIS published an Interim Final Rule in the **Federal Register** at 91 FR

51924, providing notice of the collection of information and allowing for a 60-day public comment period. USCIS received 5 comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: <http://www.regulations.gov> and enter USCIS-2026-0463 in the search box. Comments must be submitted in English, or an English translation must be provided. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* New Collection.

(2) *Title of the Form/Collection:* Request for Waiver of Electronic Filing Requirement.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I-936; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. USCIS will use the information collected on Form I-936 to discretionarily determine whether applicant or beneficiary may file a paper benefit request based on a claim that electronically filing the request would impose an undue hardship on the requestor. USCIS will consider all relevant evidence the requestor provides, such as geographical location, socioeconomic conditions, and the availability of public technology resources. If the requestor does not have personal access to the internet, the requestor must explain why he or she cannot find other ways to access the internet (for example, through public libraries, community centers, friends, or family). Being unfamiliar with the USCIS online filing system or not having an online account will generally not be enough to establish the requestor qualifies for a waiver.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of annual respondents for the information collection I-936 is 248,905 and the estimated hour burden per response is 0.50 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated total annual hour burden associated with this collection is 124,453 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is \$6,094,493.

Dated: October 27, 2026.

John R. Pfirrmann-Powell,

Acting Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2026-22139 Filed 10-29-26; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**[Docket No. FR-7109-N-13; OMB Control No.: 2577-0215]****60-Day Notice of Proposed Information Collection: Section 8 Management Assessment Program (SEMAP) Certification****AGENCY:** Office of the Assistant Secretary for Public and Indian Housing (PIH), HUD.**ACTION:** Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* December 29, 2026.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to www.regulations.gov. Interested persons are also invited to submit comments regarding this proposal and comments should refer to

the proposal by name and/or OMB Control Number and should be sent to: Eva Fulton, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Eva Fulton, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email PIH-PRAPublicComments@hud.gov; telephone (202) 402-5847. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>. Copies of available supporting documents for the proposed collection may be obtained from Eva Fulton.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in section A.

A. Overview of Information Collection

Title of Information Collection: Section 8 Management Assessment Program (SEMAP) Certification.
OMB Approval Number: 2577-0215.
Type of Request: Extension of currently approved collection.

Form Number: HUD-52648.

Description of the Need for the Information and Proposed Use: On an annual basis (or every 2 years for small agencies) public housing agencies (PHAs) are required to submit a SEMAP certification (Form HUD-52648) electronically into the Information Management System/Public and Indian Housing Information Center (IMS/PIC), with the exception of small rural PHAs. There is a maximum of 15 indicators that are either verified through IMS/PIC data or an on-site or off-site confirmatory review. HUD uses the PHA's SEMAP certification, together with other available data, to assess PHA management capabilities and deficiencies, and to assign an overall performance rating to each PHA administering a housing choice voucher program. HUD rates a PHA on each SEMAP indicator, completes a PHA SEMAP profile identifying any program management deficiencies and assigns an overall performance rating. A PHA's written report of correction of a SEMAP deficiency is used as documentation that the PHA has taken action to address identified program weaknesses. Where HUD assigns an overall performance rating of troubled, the PHA's corrective action plan is used to monitor the PHA's progress on program improvements.

Respondents: Public Housing Agencies.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hours per response	Annual burden hours	Hourly cost per response	Annual cost
Form HUD-52648							
SEMAP Certification	1,544	1	1,544	12	18,528	\$42.50	\$787,440
Corrective Action Plan	60	1	60	10	600	42.50	25,500
Report on Correction of SEMAP Deficiency ...	400	1	400	2	800	42.50	34,000
Total	2,004	1	2,004		19,928	42.50	846,940

* Estimated cost per hour is based on Bureau of Labor Statistics, May 2026 National Occupational Employment and Wages Estimates, US for 13-1041, Compliance Officer mean hourly wage.

B. Solicitation of Public Comment

This notice solicits comments from members of the public and affected parties concerning the collection of information described in section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

44 U.S.C. 3507.

Laura Kunkel,

Chief, Office of Policy, Program, and Legislative Initiatives.

[FR Doc. 2026-22188 Filed 10-29-26; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-6624-N-01]

Request for Information To Promote the Success of the Melania Trump Foster Youth to Independence (FYI) Initiative

AGENCY: Office of the Assistant Secretary for Public and Indian Housing (PIH), HUD.

ACTION: Request for information.

SUMMARY: HUD is issuing this Request for Information (RFI) to solicit feedback from stakeholders on the Melania Trump Foster Youth to Independence (FYI) initiative. HUD will use the information gathered through this RFI to make recommendations to Congress (1) to improve program operations; (2) to assist youth in navigating the housing search process and preventing returns to homelessness after the subsidized rental assistance sunsets; and (3) on how Federal, State, and local stakeholders can best support participants as they transition from foster care to successful adulthood.

DATES: Comments are requested on or before December 14, 2026. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Interested persons are invited to submit comments responsive to this RFI. Copies of all comments submitted are available for inspection and downloading at <https://www.regulations.gov>. To receive consideration as public comments, comments must be submitted through one of the two methods specified below. All submissions must refer to the docket number and title above.

1. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at <https://www.regulations.gov>. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the <https://www.regulations.gov> website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

2. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of

General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT:

Ryan E. Jones, Director, Housing Voucher Management and Operations Division, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; telephone number (202) 402-2677. (This is not a toll-free number.) HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>. Questions about this document can be sent to FUPVouchers@hud.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Melania Trump Foster Youth to Independence (FYI) was established in 2019 in response to the advocacy of foster youth and alumni regarding the need for housing assistance for young people upon their exit from foster care. According to the Adoption and Foster Care Analysis and Reporting System, on average 15,000 young people age-out of foster care each year, and nearly 25 percent of youth responding to the National Youth in Transition Database report experiencing homelessness after leaving foster care. Yet, there were no Federal housing resources solely dedicated to serving this population.

Prior to the establishment of FYI, the primary Federal housing resource for young people transitioning out of foster care was the Family Unification Program (FUP). Through public housing agencies (PHAs), FUP provides housing choice vouchers (HCVs) that can be issued to either child welfare-involved families or youth transitioning out of foster care.¹ FUP participants use their HCVs to rent housing in the private market and generally pay 30 percent of their adjusted monthly income towards rent while the voucher pays the remaining portion of the rent. However, FUP vouchers are only available in a

small number of communities² and have been primarily used to assist child welfare-involved families, rather than youth transitioning out of foster care. When FYI was established in 2019, 95 percent of FUP vouchers were being used to serve child welfare-involved families, and the remaining 5 percent were being used to serve youth transitioning out of foster care.

FYI provides a dedicated source of vouchers for youth transitioning out of foster care. Since fiscal year (FY) 2020, Congress has appropriated a total of \$165 million for new incremental FYI vouchers. Further, in FY 2021, Congress codified an on-demand distribution mechanism for FYI vouchers, meaning that any of the more than 2,000 PHAs administering the HCV program can establish an FYI program and request FYI vouchers on a rolling basis to serve youth as they are identified.³ This enables HUD to provide young people with FYI vouchers that are timed with their emancipation from foster care so that they do not experience homelessness when they leave care.

To establish an FYI program, a PHA must enter into a partnership agreement with a public child welfare agency (PCWA). Under the partnership agreement, the PHA provides the youth with FYI voucher assistance for 36 months, which may be extended for up to an additional 24 months if the youth is working toward economic self-sufficiency or meets one of the statutory exceptions to this requirement.⁴ The

² There are approximately 300 PHAs that administer FUP out of the nearly 2,000 PHAs nationwide that administer the HCV program.

³ Notice PIH 2026-19 (<https://www.hud.gov/sites/default/files/PIH/documents/PIH-2026-19.pdf>) is the most recent notice implementing this on-demand process.

⁴ The Fostering Stable Housing Opportunities (FSHO) amendments, enacted as section 103 of division Q of the Consolidated Appropriations Act, 2021 on December 27, 2020 (Pub. L. 116-260), provide an extension of FYI assistance for up to 24 months for youth participating in a Family Self-Sufficiency (FSS) program under section 23 of the U.S. Housing Act of 1937 and for youth who are unable to enroll in an FSS program who engaged in education, workforce development, or employment activities for at least 9 months of the 12-month period preceding the extension. FSHO also provides an extension of assistance for up to 24 months for youth who meet one of the following exceptions: (1) The youth is a parent or other household member responsible for the care of a dependent child under the age of 6 or for the care of an incapacitated person; (2) The youth is a person who is regularly and actively participating in a drug addiction or alcohol treatment and rehabilitation program; or (3) The youth is a person who is incapable of complying with the requirement to participate in an FSS program or engage in education, workforce development, or employment activities, as applicable, due to a documented medical condition. See HUD's FSHO implementation notice published in the **Federal Register** on January 24, 2022 (87 FR 3570).

¹ There are two eligible populations for FUP: (1) Families for whom the lack of adequate housing is a primary factor in the imminent placement of the family's child or children in out-of-home care or the delayed discharge of the child or children to the family from out-of-home care; and (2) youth who have attained at least 18 years of age and not more than 24 years of age and who have left foster care, or will leave foster care within 180 days, in accordance with a transition plan described in section 475(5)(H) of the Social Security Act, and is homeless or is at risk of becoming homeless at age 16 or older.

PCWA provides or secures the provision of supportive services for the youth for 36 months. The combination of time-limited rental assistance and supportive services is intended to provide youth with a platform to move toward economic self-sufficiency.

Since the rollout of FYI, HUD has allocated more than 9,000 FYI vouchers to assist individual youth. Yet, HUD recognizes that many more youth can benefit from the program. While FYI has experienced steady growth with the program being administered by 373 PHAs in 48 states and the U.S. Virgin Islands as of June 2026 Voucher Management System (VMS) data, there are still many communities where youth cannot access FYI. Further, as of June 2026 VMS data, eligible youth are utilizing only 64 percent of the more than 8,000 available FYI vouchers to lease a unit.

HUD has heard anecdotally that the uptake of FYI vouchers has been limited due to various administrative barriers that communities and young people face when trying to access FYI. Through this RFI, HUD is interested in learning what statutory, regulatory, and policy requirements are preventing communities from participating in FYI; what barriers young people face in accessing and utilizing an FYI voucher; and what changes can be made to reduce these barriers. Since FY 2024, Congress has provided HUD with the authority to establish waivers and alternative requirements related to the administration of waiting lists, local preferences, the initial term and extensions of tenant-based vouchers, and the timing of referral of youth leaving foster care, in order to reduce barriers to accessing and utilizing an FYI voucher. HUD implemented this waiver authority through Notice PIH 2025–08. HUD is interested in learning whether statutory or regulatory barriers remain and, if so, what statutory changes and/or waiver authority for the HCV program or FYI program beyond that which has already been provided would help increase utilization of FYI. HUD is also interested in learning how PHAs are taking advantage of the changes that were recently made through Notice PIH 2026–19 to help expand access to FYI, specifically the elimination of the utilization threshold and the removal of the cap on the number of FYI vouchers that can be requested.

HUD has also heard that the lack of dedicated Federal resources for supportive services can pose a barrier to establishing an FYI program, particularly in smaller, rural communities where there are few or no

local resources for supportive services. HUD welcomes comments on how Federal resources can be better targeted or coordinated to reduce these barriers and support youth as they transition from foster care to successful adulthood. Additionally, HUD is interested in feedback on what changes can be made to the program to ensure that it provides a platform for youth to achieve economic self-sufficiency consistent with the goals of the Fostering the Future initiative established under Executive Order 14359, *Fostering the Future for American Children and Families*.

II. Purpose of This Request for Information

HUD is interested in promoting and strengthening FYI and supporting the goals of the Fostering the Future initiative established under Executive Order 14359, *Fostering the Future for American Children and Families*. HUD will share the information received through this RFI with the U.S. Department of Health and Human Services (HHS) and separately consult with HHS on these topics. In accordance with Senate Report 119–47, HUD will use the information gathered through this RFI and its consultation with HHS to issue a report to Congress with its recommendations: (1) to improve program operations; (2) to assist youth in navigating the housing search process and preventing returns to homelessness after the subsidized rental assistance sunsets; and (3) on how Federal, State, and local stakeholders can best support participants as they transition from foster care to successful adulthood.

III. Request for Information

Senate Report 119–47 requests that HUD consult with stakeholders on FUP, which includes FYI. While FUP serves two eligible populations—families and youth—HUD interprets the Senate Report language as being specific to the youth population served under FUP. For example, the Senate Report suggests that HUD consult with stakeholders on statutory time limits, which only apply to the youth population served under FUP. Further, the Senate Report asks HUD to use the information gathered through the stakeholder consultations to make recommendations to Congress on areas that are specific to youth (*i.e.*, assisting youth in navigating the housing search process, preventing returns to homelessness after the subsidized rental assistance ends, and supporting participants as they transition from foster care to successful adulthood). Therefore, HUD is issuing this RFI to solicit feedback on FYI

specifically from current and former foster youth, PHAs, PCWAs, experts on child welfare, and other stakeholders regarding any potential program challenges due to statutory time limits, statutory criteria, policy definitions, or other operational aspects of FYI. While this RFI focuses on FYI, HUD also welcomes comments from PHAs that do not participate in FYI but administer FUP vouchers issued to youth, particularly those administering the FUP–FSS demonstration established under Notice PIH 2016–01 (<https://www.hud.gov/sites/documents/16-01pihn.pdf>). HUD also welcomes comments from PHAs that do not currently participate in FYI regarding barriers to implementing an FYI program.

Consistent with Senate Report 119–47, HUD is requesting information on the topics below but welcomes comments on all aspects of FYI.

Statutory time limits. By statute, a youth may receive FYI assistance for 36 months, which may be extended for up to an additional 24 months if the youth meets one of the following criteria:

1. The youth is participating in an FSS program under section 23 of the U.S. Housing Act of 1937;
2. If the youth is unable to enroll in an FSS program, the youth engaged in education, workforce development, or employment activities for at least 9 months of the 12-month period preceding the extension; or
3. The youth meets one of the following exceptions: the youth is a parent or other household member responsible for the care of a dependent child under the age of 6 or for the care of an incapacitated person; the youth is a person who is regularly and actively participating in a drug addiction or alcohol treatment and rehabilitation program; or the youth is a person who is incapable of complying with the requirement to participate in an FSS program or engage in education, workforce development, or employment activities, as applicable, due to a documented medical condition.

Questions for consideration:

- Is 36 months, with an opportunity for a 24-month extension, the appropriate amount of time for youth to achieve self-sufficiency? If not, what would be the appropriate amount of time?
- Have youth been able to take advantage of the 24-month extension? If not, why not?
- Are there other types of self-sufficiency activities that should qualify youth for the 24-month extension in addition to those already recognized under the law?

• Are there unique challenges for PHAs to administer a time-limited voucher in comparison to regular vouchers?

Statutory criteria. By statute, a youth must meet the following criteria to be eligible for FYI:

1. Is at least 18 years of age and not more than 24 years of age;

2. Has left foster care, or will leave foster care within 180 days,⁵ in accordance with a transition plan described in section 475(5)(H) of the Social Security Act; and

3. Is homeless or at risk of becoming homeless at age 16 or older.

Questions for consideration:

• Does the age eligibility requirement pose a barrier to otherwise eligible youth accessing FYI?

• HUD recently extended the referral timeframe from 90 days to 180 days prior to when a youth will transition out of foster care in order to allow more time for the youth to find housing with an FYI voucher prior to leaving foster care. Is 180 days enough time or would another timeframe be more appropriate?

• While not required by statute, HUD has historically defined “homeless” and “at risk of becoming homeless” in the FYI program using the definitions for “homeless” and “at risk of homelessness” in the Emergency Solutions Grant (ESG) program and the Continuum of Care (CoC) program. In the most recent FYI notice,⁶ HUD no longer uses the ESG and CoC definition of “at risk of homelessness” verbatim but has made several changes to the definition to expand who is considered “at risk of becoming homeless” for FYI vouchers awarded through the non-competitive process. Specifically, HUD revised the definition to change the income eligibility requirement from 30 percent of area median income to 50 percent of area median income, removed the requirement to not have sufficient resources or support networks immediately available to prevent moving to an emergency shelter or another place described in the ESG and CoC definition of “homeless,” and revised several items on the list of additional conditions. Are these the appropriate definitions to apply or should HUD use different definitions of

“homeless” and “at risk of becoming homeless” in the FYI program?

Policy definitions. The policy definitions applicable to FYI can be found in the various funding notices for the program.⁷ Most significantly, the funding notices establish policies in the following areas: partnership agreements, supportive services, and youth prioritization.

Questions for consideration:

• What are changes that HUD can make in these policy areas to help facilitate the provision of FYI and better support youth?

Operational aspects: HUD requests information on any other operational aspects of FYI that could be improved.

Questions for consideration:

• What changes can be made to FYI to better assist youth in navigating the housing search process?

• What changes can be made to FYI to better prevent youth from returning to homelessness after the subsidized rental assistance sunsets?

• How can Federal, State, and local stakeholders best support FYI youth?

• What barriers do communities face when trying to establish an FYI program?

• What barriers do youth face in accessing and utilizing an FYI voucher?

• Does the lack of dedicated Federal resources for supportive services pose a barrier to establishing an FYI program, and how can Federal resources be better targeted or coordinated to support youth as they transition from foster care to successful adulthood?

• Since FY 2024, Congress has provided HUD with the authority to establish waivers and alternative requirements related to the administration of waiting lists, local preferences, the initial term and extensions of tenant-based vouchers, and the timing of referral of youth leaving foster care, in order to reduce barriers to accessing and utilizing an FYI voucher. HUD implemented this waiver authority through Notice PIH 2025–08. Are there statutory changes and/or waiver authority for the HCV program or FYI program beyond that which has already been provided that would help increase utilization of FYI? If yes, please explain.

• How are PHAs taking advantage of the changes that were recently made through Notice PIH 2026–19 to help expand access to FYI, specifically the

elimination of the utilization threshold and the removal of the cap on the number of FYI vouchers that can be requested?

• What are other aspects of FYI that could be improved?

HUD is also interested in feedback on what changes can be made to the program to ensure that it provides a platform for youth to achieve economic self-sufficiency consistent with the goals of the Fostering the Future initiative established under Executive Order 14359, *Fostering the Future for American Children and Families*.

Benjamin Hobbs,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 2026–22207 Filed 10–29–26; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7107–N–26; OMB Control No.: 2577–0274]

30-Day Notice of Proposed Information Collection: Energy and Performance Information Center (EPIC)

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: Comments due November 30, 2026.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Anna Guido, PRA Compliance Officer, Paperwork Reduction Act Division (PRAD), Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email at PaperworkReductionActOffice@hud.gov, ATTN: Anna Guido, telephone

⁵ Section 8(x)(2) of the United States Housing Act of 1937 (42 U.S.C. 1437f(x)(2)) allows youth to be referred for FYI assistance within 90 days of transitioning out of foster care. HUD has used the waiver and alternative requirement authority provided in recent appropriations acts to extend the referral timeframe to within 180 days of transitioning out of foster care (see Notice PIH 2025–08 (https://www.hud.gov/sites/dfiles/OCHCO/documents/PIH_2025-08.pdf)).

⁶ Notice PIH 2026–19 (<https://www.hud.gov/sites/default/files/PIH/documents/PIH-2026-19.pdf>).

⁷ See FY 2020/2021 FYI-Competitive NOFA (FR–6400–N–41); FY 2022 FYI-Competitive NOFO (FR–6600–N–41); FY 2024 FYI-Competitive NOFO (FR–6800–N–41); FYI-Tenant Protection Voucher Notice (Notice PIH 2019–20); and FYI Non-Competitive Notices (Notices PIH 2020–28, PIH 2021–26, PIH 2023–04, and PIH 2026–19).

(202) 402–5535. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>. Available documents submitted to OMB can be found in the docket file on [reginfo.gov](https://www.reginfo.gov).

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on May 15, 2026 at 91 FR 27971.

A. Overview of Information Collection

Title of Information Collection: Energy and Performance Information Center (EPIC).

OMB Approval Number: 2577–0274.
Type of Request: Revision of currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: EPIC automates the collection of the Capital Fund program Five-Year Plan and Annual Statement/Budget/Performance and Evaluation (P&E) forms from grantees. These required forms were previously collected in hard copy on Forms HUD–50075.1 and HUD–50075.2 under collection OMB control number 2577–0157. These forms collect data on the eventual and actual use of awarded Federal funds. Electronic collection enables the Department to compile and centralize information about the way grantees use Federal funds. Tracking Federal funds paid through the Public Housing Capital Fund, the only Federal funding stream dedicated to the capital needs of the nation's last resort housing option, is crucial to understanding how the Department can properly and efficiently assist grantees to meet the

Department's goals in maintaining and improving public housing as a safe, decent, and sustainable housing option for low-income residents. EPIC also automates the collection of signed documents required by 24 CFR part 905 to gain access to funds awarded by HUD. These forms are covered under the Public Housing Capital Fund Program, OMB control number 2577–0157. Finally, EPIC allows PHAs to request additional funding sources, such as Operating Funds for Capital Fund-eligible activities. The EPIC data system is equipped to collect Physical Needs Assessment data, should this data be required in the future. EPIC is equipped to collect information about the Energy Performance Contract process, including energy efficiency improvements. EPIC is equipped to track development of public housing with Federal funds and through other means, including mixed-finance development.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hours per response	Annual burden hours	Hourly cost per response *	Annual cost
Core Activity	2,800	1	2,800	1	2,800	\$57.47	\$160,916.00
5-Yr Plan (including Utility Conservation Measures)	2,000	1	2,000	2	4,000	57.47	114,940.00
Annual Statement/Budget	2,800	3	8,400	1	8,400	57.47	482,748.00
P&E	2,800	0.5	1,400	1	1,400	57.47	80,458.00
Document Management Center (including new digital closeout form)	2,800	2	5,600	0.5	1,400	57.47	160,916.00
Additional Capital Resources	15	1	15	0.5	7.5	57.47	431.03
EPC	30	1	30	120	3600	57.47	206,892.00
Public Housing Development	60	1	60	120	7,200	57.47	413,784.00
Mixed Finance Development	60	1	60	0.33	20	57.47	1,137.91
CFP Grant Application Module	50	1	50	2	100	57.47	5,747.00
Totals	13,415	12.5	20,415	248.33	30,327	57.47	1,742,909.93

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

- (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) The accuracy of the agency's estimate of the burden of the proposed collection of information;
- (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of

information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

44 U.S.C. 3507.

Anna Guido,

Department PRA Compliance Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2026–22128 Filed 10–29–26; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7107–N–28; OMB Control No.: 2502–0059]

30-Day Notice of Proposed Information Collection: Informed Consumer Choice Disclosure and Application for HUD/FHA Insured Mortgage

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice

is to allow for 30 days of public comment.

DATES: *Comments Due Date:* November 30, 2026.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Anna Guido, PRA Compliance Officer, Paperwork Reduction Act Division (PRAD), Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email at PaperworkReductionActOffice@hud.gov, ATTN: Anna Guido, telephone (202) 402-5535. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who

are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

Available documents submitted to OMB can be found in the docket file on reginfo.gov.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on September 15, 2026 at 90 FR 44389.

A. Overview of Information Collection

Title of Information Collection: Informed Consumer Choice Disclosure and Application For HUD/FHA Insured Mortgage.

OMB Approval Number: 2502-0059.

Type of Request: Revision of currently approved collection.

Form Number: HUD-92900-A, HUD-92900-B, HUD-92900-LT, HUD-92561, Model Notice for Informed Consumer Choice Disclosure Settlement Certification, and HUD-92544.

Description of the need for the information and proposed use: Specific forms and related documents are needed to determine the eligibility of the borrower and proposed mortgage transaction for FHA’s mortgage insurance endorsement. The collection also contains additional notification requirements for lenders on refinances with existing FHA partial claim subordinate liens. Lenders seeking FHA’s insurance prepare these forms to collect and report data. This renewal also contains a revision to the prior Supporting Statement and removes the requirement that lenders provide Fannie Mae/Freddie Mac form 1103, Supplemental Consumer Information Form (SCIF). The SCIF is required by the GSE’s but is not a statutory or regulatory requirement for HUD.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUD-92900-A, its related exhibits and other forms.	2045	Varies	827,150	.17	140,615.50	\$48.49	\$6,818,445.60
HUD-92900-LT	2045	Varies	827,150	.17	140,615.50	48.49	6,818,445.60
HUD-92561 (2-4) units ...	2045	Varies	21,865	.03	655.95	48.49	31,807.02
HUD-92544 (new construction).	2045	Varies	123,690	.05	6,184.50	48.49	299,886.41
Additional burden for buy down agreements.	2045	Varies	1,056	.05	52.80	48.49	2,560.27
Additional burden for pre-insurance review.	2045	Varies	827,150	.17	140,615.50	48.49	6,818,445.60
Settlement certification (purchase transactions).	2045	Varies	603,040	.01	6,030.40	48.49	292,414.10
Flood Insurance	2045	Varies	9,852	.08	788.16	48.49	38,217.88
Totals	2045	Varies	3,240,953	.73	435,558.31	48.49	21,120,222.45

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency’s estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through

the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

44 U.S.C. 3507.

Anna Guido,

Department PRA Compliance Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2026-22136 Filed 10-29-26; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7107-N-27; OMB Control No.: 2577-0295]

30-Day Notice of Proposed Information Collection: Restrictions on Assistance to Noncitizens and Authorization To Release Information/Privacy Act

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of

information. The purpose of this notice is to allow for 30 days of public comment.

DATES: Comments due November 30, 2026.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Anna Guido, PRA Compliance Officer, Paperwork Reduction Act Division, PRAD, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email at PaperworkReductionActOffice@hud.gov, ATTN: Anna Guido, telephone (202) 402-5535. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>. Available documents submitted to OMB can be found in the docket file on reginfo.gov.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in

Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on June 22, 2026 at 91 FR 37121.

A. Overview of Information Collection

Title of Information Collection:

Restrictions on Assistance to Noncitizens and Authorization To Release Information/Privacy Act.

OMB Approval Number: 2577-0295.

Type of Request: Revision of currently approved collection.

Form Number: HUD-9886-A.

Description of the need for the information and proposed use: This is a request for a revision of a currently approved collection for HUD to require applicants and tenants to sign the form HUD-9886-A. The information collected through this PRA assist public housing agencies (PHAs) in eligibility determinations for applicable HUD-assisted housing programs and assist HUD in managing and monitoring these programs. Applicants and tenants applying for or receiving assistance in the Housing Choice Voucher, Public Housing, or Section 8 Moderate Rehabilitation programs are required to sign the Authorization for the Release of Information/Privacy Act Notice (Public and Indian Housing form HUD-9886-A).

Further, this PRA covers the burden associated with the verification required by Section 214 of the Housing and Community Development Act of 1980, as amended, (42 U.S.C. 1436a), which prohibits HUD from making financial assistance available to persons who are ineligible for assistance with respect to

citizenship or non-citizen immigration status and applies to both applicants for assistance and persons already receiving assistance under: (1) Section 235 of the National Housing Act (the Section 235 Program); (2) Section 236 of the National Housing Act (tenants paying below market rent only) (the Section 236 Program); (3) Section 101 of the Housing and Urban Development Act of 1965 (the Rent Supplement Program); and the United States Housing Act of 1937—(i) HUD's Public Housing Programs; (ii) Section 8 Housing Assistance Programs; and (iii) the Housing Development Grant Programs (with respect to low income units only). This PRA covers the following programs under Section 214: Housing Choice Voucher, Public Housing, and Section 8 Moderate Rehabilitation. Though there is no OMB form associated with the requirements of Section 214, the burden associated with the verification is included in this PRA, because for U.S. citizens or U.S. nationals, each family member, regardless of age, must submit a signed declaration of U.S. citizenship or U.S. nationality. For noncitizens who are 62 years of age or older and receiving assistance or applying for assistance, they must provide a signed declaration of eligible immigration status and proof of age document. For all other noncitizens, they are required to submit: (1) a signed declaration of eligible immigration status; (2) the original of a document designated by U.S. Citizenship and Immigration Services (USCIS) as acceptable evidence of immigration status; and (3) a signed verification consent form.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Restriction on Assistance to Noncitizens							
New tenant admissions in Public Housing and Section 8 programs	3,645	23	83,835	0.16	13,414.00	\$30.49	\$408,980.66
Annual recertification of tenants' eligible immigration status in Public Housing and Section 8 programs	3,645	11	40,095	0.08	3,208.00	30.49	97,799.72
Subtotal	3,645	34	123,930	0.24	16,621.00	30.49	506,780.39
Authorization of Release of Information/Privacy Act							
New tenant admissions of adult members in Public Housing and Housing Choice Voucher programs	144,920	1	144,920	0.16	23,187.00	30.49	706,977.73
Execution of Form HUD-9886-A by household members that turn 18 years old	36,488	1	36,488	0.08	2,919.00	30.49	89,001.53
Subtotal	181,408	2	181,408	0.24	26,106.00	30.49	795,979.26
Total	185,053	36	305,338	0.48	42,727.00	30.49	1,302,759.65

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

44 U.S.C. 3507.

Anna Guido,

Department PRA Compliance Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2026-22129 Filed 10-29-26; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7107-N-29; OMB Control No.: 2535-New]

30-Day Notice of Proposed Information Collection: Financial Documentation for the HUGS Recipient Portal

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: Comments due November 30, 2026.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed

information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Anna Guido, PRA Compliance Officer, Paperwork Reduction Act Division (PRAD), Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email at PaperworkReductionActOffice@hud.gov, ATTN: Anna Guido, telephone (202) 402-5535. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

Available documents submitted to OMB can be found in the docket file on reginfo.gov.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on July 8, 2026 at 91 FR 42209.

A. Overview of Information Collection

Title of Information Collection: Financial Documentation for the HUGS Recipient Portal.

OMB Approval Number: 2535-New.

Type of Request: New.

Form Number: N/A.

Description of the need for the information and proposed use: HUD is implementing the HUGS Recipient Portal to strengthen its oversight and stewardship of Federal grant funds and improve visibility into the use of those funds. The proposed information collection would require recipients of covered HUD grant awards to submit financial and supporting documentation associated with grant expenditures through the Recipient Portal. This may include: invoices and vendor billings; proof of payment and disbursement records; payroll or cost allocation documentation; subrecipient cost documentation; invoices for vendor and subcontractor spending made by the recipient and the subrecipient and other supporting documentation identified by HUD and described in the regulations. HUD will use the information to

substantiate expenditures, support monitoring and oversight activities, assess financial and compliance risks, and identify transactions or patterns that may warrant additional review. HUD will publish forthcoming implementation guidance that will provide additional details regarding the submission of financial documentation through the HUGS Recipient Portal, including details on scope and applicability, the Recipient Portal, submission frequency, required financial and supporting documentation, privacy safeguards, and additional resources.

This information collection aligns with cross-government priorities to strengthen stewardship of Federal funds and better identify and address potential fraud, waste, and abuse in a timely manner. The information collection is also supported by several key provisions of Part 200 of Title 2 of the Code of Federal Regulations (2 CFR 200):

- 2 CFR 200.208 (Specific conditions) authorizes Federal agencies to impose additional requirements, including requiring additional or more detailed record production and financial reports, when appropriate.

- 2 CFR 200.302 (Financial management) requires recipients to maintain records identifying the amount, source, and expenditure of Federal funds and to support records with source documentation.

- 2 CFR 200.328 (Financial reporting) requires Federal agencies and pass-through entities to collect financial reports no less than annually and no more than quarterly unless a specific condition has been implemented in accordance with 2 CFR 200.208.

- 2 CFR 200.334 (Record retention requirements) requires recipients and subrecipients to retain Federal award records, including financial records and supporting documentation, generally for three years following submission of the final financial report; and

- 2 CFR 200.337 (Access to records) provides Federal agencies and their authorized representatives the right of access to any records of the recipient or subrecipient that are pertinent to a Federal award for audits, site visits, or any other official use.

The Recipient Portal is not a reaction to an individual incident of fraud, waste, abuse, or noncompliance, though there are well-reported incidents across HUD programs. However, HUD usually does not find these issues until well after the fact, so there is a need for proactive monitoring that this information collection will allow. HUD also clarifies that this information collection will not impact existing

reimbursement or draw-down processes; required financial and supporting documentation will be submitted on a quarterly basis, not prior to the disbursement or voucher payment.

HUD has considered feedback, including concerns that HUGS duplicates existing oversight requirements and recommendations that it be limited only to certain grantees through a risk-based approach. However, while HUD already has important controls, including payment systems, program reporting, audits, and monitoring, these mechanisms were developed for different purposes and do not provide a consistent Department-wide view of supporting transactions and documentation. The proposed collection supports expenditure substantiation, monitoring, risk

assessment, and stewardship of Federal funds by providing a more complete understanding of how award funds are spent. Over time, HUD anticipates that this collection and its broader grants modernization efforts may allow existing financial monitoring collections or processes to be consolidated or replaced where appropriate.

HUD also received feedback on the burden estimate and has updated the calculation accordingly. Recipients are already required to maintain financial records and supporting source documentation associated with their Federal awards as established in 2 CFR 200. The proposed collection generally requires submission of applicable records recipients maintain in the ordinary course of administering those awards; it does not require recipients to

create a new financial analysis, recalculate expenditures, or manipulate the underlying financial information into a new format solely for submission to HUD. HUD recognizes, however, that identifying, organizing, digitizing where necessary, and submitting applicable documentation through the Recipient Portal requires administrative effort and that this effort may vary by recipient and program. Therefore, clear, proactive communication is essential. HUD is preparing for full engagement with grantees and industry and has engaged a technical assistance provider to guide grantees through the transition with hands-on support and training. After consideration, HUD has determined that the documents that HUD seeks through HUGS are authorized by existing law as described above.

Information collection	Number of respondents	Frequency of response	Response per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Total	30,000	4	120,000	4	480,000	\$45.10	\$21,648,000

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

44 U.S.C. 3507.

Anna Guido,

Department PRA Compliance Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2026-22135 Filed 10-29-26; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7107-N-30; OMB Control No.: 2528-0348]

30-Day Notice of Proposed Information Collection: Community Compass Technical Assistance and Capacity Building Post-Award Reporting

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: Comments due November 30, 2026.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Anna Guido, PRA Compliance Officer,

Paperwork Reduction Act Division (PRAD), Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email at PaperworkReductionActOffice@hud.gov, ATTN: Anna Guido, telephone (202) 402-5535. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>. Available documents submitted to OMB can be found in the docket file on reginfo.gov.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on May 5, 2026 at 91 FR 24271.

A. Overview of Information Collection

Title of Information Collection: Community Compass Technical Assistance and Capacity Building Post-Award Reporting.

OMB Approval Number: 2528-0348.

Type of Request: Revision of a currently approved collection.

Form Number: SF-424, SF-425, HUD-4133, HUD-4134, HUD-4135, HUD-4136, and HUD-4138.

Description of the need for the information and proposed use:

The U.S. Department of Housing and Urban Development (HUD) seeks to collect information that will be used to monitor and manage the cooperative agreements awarded under the

Community Compass Technical Assistance and Capacity Building program. This collection is being revised to remove all information collected during the application process for the Community Compass Technical Assistance and Capacity Building

program. Pre-award information collection for this program will now be covered by HUD's Generic Solution for Solicitation for Competitive Discretionary Funding Opportunity Announcements (2501-0044).

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response**	Annual cost
Work Plans							
HUD-4139 (Community Compass Work Plan)	35	10	350	18	6,300	\$77.94	\$491,022
Reports							
HUD-4138 (Community Compass—Monthly Report)	35	40	1,400	5.85	8,190	77.94	638,329
Record Keeping							
SF-425 *							
SF-424—Key Contacts							
HUD-4136 (Community Compass—Property Statement)	35	12	420	1.5	630	77.94	49,102
HUD-4135 (Community Compass—Closeout of Award Certification)	35	12	420	1.5	630	77.94	49,102
HUD-4134 (Experience of Staff, Contractors, and Consultants)	35	12	420	8	3,360	77.94	261,878
HUD-4133 (Community Compass—High Wage Rate Worksheet)	35	12	420	2.8	1,176	77.94	91,657
Total			3,430	37.65	20,286		1,581,091

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

44 U.S.C. 3507.

Monique Floyd,

PRA Liaison, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2026-22219 Filed 10-29-26; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR**National Park Service**

[N7590; NPS-WASO-NAGPRA-NPS0044065; PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: State University of New York at Cortland, Sociology/Anthropology Department, Cortland, NY

AGENCY: National Park Service, Interior.
ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the State University of New York (SUNY) at Cortland, Sociology/Anthropology Department, has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after November 30, 2026.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Kent Johnson, SUNY Cortland, Sociology/Anthropology Department,

P.O. Box 2000, Cortland, NY 13045,
email kent.johnson@cortland.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the SUNY Cortland Sociology/Anthropology Department, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, six individuals have been identified. The, at least, 94 bags (of various sizes) of associated funerary objects include seeds, shell fragments, rock fragments, charred wood fragments, soil, non-human animal bone fragments, and plant fragments. At minimum, six individuals and their belongings were brought to SUNY Cortland by Dr. Ellie McDowell-Loudan in around the year 2010. The individuals and their belongings had been in the possession of the widow of an avocational archaeologist, thought to be Stephen J. Petrovsky. After his passing, his widow brought the individuals and their belongings to Dr. McDowell-Loudan at

SUNY Cortland. It is unknown when and from where the individuals were removed, but Mr. Petrovsky lived in and primarily excavated in and around Susquehannock lands in the 1970s, so it is believed the individuals were removed from a location in Susquehanna County, PA or Broome or Tioga County, NY. The individuals and their belongings were discovered in the archaeology lab at SUNY Cortland several years after Dr. McDowell-Loudan's retirement, at which time they were moved to a secure location within the SUNY Cortland Sociology/Anthropology Department.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains and associated funerary objects described in this notice.

Determinations

The SUNY Cortland Sociology/Anthropology Department has determined that:

- The human remains described in this notice represent the physical remains of, at least, six individuals of Native American ancestry.
- The, at least, 94 bags of objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary objects described in this notice and the Onondaga Nation.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the SUNY

Cortland Sociology/Anthropology Department must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The SUNY Cortland Sociology/Anthropology Department is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22142 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7601; NPS–WASO–NAGPRA–NPS0044076; PPWOCRADNO–PCU00RP14.R50000]

Notice of Inventory Completion: Kansas State Historical Society, Topeka, KS

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Kansas State Historical Society (KSHS) has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains in this notice may occur on or after November 30, 2026.

ADDRESSES: Send written requests for repatriation of the human remains in this notice to Dr. Nicole Klarmann, Kansas State Historical Society, 6425 SW 6th Avenue, Topeka, KS 66615–1099, email kshs.nagpra@ks.gov.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the KSHS, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The

National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, one individual have been identified from Kingman County, KS (UBS 2025–14). No associated funerary objects are present. Human remains were found in an unnamed creek and transferred to the Kingman County Sheriff's office and then to WU–FARU to complete a forensic anthropological analysis. The remains were transferred to KSHS under the state UBS law in December 2025.

Human remains representing, at least, one individual have been identified from Finney County, KS (UBS 2025–12). No associated funerary objects are present. An individual received human remains believed to be from the vicinity of Garden City, KS from a relative. They then mailed them to a professor at Kansas University who contacted the Garden City Deputy Coroner. After forensic analysis occurred at WU–FARU, the remains were transferred to KSHS under the state UBS law in December 2025.

To our knowledge, no known hazardous substances were used to treat any of the human remains.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains described in this notice.

Determinations

The KSHS has determined that:

- The human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- There is a connection between the human remains described in this notice and the Cheyenne and Arapaho Tribes, Oklahoma; Northern Arapaho Tribe of the Wind River Reservation, Wyoming; Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco, & Tawakonie), Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains described in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the KSHS must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The KSHS is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22149 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7611; NPS–WASO–NAGPRA–NPS0044103; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: California State University, Stanislaus, Turlock, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the California State University, Stanislaus has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains in this notice may occur on or after November 30, 2026.

ADDRESSES: Send written requests for repatriation of the human remains in this notice to Jake Malsbury, NAGPRA/CalNAGPRA Repatriation Coordinator, California State University, Stanislaus, Office of the President, One University Circle, Turlock, CA 95382, email jmalsbury@csustan.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the California State University, Stanislaus, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, four individuals have been identified from an unknown location near the Columbia River, Oregon. No associated funerary objects are present. The human remains were brought to the California State University, Stanislaus by Laurence Wragg and accessioned in 2005 under the accessions CSUSTAN PAC–1, CSUSTAN PAC–2, CSUSTAN PAC–3, and CSUSTAN PAC–4. They were previously housed at the Northwestern University Dental School in Chicago, Illinois where they were listed as part of the William Bebb collection and collected by George H. Nottage of Oregon sometime prior to 1904.

The University is unaware of any treatment of the human remains listed above with pesticides, preservatives, or other substances that represent a potential hazard.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains described in this notice.

Determinations

The California State University, Stanislaus has determined that:

- The human remains described in this notice represent the physical remains of four individuals of Native American ancestry.
- There is a connection between the human remains described in this notice and the Confederated Tribes and Bands of the Yakama Nation; Confederated Tribes of the Umatilla Indian Reservation; Confederated Tribes of the Warm Springs Reservation of Oregon; and the Cowlitz Indian Tribe.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains described in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the California State University, Stanislaus must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The California State University, Stanislaus is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22154 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7608; NPS–WASO–NAGPRA–NPS0044100; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Repatriation: Putnam Museum and Science Center, Davenport, IA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Putnam Museum and Science Center intends to repatriate certain cultural items that meet the definition of unassociated funerary objects and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after November 30, 2026.

ADDRESSES: Send additional, written requests for repatriation of the cultural items in this notice to Hailey Lorenzen,

Putnam Museum and Science Center, 1717 W 12th Street, Davenport, IA 52804, email hlorenzen@putnam.org.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Putnam Museum and Science Center and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of 28 cultural items have been requested for repatriation. The 28 unassociated funerary objects are ceramics, beads, a spear point, and shell cups and digging tools. This number includes 11 unassociated funerary objects that are missing, including one ceramic, one lot of shell beads, and nine shell cups.

In 1926, Warren K. Moorehead removed one shell cup and two ceramics from burial contexts in the Etowah Mound group in Bartow County, GA, and donated them to the Museum the same year.

In 1904, Clarence B. Moore removed one lot of shell beads, two shell cups, and one spear point from burials in a mound on the north end of Creighton Island, McIntosh County, GA, and one lot of shell beads, and 20 shell cups and digging tools from burial contexts in Bourbon Field, Sapelo Island, in McIntosh County, GA and donated them to the Museum the same year.

The Putnam Museum and Science Center has no evidence of potentially hazardous substances being used to treat any of the unassociated funerary objects.

Determinations

The Putnam Museum and Science Center has determined that:

- The 28 unassociated funerary objects described in this notice are reasonably believed to have been placed intentionally with or near human remains, and are connected, either at the time of death or later as part of the death rite or ceremony of a Native American culture according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization. The unassociated funerary objects have been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to

an Indian Tribe or Native Hawaiian organization.

- There is a connection between the cultural items described in this notice and The Muscogee (Creek) Nation.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the Putnam Museum and Science Center must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The Putnam Museum and Science Center is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22159 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7612; NPS–WASO–NAGPRA–NPS0044104; PPWOCRADNO–PCU00RP14.R50000]

Notice of Inventory Completion: Tennessee Department of Environment and Conservation, Division of Archaeology, Nashville, TN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Tennessee Department of Environment and Conservation, Division of Archaeology (TDEC–DOA) has

completed an inventory of human remains from an unknown site in Polk County, TN, and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains in this notice may occur on or after November 30, 2026.

ADDRESSES: Send written requests for repatriation of the human remains in this notice to Phillip R. Hodge, Tennessee Department of Environment and Conservation, Division of Archaeology (TDEC–DOA), 1216 Foster Avenue, Cole Building #3, Nashville, TN 37243, email Phil.Hodge@tn.gov.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the TDEC–DOA, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, two individuals were donated to TDEC–DOA in 2026 by a private citizen. The donor reported that her father removed the remains from an unknown site location along the Hiwassee River in Polk County during the early 20th century. There is glue present on the jaw of one of the individuals. During consultation, it was determined that the glue would remain to prevent further damage to the remains. There are no other known exposures to hazardous substances or treatments.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains described in this notice.

Determinations

The TCED–DOA has determined that:

- The human remains described in this notice represent the physical remains of, at least, two individuals of Native American ancestry.

- There is a connection between the human remains described in this notice and the Cherokee Nation; Eastern Band of Cherokee Indians; The Muscogee (Creek) Nation; and the United Keetoowah Band of Cherokee Indians in Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under

ADDRESSES. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains described in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the TDEC–DOA must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The TDEC–DOA is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22151 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7610; NPS–WASO–NAGPRA–NPS0044102; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: University of California, Davis, Davis, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), University of California, Davis (UC Davis) has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains in this notice may occur on or after November 30, 2026.

ADDRESSES: Send written requests for repatriation of the human remains in this notice to Megon Noble, Repatriation Coordinator, University of California, Davis, 251 Mrak Hall, One Shields Avenue, Davis, CA 95616, email mnoble@ucdavis.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of UC Davis, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing at least one individual have been identified from the Cuyama Valley Site (MWFB–7253). An unknown individual collected the ancestral remains in 1972 and transferred them to John O'Kane. John O'Kane subsequently transferred the remains to Joyce Bimson in 2000 in order to transfer to the Museum of Wildlife and Fish Biology at UC Davis. There is conflicting information regarding the location where this ancestor was found. However, the extant documentation indicates the remains are most likely from the Cuyama Valley in either Santa Barbara or San Luis Obispo County.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains described in this notice.

Determinations

UC Davis has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a connection between the human remains described in this notice and the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains described in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, UC Davis must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. UC Davis is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22153 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7607; NPS–WASO–NAGPRA–NPS0044098; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Kankakee County Historical Society, Kankakee, IL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Kankakee County Historical Society has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after November 30, 2026.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice

to Curator, Kankakee County Museum, 801 S. 8th Avenue, Kankakee, IL 60901, email curator.k3museum@gmail.com.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Kankakee County Historical Society, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, one individual have been identified. They were collected by L.L. Shidler of Triangle Construction Co. likely within Kankakee County from 1933–1978. The 30 lots of associated funerary objects are 30 lots of animal teeth, bones, and fossils. The objects were donated to the historical society in 1984 by his son, Leslie N. Shidler. Records indicate no known hazardous substances were used on these items.

Human remains representing, at least, two individuals have been identified. No associated funerary objects are present with them. The remains were donated to the historical society's collection prior to 1990 by an unknown individual and were likely collected in Kankakee county or the surrounding area. Records indicate no known hazardous substances were used on these items.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains and associated funerary objects described in this notice.

Determinations

The Kankakee County Historical Society has determined that:

- The human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
- The 30 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary objects described in this notice and the Match-E-Be-Nash-She-Wish Band of Pottawatomi (previously listed as

Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians of Michigan); Pokagon Band of Potawatomi Indians, Michigan and Indiana; and the Prairie Band Potawatomi Nation.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the Kankakee County Historical Society must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The Kankakee County Historical Society is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22158 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7605; NPS–WASO–NAGPRA–NPS0044079; PPWOCRADNO–PCU00RP14.R50000]

Notice of Inventory Completion: University of Rhode Island, Kingston, RI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the

University of Rhode Island has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after November 30, 2026.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Kristine M. Bovy, Department of Sociology & Anthropology, University of Rhode Island, 507 Chafee Bldg., Kingston, RI 02881, email kbovy@uri.edu, and The Office of the General Counsel, 35 Campus Avenue, Kingston, RI 02881, email URIGeneralCounsel@uri.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the University of Rhode Island, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Barrington Case

Human remains representing, at least, one individual has been identified. The three associated funerary objects are glass vials containing soil samples. This individual was transferred by local law enforcement to the Rhode Island State Crime Laboratory at the University of Rhode Island sometime between 1958 and 1969 for evaluation. Once determined not to be of forensic concern, the Ancestor was transferred to the University's Department of Sociology & Anthropology. The only surviving documentation is a note by Dr. Harold C. Harrison, Director of the Crime Lab reading: "Bones from Medical Examiner's Office—Barrington case—age, sex, and as much as possible including time (approx. since death)." Efforts to obtain additional information through the Barrington Police Department, the Rhode Island Medical Examiner's Office, and the Crime Lab archives have yielded no results. During osteological and cultural assessments in the 1980s, URI faculty determined that the individual was of Native American descent, and that brass staining on the

remains suggests a post-contact context. Three small glass vials containing soil, presumed to have been collected from the burial context, are included with the individual and recorded as associated funerary objects.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains and associated funerary objects described in this notice.

Determinations

The University of Rhode Island has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- The three objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary objects described in this notice and the Mashpee Wampanoag Tribe; Narragansett Indian Tribe; and the Wampanoag Tribe of Gay Head (Aquinnah).

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the University of Rhode Island must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The University of Rhode Island is responsible for sending a copy of this notice to the Indian Tribes

and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22156 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7599; NPS–WASO–NAGPRA–NPS0044070; PPWOCRADNO–PCU00RP14.R50000]

Notice of Intended Repatriation: Museum of the Rockies, Bozeman, MT

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Museum of the Rockies (MOR) intends to repatriate a certain cultural item that meets the definition of an object of cultural patrimony and that has a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural item in this notice may occur on or after November 30, 2026.

ADDRESSES: Send additional, written requests for repatriation of the cultural item in this notice to Annya Jacobs, Registrar and Collections Manager of Cultural History, Museum of the Rockies, P.O. Box 172720, 600 W Kagy Boulevard, Bozeman, MT 59717, email annya.jacobs@montana.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Museum of the Rockies and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of one cultural item has been requested for repatriation. The one object of cultural patrimony is one Tobacco Bundle. The Bundle was donated to MOR by the Montana State

College (now Montana State University) School of Art through Olga Ross Hannon in 1973. The Bundle was apparently purchased by a Mrs. Ryan from Lodge Grass from a member of the Crow Tribe of Montana. The bundle was confirmed to belong to the Crow Tribe of Montana based on Traditional Tribal Knowledge.

Determinations

The Museum of the Rockies has determined that:

- The one object of cultural patrimony described in this notice have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization.

- There is a connection between the cultural item described in this notice and the Crow Tribe of Montana.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural item in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the Museum of the Rockies must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural item are considered a single request and not competing requests. The Museum of the Rockies is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22147 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR**National Park Service**

[N7597; NPS-WASO-NAGPRA-
NPS0044069; PPWOCRADN0-
PCU00RP14.R50000]

**Notice of Inventory Completion:
University of Montana Missoula,
Missoula, MT**

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of Montana Missoula (UM) has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after November 30, 2026.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Courtney Little Axe, NAGPRA Coordinator and Collections Manager, University of Montana—Missoula, 32 Campus Drive, Missoula, MT 59812, email courtney.littleaxe@umt.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of UM, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Based on the information available, human remains representing, at least, two individuals have been reasonably identified. The one adult (likely female) and one subadult (likely male) arrived at UM prior to 1991 and were assigned University of Montana Forensic Collection (UMFC) accession number UMFC 50. The 18 associated funerary objects are two unmodified copper wire bracelets, one copper wire bracelet with linear marks, and 15 machine twisted copper wire bracelets (two of which are double strand). The adult individual was reported as wearing these 18 bracelets on the forearm at the time of discovery. It is unknown whether or how the two individuals were

connected. To date, their geographic place of origin and history of how they came to be at UM remains unknown and to the best of UM's knowledge there is no recorded use of hazardous substances to treat the human remains or associated funerary objects.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location the human remains and associated funerary objects described in this notice.

Determinations

UM has determined that:

- The human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- The 18 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary objects described in this notice and the Assiniboiné and Sioux Tribes of the Fort Peck Indian Reservation, Montana.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, UM must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. UM is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25

U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22146 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR**National Park Service**

[N7600; NPS-WASO-NAGPRA-
NPS0044071; PPWOCRADN0-
PCU00RP14.R50000]

**Notice of Intended Repatriation:
Birmingham Museum of Art,
Birmingham, AL**

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Birmingham Museum of Art (BMA) intends to repatriate certain cultural items that meet the definition of unassociated funerary objects, sacred objects, and/or objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after November 30, 2026.

ADDRESSES: Send additional, written requests for repatriation of the cultural items in this notice to Dr. Anne Forschler-Tarrasch, Director of Collections & Exhibitions, Birmingham Museum of Art, 2000 Rev. Abraham Woods, Jr. Boulevard, Birmingham, AL 35203, email aforschler@artsbma.org.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the BMA, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of information Available

A total of five cultural items have been requested for repatriation. The one unassociated funerary object is a miniature totem pole carved of walrus ivory. The one object of cultural patrimony is a spoon. The three sacred objects/objects of cultural patrimony are one harpoon head, one harpoon point,

and one spear point. The items were collected on unknown dates from unknown locations, possibly in the Arctic and Subarctic. The miniature totem pole was collected by Thyrza Hamilton Orr of Birmingham, Alabama on an unknown date before 1971. Orr gifted the item to the BMA in 1971. The miniature totem pole is documented in museum records as Inupiat or Tlingit or Haida. The spoon was collected by Dr. Noble Ashworth Endicott, Jr. and Dr. Wilma Jean Gunter Endicott sometime prior to 1991. The Endicotts donated the item to the BMA in 1991. The spoon is documented in museum records as Inupiat. The harpoon head, harpoon point, and spear point were collected by Axel Rasmussen, who served as superintendent of schools in Wrangell, Alaska from 1926 to 1938, and in Skagway from 1938 until his death in 1945. In 1948 the Portland Museum of Art purchased the entire Rasmussen Collection. BMA purchased the items in 1956. The three items are documented in museum records as Inupiat.

BMA has no knowledge of any potentially hazardous substances used to treat the cultural items. However, no testing has occurred.

Determinations

The BMA has determined that:

- The one unassociated funerary object described in this notice is reasonably believed to have been placed intentionally with or near human remains, and are connected, either at the time of death or later as part of the death rite or ceremony of a Native American culture according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization. The unassociated funerary object has been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to an Indian Tribe or Native Hawaiian organization.

- The one object of cultural patrimony described in this notice has ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization.

- The three sacred objects/objects of cultural patrimony described in this notice are, according to the Native American traditional knowledge of an

Indian Tribe or Native Hawaiian organization, specific ceremonial objects needed by a traditional Native American religious leader for present-day adherents to practice traditional Native American religion, and have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision).

- There is a connection between the cultural items described in this notice and the Native Village of Barrow Inupiat Traditional Government.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the BMA must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The BMA is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026-22148 Filed 10-29-26; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7603; NPS-WASO-NAGPRA-NPS0044078; PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: University of California, Santa Barbara, Repository for Archaeological and Ethnographic Collections, Santa Barbara, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of California, Santa Barbara (UCSB), Repository for Archaeological and Ethnographic Collections has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains in this notice may occur on or after November 30, 2026.

ADDRESSES: Send written requests for repatriation of the human remains in this notice to Hugh Radde, University of California, Santa Barbara, Santa Barbara, CA 93106, email NAGPRA@ucsb.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the UCSB Repository for Archaeological and Ethnographic Collections, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, two individuals have been identified. No associated funerary objects are present. The ancestral human remains were collected from an unknown location near Lompoc in Santa Barbara County, CA. The collector and date of removal are unknown. Around 1984, the ancestral remains were donated to UC Santa Barbara by Helen Loney. It is unknown whether they were treated with preservatives or other potentially hazardous substances.

Cultural Affiliation

Based on the information available and the results of consultation, cultural

affiliation is reasonably identified by the geographical location or acquisition history of the human remains.

Determinations

The UCSB Repository for Archaeological and Ethnographic Collections has determined that:

- The human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- There is a connection between the human remains described in this notice and the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under

ADDRESSES. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains described in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the UCSB Repository for Archaeological and Ethnographic Collections must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The UCSB Repository for Archaeological and Ethnographic Collections is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026-22152 Filed 10-29-26; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7604; NPS-WASO-NAGPRA-NPS0044099; PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: University of Rhode Island, Kingston, RI

AGENCY: National Park Service, Interior.
ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of Rhode Island (URI) has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after November 30, 2026.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Kristine M. Bovy, Department of Sociology & Anthropology, University of Rhode Island, 507 Chafee Bldg., Kingston, RI 02881, email kbovy@uri.edu, and The Office of the General Counsel, 35 Campus Avenue, Kingston, RI 02881, email URIGeneralCounsel@uri.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the University of Rhode Island, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Dartmouth Case

Human remains representing, at least, three individuals have been identified. No associated funerary objects are present. The only original documentation associated with this case is a handwritten label on the original storage box reading "Dartmouth Material." Based on the box label and research practices of the 1980s, when we believe these Ancestors arrived at the University, the remains are reasonably determined to have

originated from Dartmouth, Massachusetts, though this cannot be confirmed. At the request of consulting parties, non-invasive analysis of the skeletal remains was conducted on campus in 2026 to confirm Native American ancestry, at which time the individuals were deemed to be very likely of Native American descent.

Luce Collection (Ridge Hill Site, Main Street Site, Kenoza Camp Site): Human remains representing, at least, three individuals have been identified. The one associated funerary object is animal bone. The Luce Collection originates from archaeological work conducted by Fred and Thera Luce and was originally curated at the Buttonwoods Museum in Haverhill, Massachusetts. In the mid-1980s, several Ancestors were loaned to the University of Rhode Island for osteological study, as documented in a 1986 report by Thomas Mahlstedt of the Massachusetts Historical Commission. Some Ancestors were returned to Buttonwoods, while others remained at URI. In 2022, URI staff confirmed that Buttonwoods retained two Ancestors whose remains were intermingled with those held by the University. In consultation with the Museum, it was agreed that the Ancestors from the Ridge Hill, Main Street, and Kenoza Camp sites would be reunited under URI's legal control. The Buttonwoods Museum retains all original documentation, including notebooks and photographs, from the Luce Collection.

Ridge Hill Site (19-ES-41; Luce #4907): On June 16, 1932, an eroding cairn burial containing one individual was recorded in Groveland, Massachusetts, near the Merrimack River. Fred Luce and assistants documented the burial and removed approximately sixty cobblestones to expose the remains, which were later examined by the local Medical Examiner and identified as Native American. Luce retained the remains and they entered into the Luce Collection.

Main Street Site (19-ES-559; Luce #3292): On June 12, 1915, workmen excavating a water line trench in Groveland uncovered a burial. The remains were recovered by a local resident and documented by Thera Luce in her register of excavations, thus becoming part of the Luce Collection.

Kenoza Camp Site (19-ES-27; Luce #2398): In August 1913, during road construction near Kenoza Lake and Winnekenni Park in Haverhill, workmen encountered a burial later attributed to site 19-ES-27. Fred Luce purchased these skeletal remains from the workmen and they subsequently

became part of the Luce Collection. Cultural materials were found in the area, but documentation indicates this burial contained no associated funerary objects.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains and associated funerary objects described in this notice.

Determinations

The University of Rhode Island has determined that:

- The human remains described in this notice represent the physical remains of six individuals of Native American ancestry.
- The one object described in this notice is reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary objects described in this notice and the Mashpee Wampanoag Tribe and the Wampanoag Tribe of Gay Head (Aquinnah).

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the University of Rhode Island must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The University of Rhode Island is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations

identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22155 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7602; NPS–WASO–NAGPRA–NPS0044077; PPWOCRADNO–PCU00RP14.R50000]

Notice of Intended Repatriation: Tennessee Department of Environment and Conservation, Division of Archaeology, Nashville, TN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Tennessee Department of Environment and Conservation, Division of Archaeology (TDEC–DOA) intends to repatriate certain cultural items removed from an unknown site in Coffee County, TN that meet the definition of unassociated funerary objects and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after November 30, 2026.

ADDRESSES: Send additional, written requests for repatriation of the cultural items in this notice to Phillip R. Hodge, Tennessee Department of Environment and Conservation, Division of Archaeology (TDEC–DOA), 1216 Foster Avenue, Cole Building #3, Nashville, TN 37243, email Phil.Hodge@tn.gov.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the TDEC–DOA, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of one lot of cultural items has been requested for repatriation. The one lot of unassociated funerary objects are two-hole stone gorgets. These gorgets were previously on display in Old Stone Fort State Archaeological Park's Museum in Coffee County, Tennessee. There is no record regarding the Park's acquisition of these objects other than that they were donated by local members of the public years prior. There is no known exposure to hazardous substances or treatments.

Determinations

The TDEC–DOA has determined that:

- The one lot of unassociated funerary objects described in this notice are reasonably believed to have been placed intentionally with or near human remains, and are connected, either at the time of death or later as part of the death rite or ceremony of a Native American culture according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization. The unassociated funerary objects have been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to an Indian Tribe or Native Hawaiian organization.

- There is a connection between the cultural items described in this notice and the Cherokee Nation; Eastern Band of Cherokee Indians; The Chickasaw Nation; The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; and the United Keetoowah Band of Cherokee Indians in Oklahoma.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the TDEC–DOA must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural

items are considered a single request and not competing requests. The TDEC-DOA is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026-22150 Filed 10-29-26; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7596; NPS-WASO-NAGPRA-NPS0044068; PPWOCRADN0-PCU00RP14.R50000]

Notice of Intended Repatriation: Bernice Pauahi Bishop Museum, Honolulu, HI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Bernice Pauahi Bishop Museum (BPBM) intends to repatriate certain cultural items that meet the definition of unassociated funerary objects and that have a cultural affiliation with the Native Hawaiian organizations identified in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after November 30, 2026.

ADDRESSES: Send additional, written requests for repatriation of the cultural items in this notice to Jill Sommer, NAGPRA Coordinator, Bernice Pauahi Bishop Museum, 1525 Bernice Street, Honolulu, HI 96817, email BM.NAGPRA@bishopmuseum.org.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the BPBM and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of nine cultural items, identified as Honoko'a Gulch items "Lots 1-9," have been requested for

repatriation by the Native Hawaiian organizations identified in this notice. The nine unassociated funerary objects include carved ki'i (stick images), 'ipu 'aina (refuse bowls), nae (feather cape fragment), ki'i wahine (carved female figure), hair helmet/wig, and a boar tusk bracelet. These items were collected by David Forbes, Friedrich Haenisch, and William Wagner in 1905 from the Honoko'a Gulch Cave Complex, in an area known as Forbes Cave, in Kawaihae, Hawai'i Island, and received by BPBM in 1907.

Determinations

The BPBM has determined that:

- The nine unassociated funerary objects described in this notice are reasonably believed to have been placed with or near human remains at the time of death or later as part of the death rite or ceremony of a Native American culture. The unassociated funerary objects have been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to an Indian Tribe or Native Hawaiian organization.

- There is a connection between the cultural items described in this notice and the Mary Kawena Pukui Cultural Preservation Society; the 'Ohana Diamond; the 'Ohana Kekumano; the 'Ohana Keohokālole; the 'Ohana Olds; and the Temple of Lono (collectively, the Pukui Society Group) and Aloha 'Āina o Hawai'i, Inc.

- The Mary Kawena Pukui Cultural Preservation Society; the 'Ohana Diamond; the 'Ohana Kekumano; the 'Ohana Keohokālole; the 'Ohana Olds; and the Temple of Lono (collectively, the Pukui Society Group) have the closest cultural affiliation and are the most appropriate requestors for these unassociated funerary objects.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are

received, the BPBM must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The BPBM is responsible for sending a copy of this notice to the Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026-22145 Filed 10-29-26; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7609; NPS-WASO-NAGPRA-NPS0044101; PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: University of Missouri, Museum of Anthropology, Columbia, MO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of Missouri, Museum of Anthropology has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after November 30, 2026.

ADDRESSES: Send written requests for repatriation of the human remains and associated funerary objects in this notice to Dr. Candace Sall, University of Missouri, Museum of Anthropology, 1020 Lowry Street, Columbia, MO 65211, email nagpra@missouri.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the University of Missouri, Museum of Anthropology, and additional information on the determinations in this notice, including the results of consultation, can be found

in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, 94 individuals have been identified. The 94 lots, representing approximately 3,770 associated funerary objects, are ceramics, stone tools (including projectile points and bifaces), faunal bone fragments, charcoal, soil, copper fragments, shell, a pipe. The individuals and associated funerary objects described in this notice were removed from sites in Boone, Carroll, Cedar, Crawford, Dunklin, Jefferson, Montgomery, New Madrid, Pemiscot, Pettis, Phelps, St Genevieve, St Louis, Warren, Washington Counties, and two unknown locations in Missouri.

The sites include: Mendenhall (23BO86) with one MNI and four lots; Mendenhall Mounds (23BO87) with 12 MNI and five lots; Wakenda (23CA1) with two MNI and three lots; no site name (23CE1) with one MNI and no lots; Boulder Cave (23CR58) with three MNI and six lots; unknown site (23CRunprov) one MNI and no lots; Langdon (23DU1) with one MNI and one lot; Vancil Mounds (23DU4) with two MNI and five lots; Blakemore/Joel Todd (23DU126) with one MNI and no lots; Hankins (23DU335) with two MNI and three lots; Northern & Southern Blowholes (23DU386) with one MNI and no lots; Costephens (23DU391) with one MNI and four lots; Johnson, (23DU398) with one MNI and two lots; Jerry Stillman (23DU446) with two MNI and two lots; Missin Massey (23DU457) with one MNI and two lots; S. Pete Cross (23DU486) with one MNI and no lots; Tom True's Leveled (23DU493) with one MNI and no lots; N. Deadman's Slough (23DU498) with one MNI and no lots; Tommy Cook (23DU515) with one MNI and no lots; Ron Nichols Central (23DU611) with one MNI and five lots; Wilson Farm (23J Eunpro2) with one MNI and six lots; no site name (23MT1) with one MNI and six lots; Atterberry Cave (23MT28) with one MNI and three lots; Matthews (23NM156) with one MNI and two lots; Ross (23NM600) with one MNI and no lots; Pigeon East (23NM606) with one MNI and one lot; Keel (23NMunprov2) with one MNI and two lots; Jerry Stillman (23 PM660) with one MNI and four lots; Hieronymus Mound (23PE12) with 17 MNI and no lots; no site name (23PH38) with one MNI and one lot; Saline Creek/Keslin (23SG218/23SG300) with seven MNI and nine lots; no site name (23SGunprov1) with one MNI and no lots; Sisters of Notre Dame Convent (23SL70) with one MNI and two lots;

Schroer Cave (23WN1) with seven MNI and six lots; Albert Wideman Farm (23WA23) with two MNI and four lots; Keel (23unprov19) with 11 MNI and five lots; unknown site (23unprov46) with two MNI and one lot.

All of the sites in this notice were excavated or collected by members of the Missouri Archaeological Society. In 2019, control of the collections was transferred from the Society to the University of Missouri, Museum of Anthropology, to facilitate NAGPRA compliance. Sites from Dunklin County (23DU1, 23DU4, 23DU126, 23DU335, 23DU386, 23DU391, 23DU398, 23DU446, 23DU457, 23DU486, 23DU493, 23DU498, 23DU515, 23DU611) and 23 PM660, 23NM606, and 23SGunprov, were surface collected and donated by Ralph Wayne before 2001. Sites 23MT28 and 23WN1 were donated by C.K. Sheets in 1958. Thomas Keel donated the ancestors and collections in 1967 from sites 23NM156, 23NM600, 23NMunprov2, and 23unprov19. Leonard Blake donated collections from 23SG218, 23SL70, and 23WA23. Ted Hamilton excavated the Wakenda site (23CA1) in 1952. The Mendenhall sites (23BO86 and 23BO87) were excavated with Earl Lubensky and Missouri Archaeological Society members. Harry and Florence Collins excavated Hieronymus Mound (23PE12) in 1950. Site 23unprov46 was found in Judge Dalton's collection from his 1965 donation, during the 2021 collections review. Sites: 23CE1, 23CR58, 23CRunprov, 23J Eunprov, and 23PH38 were excavated by members of the Missouri Archaeological Society. No known hazardous substances were used to treat the human remains or associated funerary objects.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is clearly identified by the information available about the human remains and associated funerary objects described in this notice.

Determinations

The University of Missouri, Museum of Anthropology has determined that:

- The human remains described in this notice represent the physical remains of 94 individuals of Native American ancestry.
- The 94 lots of objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a connection between the human remains and associated funerary

objects described in this notice and The Osage Nation.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the University of Missouri, Museum of Anthropology must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The University of Missouri, Museum of Anthropology is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026-22160 Filed 10-29-26; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7606; NPS-WASO-NAGPRA-NPS0044080; PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: University of Rhode Island, Kingston, RI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of Rhode Island (URI) has completed an inventory of human

remains and has determined that there is no lineal descendant and no Indian Tribe or Native Hawaiian organization with cultural affiliation.

DATES: Upon request, repatriation of the human remains in this notice may occur on or after November 30, 2026.

ADDRESSES: Send written requests for repatriation of the human remains in this notice to Kristine M. Bovy, Department of Sociology & Anthropology, University of Rhode Island, 507 Chafee Bldg., Kingston, RI 02881, email kbovy@uri.edu, and The Office of the General Counsel, 35 Campus Avenue, Kingston, RI 02881, email URIGeneralCounsel@uri.edu.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the University of Rhode Island, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Unaffiliated "Box 1," "Box 2," "Box 3"

Human remains representing, at least, six individuals have been identified. No associated funerary objects are present. The University of Rhode Island presently holds no documentation within its archives indicating geographic origin, archaeological context, or acquisition history for the remains housed in "Box 1," "Box 2," and "Box 3." Based on a 2022 osteological inventory, human remains representing, at least, seven individuals were present. At the request of consulting parties, non-invasive analysis of the skeletal remains was conducted on campus in 2026 to confirm Native American ancestry, at which time the remains of one individual determined not to be of Native American ancestry were removed, bringing the minimum number of individuals to six.

Consultation

Invitations to consult were sent to the Mashantucket Pequot Indian Tribe (2026); Mashpee Wampanoag Tribe (2026); Mohegan Tribe of Indians of Connecticut (2026); Narragansett Indian Tribe (2026); and the Wampanoag Tribe of Gay Head (Aquinnah) (2026).

An invitation to consult was also sent to the Assonet Band of the Wampanoag Nation (2024), a non-federally recognized Indian group.

The Mashpee Wampanoag Tribe; Mohegan Tribe of Indians of Connecticut; Narragansett Indian Tribe; and the Wampanoag Tribe of Gay Head (Aquinnah) responded to the invitation and participated in consultation.

Cultural Affiliation

The following types of information about the cultural affiliation of the human remains in this notice are available: biological, expert opinion, Native American traditional knowledge. The information, including the results of consultation, identified:

1. No earlier group connected to the human remains.
2. No Indian Tribe or Native Hawaiian organization connected to the human remains.
3. No relationship of shared group identity between the earlier group and the Indian Tribe or Native Hawaiian organization that can be reasonably traced through time.

Determinations

The University of Rhode Island has determined that:

- The human remains described in this notice represent the physical remains of six individuals of Native American ancestry.
- No known lineal descendant who can trace ancestry to the human remains in this notice has been identified.
- No Indian Tribe or Native Hawaiian organization with cultural affiliation to the human remains described in this notice has been clearly or reasonably identified.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under

ADDRESSES. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Upon request, repatriation of the human remains described in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the University of Rhode Island must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The University of Rhode Island is responsible for sending a copy of this notice to the Indian Tribes or Native

Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026-22157 Filed 10-29-26; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7594; NPS-WASO-NAGPRA-NPS0044067; PPWOCRADN0-PCU00RP14.R50000]

Notice of Intended Repatriation: Wichita-Sedgwick County Historical Museum, Wichita, KS

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Wichita-Sedgwick County Historical Museum (WSCHM) intends to repatriate a certain cultural item that meets the definition of a sacred object and that has a cultural affiliation with the Indian Tribes in this notice.

DATES: Repatriation of the cultural item in this notice may occur on or after November 30, 2026.

ADDRESSES: Send additional, written requests for repatriation of the cultural item in this notice to Jami Frazier Tracy, Wichita-Sedgwick County Historical Museum, 204 South Main Street, Wichita, KS 67202, email jami@wichitahistory.org.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the WSCHM and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of one cultural item have been requested for repatriation. The one sacred object is a shield. This shield was collected by Finlay Ross (1847-1933) and donated to the WSCHM in 1939 by his widow, Ella Fuller Ross. This shield is associated with the Anadarko Affair, also known as the Battle of the Wichita

Agency, a conflict between the Comanche and Kiowa tribes against the Agency. A 1930 article published in the "Wichita Beacon" newspaper mentioning both the shield and battle stated, "The battle at the Wichita agency is commemorated by a beautiful round shield. . . belonging to Mr. Finlay Ross." The article further states that Ross "took it from the Comanche village after it was captured by the calvary" This provenance is further supported by the WSCHM accession ledger, stating, "Shield captured at battle . . . Anadarko Indian Territory between US Troops, Civilians, and Comanche Indians August 22, 1874." The WSCHM records indicate no known hazardous substances used to treat the item.

Determinations

The WSCHM has determined that:

- The one sacred object described in this notice is a specific ceremonial object needed by a traditional Native American religious leader for present-day adherents to practice traditional Native American religion, according to the Native American traditional knowledge of an Indian Tribe.

- There is a connection between the cultural item described in this notice and the Comanche Nation, Oklahoma.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural item in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the WSCHM must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural item are considered a single request and not competing requests. The WSCHM is responsible for sending a copy of this notice to the Indian Tribes identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22144 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[N7593; NPS–WASO–NAGPRA–NPS0044066; PPWOCRADNO–PCU00RP14.R50000]

Notice of Intended Repatriation: Wichita-Sedgwick County Historical Museum, Wichita, KS

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Wichita-Sedgwick County Historical Museum (WSCHM) intends to repatriate certain cultural items that meet the definition of sacred objects and that have a cultural affiliation with the Indian Tribes in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after November 30, 2026.

ADDRESSES: Send additional, written requests for repatriation of the cultural items in this notice to Jami Frazier Tracy, Wichita-Sedgwick County Historical Museum, 204 South Main Street, Wichita, KS 67202, email jami@wichitahistory.org.

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the WSCHM and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of 10 cultural items have been requested for repatriation. The 10 sacred objects are child's leggings, child's vests, moccasins, pipe bags, and a breastplate. Carl Eldridge Bitting collected seven items (leggings, vests, pipe bags, moccasins) affiliated with the Sioux and Plains in the 1930s and 1940s during his travels throughout the Plains as a wholesale jewelry salesman, donated to the WSCHM in 1957. One item (breastplate) collected by Fern Mead Jordan (1882–1959), wife of 19th century Kansas trading post operator James R. Mead (1836–1910) and donated

to the WSCHM in 1972 by their daughter, Ignace Mead Jones. One item (moccasins) collected by unknown and donated by Mr. and Mrs. Bond Hammond in 1977. One item (moccasins) collected by Mattie Fabrique Nolley (1867–1963) at an unknown time and donated by F. Ross and Evelyn Little in 1988. The WSCHM records indicate no known hazardous substances used to treat the items.

Determinations

The WSCHM has determined that:

- The 10 sacred objects described in this notice are specific ceremonial objects needed by a traditional Native American religious leader for present-day adherents to practice traditional Native American religion, according to the Native American traditional knowledge of a lineal descendant or Indian Tribe.

- There is a connection between the cultural items described in this notice and the Assiniboiné and Sioux Tribes of the Fort Peck Indian Reservation, Montana.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after November 30, 2026. If competing requests for repatriation are received, the WSCHM must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The WSCHM is responsible for sending a copy of this notice to the Indian Tribes identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 22, 2026.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2026–22143 Filed 10–29–26; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–809 and 731–TA–1810 (Preliminary)]

Railway Tank Cars and Parts Thereof From Mexico; Revised Schedule for the Subject Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: October 26, 2026.

FOR FURTHER INFORMATION CONTACT:

Celia Feldpausch (202–205–2387) or Jeff Clark (202–205–3318), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: On September 30, 2026, the Commission established a schedule for the conduct of the preliminary phase of the subject investigations (91 FR 63308, October 5, 2026). Subsequently, the Department of Commerce ("Commerce") extended the deadline for its initiation determination by 20 days, or by no later than November 9, 2026 (91 FR 67288, October 26, 2026). The Commission, therefore, is revising its schedule to conform with Commerce's new schedule.

The Commission must reach preliminary determinations within 25 days after the date on which the Commission receives notice from Commerce of initiation of the investigations, and the Commission's views must be transmitted to Commerce within five business days thereafter.

For further information concerning this proceeding, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

Issued: October 28, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22191 Filed 10–29–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1092 (Third Review)]

Diamond Sawblades and Parts Thereof From China; Determination

On the basis of the record¹ developed in the subject five-year review, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that revocation of the antidumping duty order on diamond sawblades and parts thereof from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.²

Background

The Commission instituted this review on March 2, 2026 (91 FR 10131) and determined on June 5, 2026 that it would conduct an expedited review (91 FR 41084, July 6, 2026).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on October 28, 2026. The views of the Commission are contained in USITC Publication 5807 (October 2026), entitled *Diamond Sawblades and Parts Thereof from China: Investigation No. 731–TA–1092 (Third Review)*.

By order of the Commission.

Issued: October 28, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22244 Filed 10–29–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1047 (Fourth Review)]

Ironing Tables and Certain Parts Thereof From China; Scheduling of an Expedited Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of an expedited review pursuant to the Tariff Act of 1930 ("the Act") to determine whether revocation of the antidumping duty order on ironing tables and certain parts thereof from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: October 5, 2026.

FOR FURTHER INFORMATION CONTACT:

Alexis Yim (202–708–1446), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—On October 5, 2026, the Commission determined that the domestic interested party group response to its notice of institution (91 FR 40585, July 2, 2026) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting a full review.¹ Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).²

For further information concerning the conduct of this review and rules of

¹ The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

² Commissioner Samuel T. Negatu not participating.

¹ A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

² Commissioner Negatu did not participate.

general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the review has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for this review on January 20, 2027. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,³ and any party other than an interested party to the review may file written comments with the Secretary on what determination the Commission should reach in the review. Comments are due on or before 5:15 p.m. on January 27, 2027, and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by January 27, 2027. However, should the Department of Commerce ("Commerce") extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures*, available on the Commission's website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined this review is extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.62 of the Commission's rules.

By order of the Commission.

Issued: October 27, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22167 Filed 10–29–26; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Housing Occupancy Certificate—Migrant and Seasonal Agricultural Worker Protection Act

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Wage and Hour Division (WHD)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before November 30, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Nora Hernandez by telephone at 202–693–8633, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: The Department's Wage and Hour Division (WHD) administers the Migrant and Seasonal Agricultural Worker Protection Act (MSPA), 29 U.S.C. 1801 *et seq.* MSPA protects migrant and seasonal agricultural workers by establishing employment standards related to wages,

housing, transportation, disclosures, and recordkeeping. MSPA also requires farm labor contractors and farm labor contractor employees to register with the Department and to obtain special authorization before housing workers, using a vehicle to transport workers, or driving such vehicles.

Related to this information collection, MSPA requires any person who owns or controls any facility or real property that is used to house migrant agricultural workers to post a copy of the certificate of occupancy at the site of the facility or real property. The certificate attests that a state, local, or federal agency conducted a housing safety and health inspection and verified that the facility or real property meets the applicable safety and health standards. See 29 CFR 500.135. Migrant agricultural workers may not be housed at any facility or real property without such certificate of occupancy. The original certificate must be retained by the person who owns or controls the facility or real property for three years and must be made available for inspection upon the Department's request. See 29 U.S.C. 1862(a). The Department makes optional Form WH–520 available for these purposes. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on July 27, 2026 (91 FR 46969).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology. To help ensure appropriate consideration, comments should reference OMB Control Number 1235–0006.

This information collection is subject to PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a

³ The Commission has found the response submitted on behalf of Seymour Mfg. LLC (d/b/a Seymour Home Products) to be individually adequate. Comments from other interested parties will not be accepted (see 19 CFR 207.62(d)(2)).

collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review. The Department of Labor seeks approval for the revision of this information collection to ensure effective administration of the laws administered by the WHD.

Agency: DOL–WHD.

Title of Collection: Housing Occupancy Certificate—Migrant and Seasonal Agricultural Worker Protection Act.

OMB Control Number: 1235–0006.

Affected Public: Private Sector: Businesses or other for-profits.

Total Estimated Number of Respondents: 10.

Total Estimated Number of Responses: 10.

Total Estimated Annual Time Burden: 1 hour.

Total Estimated Annual Other Costs Burden: \$0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nora Hernandez,

PRA Department Clearance Officer.

[FR Doc. 2026–22212 Filed 10–29–26; 8:45 am]

BILLING CODE 4510–27–P

OFFICE OF PERSONNEL MANAGEMENT

Agency Information Collection

Request: 3206–0170, Application for Refund of Retirement Deductions, SF 3106 and Current/Former Spouse(s) Notification of Application for Refund of Retirement Deductions Under FERS, SF 3106A

AGENCY: Office of Personnel Management.

ACTION: 60-Day Notice and request for comments.

SUMMARY: Retirement Services offers the general public and other Federal agencies the opportunity to comment on the reinstatement of an expired information collection request (ICR), Application for Refund of Retirement Deductions, Federal Employees Retirement System, SF 3106 and Current/Former Spouse's Notification of Application for Refund of Retirement Deductions under FERS, SF 3106A.

DATES: Comments are encouraged and will be accepted until December 29, 2026.

ADDRESSES: You may submit comments on the Federal Rulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at <https://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT:

Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 6500–AS, Washington, DC 20415, Attention: Cyrus S. Benson, or sent by email to RSPublicationsTeam@opm.gov or eFax to 202-315-3288@efaxsend.com.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13), as amended (44 U.S.C. chapter 35), OPM is soliciting comments for this collection (OMB No. 3206–0170). The Office of Personnel Management is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Suggest ways to enhance the quality, utility, and clarity of the information to be collected; and
4. Suggest ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

Standard Form 3106, Application for Refund of Retirement Deductions under FERS is used by former Federal employees under FERS, to apply for a refund of retirement deductions withheld during Federal employment, plus any interest provided by law. Standard Form 3106A, Current/Former Spouse(s) Notification of Application for Refund of Retirement Deductions under FERS, is used by refund applicants to notify their current/former spouse(s) that they are applying for a refund of retirement deductions, which is required by law.

Analysis

Agency: Retirement Services, Office of Personnel Management.

Title: Application for Refund of Retirement Deductions (FERS) and Current/Former Spouse's Notification of Application for Refund of Retirement Deductions under FERS.

OMB Number: 3206–0170.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: SF 3106 = 8,000; SF 3106A = 6,400.

Estimated Time per Respondent: SF 3106 = 30 minutes; SF 3106A = 5 minutes.

Total Burden Hours: 4,533.

Office of Personnel Management.

Alexys Stanley,

Federal Register Liaison.

[FR Doc. 2026–22224 Filed 10–29–26; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0235, Letter Reply To Request for Information, RI 20–64; Former Spouse Survivor Annuity Election, RI 20–64A; Information on Electing a Survivor Annuity for Your Former Spouse, RI 20–64B

AGENCY: Office of Personnel Management.

ACTION: 60-day notice and request for comments.

SUMMARY: Retirement Services offers the general public and other federal agencies the opportunity to comment on the reinstatement of an expired information collection request (ICR), Letter Reply to Request for Information, RI 20–64; Former Spouse Survivor Annuity Election, RI 20–64A; and Information on Electing a Survivor Annuity for Your Former Spouse, RI 20–64B.

DATES: Comments are encouraged and will be accepted until December 29, 2026.

ADDRESSES: You may submit comments on the Federal Rulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at <https://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT:

Retirement Services Publications Team,
Office of Personnel Management, 1900 E
Street NW, Room 6500-AS,
Washington, DC 20415, Attention: Cyrus
S. Benson, or sent via electronic mail to
RSPublicationsTeam@opm.gov.

SUPPLEMENTARY INFORMATION:

As required by the Paperwork Reduction
Act of 1995 (Pub. L. 104-13, 44 U.S.C.
chapter 35) as amended by the Clinger-
Cohen Act (Pub. L. 104-106), OPM is
soliciting comments for this collection
(OMB No. 3206-0235). The Office of
Management and Budget is particularly
interested in comments that:

1. Evaluate whether the proposed
collection of information is necessary
for the proper performance of functions
of the agency, including whether the
information will have practical utility;

2. Evaluate the accuracy of the
agency's estimate of the burden of the
proposed collection of information,
including the validity of the
methodology and assumptions used;

3. Enhance the quality, utility, and
clarity of the information to be
collected; and

4. Minimize the burden of the
collection of information on those who
are to respond, including through the
use of appropriate automated,
electronic, mechanical, or other
technological collection techniques or
other forms of information technology,
e.g., permitting electronic submissions
of responses.

RI 20-64, Letter Reply to Request for
Information, is used by OPM to explain
the annuity reductions required to pay
for the cost of a former spouse survivor
annuity benefit under the Civil Service
Retirement System (CSRS), and to
provide annuitants with information
about what the beginning rate of the
survivor annuity would be if the
annuitant ultimately elects a former
spouse survivor annuity benefit. RI 20-
64A, Former Spouse Survivor Annuity
Election, is used by OPM to obtain an
annuitant's former spouse survivor
annuity election. RI 20-64B,
Information on Electing a Survivor
Annuity for Your Former Spouse, is a
pamphlet that provides important
information to retirees who want to
provide a CSRS survivor annuity for a
former spouse.

Analysis

Agency: Office of Personnel
Management, Retirement Services.

Title: Letter Reply to Request for
Information; Former Spouse Survivor
Annuity Election.

OMB Number: 3206-0235.

Frequency: On occasion.

Affected Public: Individuals or
Households.

Number of Respondents: 38.

Estimated Time per Respondent: 45
minutes for RI 20-64A and 8 minutes
for RI 20-64.

Total Burden Hours: 24 hours.

Office of Personnel Management.

Alexys Stanley,

Federal Register Liaison.

[FR Doc. 2026-22225 Filed 10-29-26; 8:45 am]

BILLING CODE 6325-38-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-106742; File No. SR-
NYSEAMER-2026-92]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend Article I, Sections 1.05 and 1.06 of Its Operating Agreement

October 27, 2026.

Pursuant to Section 19(b)(1)¹ of the
Securities Exchange Act of 1934
("Act")² and Rule 19b-4 thereunder,³
notice is hereby given that, on October
14, 2026, NYSE American LLC ("NYSE
American" or the "Exchange") filed
with the Securities and Exchange
Commission (the "Commission") the
proposed rule change as described in
Items I and II below, which Items have
been prepared by the self-regulatory
organization. The Commission is
publishing this notice to solicit
comments on the proposed rule change
from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to (a) amend
Article I, Sections 1.05 and 1.06 of its
operating agreement to reflect the
change of the address of the registered
office; (b) amend Article II, Section 2.02
of its operating agreement to change
cross references; (c) amend Article II,
Section 2.03(a) of its operating
agreement to reflect the inclusion of
Limited Underwriting Members as
members, and (d) make certain
clarifying, technical and conforming
changes to the operating agreement. The
proposed rule change is available on the
Exchange's website at www.nyse.com
and at the principal office of the
Exchange.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the
self-regulatory organization included
statements concerning the purpose of,
and basis for, the proposed rule change
and discussed any comments it received
on the proposed rule change. The text
of those statements may be examined at
the places specified in Item IV below.
The Exchange has prepared summaries,
set forth in sections A, B, and C below,
of the most significant parts of such
statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend
Article I, Sections 1.05 (Registered
Office) and 1.06 (Registered Agent) of
the Thirteenth Amended and Restated
Operating Agreement of the Exchange
("Operating Agreement") to reflect the
change of the address of the registered
office; (b) amend Article II, Section 2.02
(Rules; Supervision of Member
Organizations) of the Operating
agreement to change cross references; (c)
amend Article II, Section 2.03(a) (Board)
of the Operating Agreement to reflect
the inclusion of Limited Underwriting
Members as members, and (c) make
certain clarifying, technical and
conforming changes to the operating
agreement.

Proposed Amendments to Article I, Sections 1.05 and 1.06

The Exchange proposes to amend the
Operating Agreement to make a
technical change updating the address
of the registered office of the registered
agent in the state of Delaware. The
changes are non-substantive technical
administrative changes.

The Exchange is a limited liability
company organized under the laws of
the state of Delaware. As such, it has
and maintains a registered office and
registered agent in Delaware.⁴

Article I, Section 1.05 of the
Operating Agreement provides that the
address of the registered office of the
Exchange in the State of Delaware is

⁴ See Del. Code tit. 6, § 18-104(a). See also
Exchange Act Release No. 82923 (March 22, 2018),
83 FR 13161 (March 27, 2018) (SR-NYSEAMER-
2018-10) (Notice of Filing and Immediate
Effectiveness of Proposed Change Amending
Certain Governing Documents of the Exchange and
NYSE Market, Inc. To Make a Technical Change
Updating the Entities' Registered Offices and
Registered Agents and Update the Date as
Required).

Silverside Road, Tatnall Building No. 104, Wilmington, County of New Castle, State of Delaware, 19810. The Exchange proposes to amend such provision to provide that the address is c/o United Agent Group Inc., 1521 Concord Pike, Suite 201, Wilmington, County of New Castle, State of Delaware 19813.

Article I, Section 1.06 of the Operating Agreement provides that the address of the registered agent of the Exchange for service of process on the Exchange in the State of Delaware is Silverside Road, Tatnall Building No. 104, Wilmington, County of New Castle, State of Delaware 19810. The Exchange proposes to amend such provision to provide that the address is 1521 Concord Pike, Suite 201, Wilmington, County of New Castle, State of Delaware 19813.

Proposed Amendments to Article II, Section 2.02

The Exchange proposes to amend Section 2.02 to change the cross references. Currently, Section 2.02 refers to members and member organizations “as defined in Rule 18 and 24 of the Company, respectively” and to specialists and designated market makers “as defined in Rule 2 of the Company Rules”. Because the cross references are no longer correct, the Exchange proposes to make a more general reference to the Exchange’s rules. The changes are non-substantive.

To that end, the Exchange proposes to make the following changes to the first two sentences of Section 2.02 (proposed additions italicized, proposed deletions in brackets):

In furtherance and not in limitation of the foregoing, the Board shall have general supervision over members and member organizations [(as defined in Rules 18 and 24 of the Company, respectively)] of the Company (collectively, “Member Organizations”) and over approved persons [(as defined in Rule 25 of the Company)] *as these terms are defined in the Company’s Rules* in connection with their conduct with or affecting Member Organizations. The Board may examine into the business conduct and financial condition of Member Organizations, shall have supervision over partnership and corporate arrangements and over all offices of Member Organizations, whether foreign or domestic, and over all persons employed by such Member Organizations (and may, by affirmative vote of a majority of the Directors then in office, adopt, amend or repeal rules with respect to the employment, compensation and duties of such employees), shall have supervision relating to the collection, dissemination and use of quotations and of reports of prices on the exchange operated by the Company, shall have the power to approve or disapprove of any connection or means of communication with the floor and may require the

discontinuance of any such connection or means of communication, may disapprove of any member acting as a specialist, designated market maker [(as defined in Rule 2 of the Company Rules)] (“DMM”) or odd lot dealer *as these terms are defined in the Company’s Rules*, and may, by affirmative vote of a majority of the Directors then in office, adopt, amend or repeal any rules as it may deem necessary or appropriate in connection with any of the foregoing, including, without limitation, rules relating to: the discipline of Member Organizations, approved persons and registered and non-registered employees of Member Organizations for the violation of applicable law or the rules of the Company; and the arbitration of any controversy between parties who are Member Organizations and any controversy between a Member Organization and any other person arising out of the business of such Member Organization.

Proposed Amendments to Article II, Section 2.03(a)

The Exchange Act requires that every exchange have rules that “assure a fair representation of its members in the selection of its directors and administration of its affairs”.⁵ In compliance with this requirement, the Exchange sets forth, in Article II, Section 2.03(a) of its Operating Agreement, the process by which its fair representation directors, the “Non-Affiliated Directors,” are chosen. The Exchange now proposes to amend Article II, Section 2.03(a) of the Operating Agreement to ensure that it remains in compliance with the cited Exchange Act requirement.

More specifically, the Exchange proposes to amend the Operating Agreement consistent with a recent filing by the Exchange to add a new membership category known as “Limited Underwriting Members.” Limited Underwriting Members are a type of non-trading Exchange membership solely for the limited purpose of acting as a principal underwriter of an underwritten public offering.⁶ As such, they do not have trading permits. Accordingly, the Exchange proposes to amend Section 2.03(a)(iv) and (v) to state that member organizations that do not have trading permits may both sign petitions and vote in any election for fair representation directors. The proposed

⁵ 15 U.S.C. 78ff(b)(3).

⁶ See Securities Exchange Act Release No. 103462 (July 15, 2025), 90 FR 34059 (July 18, 2025) (SR–NYSEAMER–2025–40) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Establishing Limited Underwriting Members). The filing stated that “Limited Underwriting Members would be ‘members’ of a national securities exchange under the [Exchange] Act based on their agreement to be regulated by the Exchange in connection with underwriting activity.” See *id.* at note 10.

change is designed to ensure that all “members” (as defined in the Exchange Act) have “fair representation . . . in the selection of its directors and administration of its affairs”.⁷

To that end, the Exchange proposes to make the following changes to Section 2.03(a) (proposed additions italicized):

(iv) Petition Candidates. * * * * * For purposes of determining whether a person has been endorsed by the requisite ten percent (10%) of signatures to be a Petition Candidate, each Member Organization in good standing shall be entitled to one signature for each 86 Trinity Permit (as the term is defined in the rules of the Company), equity trading permit or options trading permit issued by the Company owned by it, *and each Member Organization in good standing that does not own a trading permit shall be entitled to one signature*; provided, however, that no Member Organization, either alone or together with its affiliates as defined under Rule 12b–2 under the Exchange Act (“Affiliates”), may account for more than fifty percent (50%) of the signatures endorsing a particular Petition Candidate, and any signatures of such Member Organization, either alone or together with its Affiliates, in excess of such fifty percent (50%) limitation shall be disregarded.

* * * * * (v) Voting. * * * * * For purposes of determining which candidates received the highest number of votes and therefore should be the Fair Representation Candidates nominated by the NYSE American DCRC, each Member Organization in good standing shall be entitled to one vote for each 86 Trinity Permit (as the term is defined in the rules of the Company), equity trading permit or options trading permit issued by the Company owned by it, *and each Member Organization in good standing that does not own a trading permit shall be entitled to one vote*; provided, however, that no Member Organization, either alone or together with its Affiliates, may account for more than twenty percent (20%) of the votes cast for a candidate, and any votes cast by such Member Organization, either alone or together with its Affiliates, in excess of such twenty percent (20%) limitation shall be disregarded.

The proposed change would make the Operating Agreement consistent with the operating agreement of the Exchange’s affiliate New York Stock Exchange LLC. More specifically, Article II, Section 2.03(a)(iv) of the Fourteenth Amended and Restated

⁷ 15 U.S.C. 78ff(b)(3).

Operating Agreement of the New York Stock Exchange provides that “each Member Organization in good standing that does not own a Trading License shall be entitled to one signature” and Section 2.03(a)(v) of the same operating agreement provides that “each Member Organization in good standing that does not own a Trading License shall be entitled to one vote”.⁸

Additional Proposed Amendments

The Exchange proposes to make the following non-substantive technical and conforming changes to the title, recitals and signature page of the Operating Agreement:

- Update references to the “Thirteenth Amended and Restated Operating Agreement” to the “Fourteenth Amended and Restated Operating Agreement.”
- Update the dates in the introduction and signature line.
- Update the recitals.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act,⁹ in general, and furthers the objectives of Section 6(b)(1)¹⁰ in particular, in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(3) of the Exchange Act,¹¹ in that it would ensure a fair representation of its members in the selection of its directors and administration of its affairs. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(5) of the Exchange Act,¹² in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in

general, to protect investors and the public interest.

The proposed rule changes to Article I, Article II, Section 2.02, and the additional proposed amendments (together, the “Non-Substantive Changes”) are non-substantive changes that do not impact the governance or ownership of the Exchange. The Exchange believes that the proposed Non-Substantive Changes would enable the Exchange to continue to be so organized as to have the capacity to carry out the purposes of the Exchange Act and comply and enforce compliance with the provisions of the Exchange Act by its members and persons associated with its members, because identifying the registered office in Delaware, making cross-references more accurate, and making conforming changes to the title and date of the Operating Agreement would contribute to the orderly operation of the Exchange by adding clarity and transparency to its rules.

The proposed rule change to Sections 2.03(a)(iv) and (v) would be consistent with the recent filing setting forth, among other things, that Limited Underwriting Members are members, consistent with the definition of “member” in the Exchange Act, by stating that member organizations that do not have trading permits may both sign petitions and vote in any election for fair representation directors.

The proposed rule change to Sections 2.03(a)(iv) and (v) would allow the Exchange to ensure that all “members” (as defined in the Exchange Act) have “fair representation . . . in the selection of its directors and administration of its affairs”¹³ by including member organizations that do not have trading permits. The proposed rule change would allow the Exchange to ensure that it remains in compliance with the cited Exchange Act requirement and make the Operating Agreement consistent with the rules of the Exchange. What is more, the change proposed is based on, and would be consistent with, the wording in the operating agreement of the New York Stock Exchange LLC.

The Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposed Non-Substantive Changes would ensure that market participants can more easily navigate, understand and comply with the governing documents of the Exchange. The proposed rule change to Sections

2.03(a)(iv) and (v) would make the Operating Agreement consistent with the rules of the Exchange and therefore would ensure that market participants can more easily navigate, understand and comply with the governing documents of the Exchange.

The Exchange believes that, by ensuring that the rules accurately identify the registered office in Delaware, making cross-references more accurate, making conforming changes to the title and date of the Operating Agreement, and making the Operating Agreement consistent with the rules of the Exchange, the proposed rule change would reduce potential investor or market participant confusion. The proposed changes would make the Operating Agreement consistent with the rules of the Exchange and therefore would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from increased transparency and clarity, thereby reducing potential confusion.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. The proposed rule change is not intended to address competitive issues but rather is concerned solely with making non-substantive changes to the Operating Agreement and making the Operating Agreement consistent with the rules of the Exchange.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁴ and Rule 19b-4(f)(6) thereunder.¹⁵ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if

⁸ See Fourteenth Amended and Restated Operating Agreement of the New York Stock Exchange, Article II, Section 2.03(a)(iv) and (v). Apart from referring to Trading Licenses instead of trading permits, the wording is the same.

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(1).

¹¹ 15 U.S.C. 78f(b)(3).

¹² 15 U.S.C. 78f(b)(5).

¹³ 15 U.S.C. 78f(b)(3).

¹⁴ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁵ 17 CFR 240.19b-4(f)(6).

consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹⁶

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹⁷ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEAMER-2026-92 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSEAMER-2026-92. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish

to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEAMER-2026-92 and should be submitted on or before November 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-22131 Filed 10-29-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-106743; File No. SR-NYSEAMER-2026-96]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Binary Return Derivatives Rules

October 27, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 21, 2026, NYSE American LLC ("NYSE American" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify Rule 900ByRDs (Applicability; Definitions), Rule 910ByRDs (Determination of the Settlement Price), Rule 915ByRDs (Criteria for Underlying Securities), Rule 916ByRDs (Withdrawal of Approval of Underlying Securities), Rule 958ByRDs (Maximum Bid-Ask Differentials), Rule 980ByRDs (Automatic Exercise of Binary Return Derivatives) and Rule 928.1NYP (Price Reasonability Checks—Orders and Quotes) with respect to the trading of Binary Return Derivatives ("ByRDs") on the Exchange. The proposed rule change is available on the Exchange's website at www.nyse.com and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify Rule 900ByRDs (Applicability; Definitions), Rule 910ByRDs (Determination of the Settlement Price), Rule 915ByRDs (Criteria for Underlying Securities), Rule 916ByRDs (Withdrawal of Approval of Underlying Securities), Rule 958ByRDs (Maximum Bid-Ask Differentials), Rule 980ByRDs (Automatic Exercise of Binary Return Derivatives) and Rule 928.1NYP (Price Reasonability Checks—Orders and Quotes) with respect to trading of ByRDs on the Exchange. More specifically, the Exchange proposes to use the closing price of the security underlying a ByRD options contract as reported by the primary listing market ("Closing Price") in place of using the "composite price" volume weighted average price ("VWAP") to determine the settlement price of the ByRD options contract on the date of expiration and adopt a new initial and continued listing criteria for ByRDs whose underlying security is an individual stock. The Exchange also proposes to eliminate settlement price rounding practices, instead redefining Finish High ByRDs to return the settlement amount if the underlying security closes at or above the strike price.

¹⁶ 17 CFR 240.19b-4(f)(6)(iii). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁷ 15 U.S.C. 78s(b)(2)(B).

¹⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Overview of ByRDs³

ByRDs⁴ are European-style option contracts on individual stocks, exchange-traded funds (“ETFs”) and Index-Linked Securities that have a fixed return in cash based on a set strike price; satisfy specified listing criteria;⁵ and are auto-exercised at expiration pursuant to the Rules of the Options

³ ByRDs have been approved since 2007. *See* note 5, *infra*. Under the current rules, ByRDs would be available for trading during the Exchange’s Core Trading Session, *i.e.*, from 9:30 a.m. to 4:00 p.m., and until 4:15 p.m. for certain highly liquid ETPs that are approved for trading until such time. While the Exchange does not anticipate that ByRDs on such ETPs would trade after 4:00 p.m. on the day of expiration, the Exchange’s trading system is currently configured to allow ByRDs to trade until 4:15 p.m. because the Exchange’s trading system currently operates ByRDs on the same session schedule as standard options and cannot apply a different close time for ByRDs on such ETPs. Because ByRDs would be settled on the 4:00 p.m. Closing Price, the Exchange does not expect trading in ByRDs on such ETPs to occur between 4:00 p.m. and 4:15 p.m. on the day of expiration, after the settlement price has been determined. The Exchange represents to monitor trading activity after 4:00 p.m. on expiration day, and to examine making trading system changes to prevent the trading of a ByRDs option contract on such ETPs after 4:00 p.m. on the day of expiration. The Exchange will submit a proposed rule change to reflect such changes to the trading system. ByRDs are not currently available for trading during Extended Trading Hours (ETH), even if an underlying security is eligible for trading during ETH. ByRDs are also not currently available for trading as FLEX Options or Complex Options.

⁴ ByRDs were approved for listing and trading under their prior name, Fixed Return Options, or FROs. *See* Securities Exchange Act Release No. 56251 (August 14, 2007), 72 FR 46523 (August 20, 2007) (Notice of Filing of Amendment No. 4 to a Proposed Rule Change and Order Granting Accelerated Approval to a Proposed Rule Change, as Modified by Amendment Nos. 2, 3, and 4 Thereto, Relating to the Listing and Trading of Fixed Return Options). *See also* Securities Exchange Act Release No. 71957 (April 16, 2014), 79 FR 22563 (April 22, 2014) (SR–NYSEMKT–2014–06) (Order approving name change from FROs to Binary Return Derivatives (ByRDs) and re-launch of these products, with certain modification, and amending Obvious Errors rules to include ByRDs).

⁵ For an initial listing of a ByRD, individual stocks must meet the criteria set forth in Rule 915 and must also meet the following additional criteria: (i) a minimum market capitalization of at least \$40 billion, (ii) a minimum trading volume (in all markets in which the underlying security is traded) of at least 1 billion shares in the preceding twelve (12) months, (iii) a minimum average daily trading volume of 4 million shares, (iv) a minimum average daily trading value of at least \$200 million during the prior six (6) months and (v) an underlying market price per share of at least \$10 over the previous five (5) consecutive business days preceding the date on which the Exchange submits a certificate to the OCC for listing and trading, as measured by the closing price reported in the primary listed market in which the underlying security is traded. *See* Rule 915ByRDs, Commentary .01. For an initial listing of a ByRD, ETFs and Index-Linked Securities must also meet the criteria set forth in Rule 915 and must also meet the criteria for individual stocks set forth in Commentary .01 except for the minimum market capitalization requirement in Commentary .01(i). *See* Rule 915ByRDs, Commentary .02.

Clearing Corporation (the “OCC”).⁶ ByRDs are binary options and, as such, differ from traditional options traded on U.S. options exchanges by providing a discontinuous or non-linear payout. The payout of a ByRD options contract is an amount contingent upon the occurrence of the option being in- or at-the-money at expiration rather than the degree to which the option is in-the-money.⁷ An in-the-money ByRD options contract will pay a fixed sum at expiration regardless of the magnitude of the difference between the option’s strike price and the settlement price.⁸ A “Finish High” ByRD (equivalent to a call option) returns \$100 per contract if the settlement price of the underlying security is above the strike price at expiration, and a “Finish Low” ByRD (equivalent to a put option) returns \$100 per contract if the settlement price of the underlying security is below the strike price at expiration.⁹

Currently, Rule 910ByRDs(a) provides that the Exchange will use the “composite price” VWAP during regular trading hours for the entire business day of their expiration, or, in the case of an option contract expiring on a day that is not a business day, the entire business day immediately preceding the expiration date. The rule further provides that to calculate the VWAP, the Exchange would use composite prices during regular trading hours as reported by industry price vendors.¹⁰

If the security underlying a ByRDs option contract does not trade or is unavailable during regular trading hours at expiration, the settlement price may be fixed pursuant to the OCC’s rules on a basis that the OCC believes is appropriate under the circumstances,

⁶ *See* Rule 900ByRDs(b)(1).

⁷ The Exchange proposes to add this sentence to the definition of Binary Return Derivatives in Rule 900ByRDs(b)(1). The purpose for amending the current definition is to illustrate that a transaction in a ByRDs contract is an ‘all-or-none’ proposition.

⁸ Under Rule 900ByRDs(b)(5), the term “settlement price” means the all-day VWAP of the composite prices of the security underlying the Binary Return Derivatives during regular trading hours on the business day of their expiration, or, in the case of an option contract expiring on a day that is not a business day, on the last trading day prior to expiration.

⁹ *See* Rule 900ByRDs(b)(2) and (3). Each of the “Finish High” or “Finish Low” ByRDs option contract may be bought or sold.

¹⁰ Composite prices are prices reported to the consolidated tape from any participating exchange or market. The OCC currently uses composite pricing in connection with the settlement of expiring equity options. The composite closing price is the last reported sale price from any eligible trade source (*i.e.*, primary listing market or participating regional market). It is not an average price. *See* Securities Exchange Act Release No. 49045 (January 8, 2004), 69 FR 2377 (January 15, 2004) (notice of filing and immediate effectiveness of File No. SR–OCC–2003–01).

including using the last sale price during regular trading hours on the most recent trading day for which a last sale price is available.¹¹

Exchange rules also currently provide that the settlement price is calculated such that it will always round up \$.01 in those instances when the settlement price exactly equals an expiring strike price.¹² For example, if the calculated settlement price is \$20.00, and there are expiring ByRDs Finish High and Finish Low contracts with a strike price of \$20.00, the settlement price is rounded up to \$20.01 so that the Finish High options will pay off. The effect of rounding is to have long \$20.00 strike Finish High holders receiving \$100.00 and long \$20.00 strike Finish Low holders receiving \$0. Absent this rounding, a participant may potentially have a position that appears to guarantee a pay-off of \$100 at expiration but would instead receive \$0. For example, if an investor holds both a \$20.00 strike Finish High contract and a \$20.00 strike Finish Low contract, the investor will receive \$0 if the settlement price was calculated to exactly equal the \$20.00 strike price. Although the risk of the settlement price equaling the strike price is small, the Exchange believes that this could cause problems both for hedging and explaining to investors what would happen in the unusual circumstance where the settlement price matched the strike price of an expiring ByRDs option contract exactly. This rounding method ensures that either the Finish High or the Finish Low ByRDs option contracts will always pay off at expiration. The Exchange believes this results in less opportunity for investor confusion and less uncertainty for participants as a whole.

Proposed Rule Change

The purpose of the proposed rule change is to determine the settlement price of a ByRDs options contract by using the underlying security’s Closing Price, in place of using the security’s composite price VWAP on the day of expiration. In connection with the proposed rule change, the Exchange proposes the following changes to certain of the rules that permit the listing and trading of ByRDs.

First, the Exchange proposes to modify Rule 900ByRDs(b)(1) by amending the definition of “Binary Return Derivatives,” maintaining that ByRDs are European-style, but specifying more clearly via a new sentence that “ByRDs are automatically exercised at expiration pursuant to the

¹¹ *See* Rule 910ByRDs, Commentary .01.

¹² *See* Rule 910ByRDs, Commentary .02.

Rules of the Options Clearing Corporation, returning the settlement amount, equal to \$100, if the underlying security closes (1) at or above the strike price at expiration for Finish High ByRDs or (2) below the strike price at expiration for Finish Low ByRDs.” The Exchange also proposes to modify Rule 900ByRDs(b)(2) and Rule 900ByRDs(b)(3) to reflect the elimination of settlement price rounding practices, specifying instead that “Finish High” ByRDs return \$100 if the underlying security closes at or above the strike price at expiration (*i.e.*, in- or at-the-money) and “Finish Low” ByRDs return \$100 if the underlying security closes below the strike price at expiration (*i.e.*, in-the-money).

The Exchange next proposes to modify current Rule 900ByRDs(b)(5) by amending the definition of “Settlement Price” to mean the closing price of the security underlying the Binary Return Derivatives as reported by the primary listing market on the business day of their expiration, or, in the case of an option contract expiring on a day that is not a business day, on the last trading day prior to expiration. In connection with this change, the Exchange also proposes to delete Rule 900ByRDs(b)(4) in its entirety and renumber current Rule 900ByRDs(b)(5) and current Rule 900ByRDs(b)(6) (while also implementing minor language changes to current Rule 900ByRDs(b)(6) to further specify that the ByRDs settlement amount is a fixed amount in cash equal to \$100) as Rule 900ByRDs(b)(4) and Rule 900ByRDs(b)(5), respectively.

Next, the Exchange proposes to modify the first sentence of Rule 910ByRDs(a) to specify that ByRDs are “at-the-money,” “in-the-money,” or “out-of-the-money” as a function of the settlement price of the underlying security in relation to the type of ByRDs option (*i.e.*, Finish High or Finish Low) and the exercise price. The Exchange also proposes to revise the second sentence of Rule 900ByRDs(a). As proposed, the revised sentence would be as follows: “The Exchange will use the closing price of the security underlying the Binary Return Derivative as reported by the primary listing market on the business day of their expiration, or, in the case of an option contract expiring on a day that is not a business day, the business day immediately preceding the expiration date as reported by industry price vendors.”

Next, the Exchange proposes to delete current rule text in Rule 910ByRDs, Commentary .02, which discusses current settlement price rounding

practices, and replace it with proposed new rule text on how Finish High ByRDs will instead return the settlement amount if the underlying security closes at or above the strike price, while Finish Low ByRDs will return the settlement amount if the underlying security closes below the strike price.

The Exchange also proposes to amend Rule 915ByRDs, Commentary .01, to (a) raise the minimum market capitalization requirement in Rule 915ByRDs, Commentary .01(i) from \$40 billion to \$290 billion; and (b) adopt a new listing standard in Rule 915ByRDs, Commentary .01(vi), which would require a newly listed ByRDs option contract to “maintain an average daily trading value in the primary listing market’s closing auction of at least \$10 million over the prior six months.” The Exchange proposes to adopt the same listing criteria as a continued listing requirement in Rule 916ByRDs, Commentary .01(vi), for a ByRDs option contract.

Pursuant to Rule 958ByRDs, a Market Maker appointed to a ByRDs option contract is expected to quote with no more than \$0.25 between the bid and the offer for each ByRDs contract, except during the last trading day prior to expiration, when the maximum width may be \$0.50.¹³ The Exchange proposes to adopt new Commentary .02 under Rule 958ByRDs, which would provide that a Market Maker is not required to enter quotations in the ByRDs option contract in which it is appointed, but will be subject to the expectations set forth in Rule 958ByRDs if it chooses to do so. The Exchange believes not requiring Market Makers to continuously enter quotations in their appointed ByRDs class is appropriate because Market Maker appointments apply at the underlying security level, and a Market Maker appointed in an underlying security is therefore automatically appointed in that security’s corresponding ByRDs option contract as well, regardless of whether the Market Maker has chosen to participate in that product. Given that an appointment occurs automatically rather than by a Market Maker’s election, the Exchange does not believe it would be appropriate to enforce continuous quoting obligations in a ByRDs option contract absent some affirmative indication, such as entering a quote, that the Market Maker has chosen to participate in a particular series. If the Exchange required Market Makers to meet continuous quoting obligations in ByRDs option contracts regardless of this automatic

appointment, a Market Maker could be penalized for choosing not to quote despite never having elected to make a market in that product. The Exchange believes providing Market Makers with this flexibility promotes clarity and would encourage Market Maker participation without inadvertently penalizing them for not continuously quoting in a product in which they were automatically, rather than voluntarily, appointed.

The Exchange also proposes to amend Rule 980ByRDs to specify that at-the-money Finish High ByRDs will be automatically exercised in accordance with changes made to eliminate settlement price rounding practices, as proposed in amended Rule 910ByRDs, Commentary .02, discussed above.

Finally, the Exchange proposes to add new paragraph (v) to current Rule 928.1NYP(a)(3) to specify that the Arbitrage Checks for buy orders or quotes set forth in Rule 928.1NYP(b) and the Intrinsic Value Checks for sell orders or quotes set forth in Rule 928.1NYP(c) would not apply to Binary Return Derivatives. The Price Reasonability Checks are intended to prevent erroneous executions by automatically rejecting or cancelling orders that breach historical boundaries or arbitrage limits (such as buying a put option for more than its strike price). However, since ByRDs have a non-linear, “all-or-nothing” payout, the protections provided in Rule 928.1NYP are not needed. At expiration, they pay a completely flat, fixed return of exactly \$100.00 per contract if they finish in-the-money or at-the-money, regardless of whether the stock clears the strike price by one penny or one hundred dollars; If they finish out-of-the-money, they pay \$0.00. Because ByRDs lack traditional standard intrinsic value curves, the Exchange’s standard algorithmic checks designed for traditional equity options would not apply.¹⁴ In connection with this change, the Exchange proposes to adopt new Rule 928.1NYP(e) to reject all Limit Orders and quotes for ByRDs above the Exchange-designated maximum price for that class as determined on a class basis.¹⁵ Pursuant to Rule

¹⁴ The proposal to exclude Price Reasonability Checks from applying to ByRDs is not novel. See Rules 967NY, Commentary .01, and 967.1NY, Commentary .01. These rules applied to the trading of ByRDs on the Exchange’s legacy trading platform before the Exchange migrated to Pillar, the Exchange’s current trading platform. With this proposed rule change, the Exchange proposes to re-establish the exclusion that previously applied to ByRDs.

¹⁵ See proposed Rule 928.1NYP(e), which provides that the “Exchange will apply a maximum

¹³ See Rule 958ByRDs.

975NY(d)(3)(A), any transaction in ByRDs that is (1) higher or lower than the Theoretical Price by \$0.50 or more or (2) at a price greater than \$1.02 shall be deemed a Catastrophic Error, subject to the adjustment procedures of Rule 975NY(d)(3) unless such adjustment would result in a price higher than \$1.02, in which case the adjustment price shall be \$1.02. As a result, the Exchange believes it is appropriate to reject all Limit Orders and quotes for ByRDs above the Exchange-designated maximum price, *i.e.*, \$1.02.

The Exchange believes adopting the Closing Price to determine the settlement price of an expiring ByRDs option contract has several benefits and is appropriate for four reasons. First, the Closing Price is considered the most carefully determined price of the day. The Closing Price is determined by a call auction process run by the underlying security's primary listing exchange, which allows market participants to participate in real-time price discovery. It represents the consensus value after a full day of price discovery, with maximum participation from all market participants. Second, auctions are the among the most transparent parts of the market. Primary listings markets disseminate auction information frequently during a prescribed period of time, providing transparency to all market participants. This real-time flow of data—including indicative prices, imbalances, and matched volumes—gives all participants equal visibility in where the market is heading before the price is set. Third, Closing Prices (especially in highly-liquid securities such as those that qualify for ByRDs listings) are stable and not susceptible to manipulation. Because the Closing Price is set through a structured, transparent, rules-based auction aggregating broad order flow, it is far less susceptible to end-of-day price manipulation than other point-in-time benchmarks. Closing auction mechanisms are designed to make Closing Prices more reliable and less vulnerable to manipulation, providing a more robust and manipulation-resistant closing price discovery mechanism that reflects true supply and demand. Fourth, there is a concentration of liquidity to determine the Closing Price. Closing auctions within U.S. equity markets have grown significantly—in 2026, they have matched just over \$100 billion per day and accounted for 9.4%

price protection for Binary Return Derivatives on a class basis, pursuant to which the Exchange rejects all Limit Orders and quotes for Binary Return Derivatives above the Exchange-designated maximum price for that class.”

of total notional value traded.¹⁶ This concentration of liquidity makes closing auctions an especially efficient execution point, as large orders can be filled with minimal price impact.¹⁷

The continually-growing liquidity in closing auctions has been highlighted by numerous market practitioners and academics. NYSE and Nasdaq, in their capacity as primary listing exchanges, have each published several articles detailing liquidity trends and price-formation dynamics in their respective closing auctions.¹⁸ Due to the significant liquidity now present in closing auctions, auction “price impact is lower than during continuous trading.”¹⁹ Closing auctions’ growing liquidity encourages market participants to optimize their participation,²⁰ in turn adding still more liquidity and contributing to rising closing auction trade sizes. As State Street Investment Management recently stated:

“If the rise of Market-on-Close volume is best viewed as a structural response to the growth of indexing and benchmark-centric execution, we believe this cycle will continue: more indexing leads to more reliance on the close, which deepens liquidity at the final print and further anchors execution to that benchmark.”²¹

Additionally, the Commission has also recently issued Release No. 34–105882, “. . . Granting Conditional Exemptive Relief to the Chicago Mercantile Exchange Inc. from the Opening Price Settlement Requirements of Rule 6h–1(b) Under the Exchange Act for Certain Cash-Settled Security Futures.”²² To establish a single-stock futures product, which like binary options, is cash-settled, CME has received an exemption to use a closing price rather than an opening price settlement. In their application for this exemption, CME highlighted the growth in closing auction volumes in US equity markets and the use of official closing

prices in other products to support the position that closing auction liquidity was sufficiently robust to absorb any additional liquidity needs related to new derivative products.²³

When ByRDs were designed, the Exchange noted that by using a VWAP a trader may “smooth” the average price paid or realized for a large position. Specifically, the VWAP for a given underlying security means the sum of the dollar value of trades reported to the Consolidated Tape (price multiplied by number of shares traded) divided by the total number of shares traded during the entire last day of trading on the business day of their expiration. The concern at the time was that a single closing price could be more susceptible to manipulation, and that smoothing over a full day of trading would produce a more representative settlement value. The Exchange believes that rationale has been substantially overtaken by market structure developments over the last 2 decades, and that the Closing Price is now a superior alternative. For one, a VWAP settlement requires aggregating all trades reported to the Consolidated Tape across the entire trading day. This creates several practical problems: it depends on data vendor accuracy and timeliness, it requires handling of out-of-sequence and late reported trades (which can distort the calculation), and it is not a number any participant can observe in real time. By contrast, the closing price from the primary listing market is a single, publicly observable, instantaneous value produced by a supervised exchange auction process, available immediately and unambiguously at 4:00 p.m. Second, a full-day VWAP creates hedging complexity and mismatch. Because ByRDs currently settle on the full-day VWAP, a holder trying to hedge a ByRDs position on expiration day cannot do so cleanly—their hedge would need to track the cumulative weighted average of all trades from open to close, which shifts continuously throughout the day in ways that are difficult to replicate. A closing-price settlement, by contrast, would allow hedgers to concentrate their activity in the closing auction, which is exactly what participants in standard listed equity options already do. This alignment with standard options hedging practice would reduce friction and basis risk. The Exchange acknowledges that for cash-settled options generally, settlement based on the Closing Price may concentrate the unwinding of hedge positions in the

¹⁶ NYSE TAQ Consolidated Trade Data. Data through August 21, 2026.

¹⁷ *Id.*

¹⁸ See <https://www.nyse.com/data-insights/nyse-closing-auction-price-discovery-opportunities-reach-new-highs> and <https://www.nasdaq.com/articles/market-close-most-important-price-day>.

¹⁹ Vincent Bogousslavsky, Dmitriy Muravyev, *Who trades at the close? Implications for price discovery and liquidity*, Journal of Financial Markets, Volume 66, 2023, 100852, ISSN 1386–4181, <https://doi.org/10.1016/j.finmar.2023.100852>.

²⁰ “We are spending as much time as we ever have to understand the close and to optimizing engaging in the close,” Reyes said. From https://www.tradersmagazine.com/featured_articles/liquidity-remains-holy-grail-in-equities/.

²¹ <https://www.ssga.com/us/en/intermediary/insights/how-passive-investing-reshaping-microstructure>.

²² <https://www.sec.gov/files/rules/exorders/2026/34-105882.pdf>.

²³ <https://www.sec.gov/files/rules/exorders/2026/34-104786.pdf>.

closing auction, which adds a layer of mechanical flow that can amplify volatility. The Exchange believes, however, that this consideration does not raise significant concerns with respect to ByRDs, for the following reasons. First, ByRDs are subject to comparatively low position limits. Pursuant to Rule 904ByRDs, Binary Return Derivatives on each underlying security are subject to a position limit of 25,000 contracts on the same side of the market. This is the lowest position limit applicable to any options product under Rule 904, Commentary .07(e). The Exchange believes that this limit constrains the size of any hedge position that a market participant could be required to unwind at expiration. Second, the need to unwind positions in the underlying security at or near expiration is not a new risk introduced by closing-price settlement. Such activity was equally present under the VWAP settlement methodology when ByRDs were initially approved. Accordingly, the Exchange believes that the proposal does not introduce a new category of hedging activity. Third, the universe of eligible underlying securities is highly liquid. As set forth in Rule 915ByRDs, Commentary .01, an underlying security must satisfy heightened eligibility requirements, including a minimum market capitalization of \$290 billion and a minimum average daily trading value of \$10 million in the primary listing market's closing auction. In light of these requirements, the Exchange believes that any hedge unwinding at the close can be absorbed by the market without undue price impact. Lastly, VWAP is more susceptible to intraday manipulation than a supervised closing auction. This is somewhat counterintuitive given the original rationale for VWAP, but it is well-supported. "Marking the close"—where participants deliberately transact in the final period to move the VWAP toward a favorable settlement—is classified as market manipulation. Because VWAP is computed from all Consolidated Tape prints throughout the day, large coordinated order flow at any point during the session can shift the VWAP in ways that are difficult to detect in real time. A closing auction, by contrast, is a supervised, transparent, single-price process with published imbalance information that regulators and surveillance systems can monitor closely.²⁴

²⁴ NYSE improved transparency by moving the publication of auction imbalance information to 3:50 p.m., further hardening the auction against manipulation by giving market participants more

To reinforce the resilience of the ByRDs settlement price against manipulation, the Exchange proposes to condition ByRDs listing eligibility on the presence of sufficient closing auction liquidity. Specifically, as noted above, the Exchange proposes to amend Rule 915ByRDs, Commentary .01, to add a new eligibility requirement for the initial listing of a ByRDs option contract on an underlying stock. Proposed Rule 915ByRDs, Commentary .01(vi) would provide that to be eligible for an initial listing, individual stocks "maintain an average daily trading value in the primary listing exchange's closing auction of at least \$10 million over the prior six months."²⁵ The proposed new eligibility requirement would apply to the initial and continued listing of ETFs and Section 107 Securities also as the current rule provides that to be eligible for an initial listing of a ByRDs option contract, an ETF or Section 107 Security must meet the criteria for individual stocks set forth in Rule 915ByRDs, Commentary .01. Additionally, the proposed increase to the minimum market capitalization requirement, from \$40 billion to \$290 billion, would limit the number of underlying securities that would be eligible for an initial listing of a ByRDs option contract.²⁶

Applying both the amended ByRDs listing liquidity thresholds and the newly-proposed auction liquidity threshold to eligible listed securities yields 100 eligible ByRDs underliers, as opposed to the 305 eligible ByRDs underliers without the newly proposed criteria. The median closing auction value traded across these 100 eligible securities is \$92.5 million per day, based on a recent review conducted by the Exchange.

The Exchange believes the proposed new eligibility requirement makes using Closing Price to determine the settlement price less susceptible to manipulation. Because the Closing Price is set through a single, centralized auction that consolidates the full day's residual buying and selling interest into one print, influencing that price requires trading against the entire pool

time to respond to imbalances. See Securities Exchange Act Release No. 100327 (June 13, 2024), 89 FR 51918 (June 20, 2024) (SR-NYSE-2024-13) (Order Approving a Proposed Rule Change Amending Rule 7.35 and Rule 7.35B).

²⁵ The Exchange proposes amending Rule 916ByRDs, Commentary .01, which would require the proposed new eligibility requirement for the continued listing of a ByRD contract also.

²⁶ The Exchange represents that it will monitor both initial and continued listing criteria applicable to ByRDs on an ongoing basis and will submit a proposed rule change to make changes no later than four months from the date that ByRDs begin to trade on the Exchange.

of auction liquidity rather than a thin, point-in-time quote. At the liquidity levels required by proposed new Rule 915ByRDs, Commentary .01(vi), a participant seeking to move the close by any meaningful amount would have to commit substantial capital against prevailing order flow and absorb the offsetting interest of other participants, all within a brief and closely observed window. The closing auction's transparency compounds that burden: with indicative prices, imbalances, and matched volumes disseminated in real time, a distortive order becomes visible to the market and tends to draw offsetting liquidity that both counters it and further stabilizes the Closing Price. The economic cost and ready detectability of such conduct, together with the deep and growing liquidity of U.S. closing auctions described above, make the closing auction a robust and manipulation-resistant basis for determining ByRDs settlement prices.

Similarly, the Exchange believes eliminating the settlement price rounding convention is reasonable and appropriate because it removes an unnecessary and artificial adjustment to price data that is no longer needed to achieve its intended purpose. Under the current rules, the Settlement Price is rounded up \$0.01 whenever it would otherwise exactly match the strike price of an expiring ByRDs option contract, solely to ensure that a Finish High contract pays off rather than leaving both the Finish High and Finish Low contracts unexercised. However, because Finish High ByRDs as proposed would be defined to pay off whenever the underlying security closes at or above the strike price—a category that already includes an exact match—this outcome is achieved automatically by the definition itself, without requiring any adjustment of the reported price.

The Exchange believes that removing the rounding convention has several benefits. First, it allows the Settlement Price to reflect the underlying security's actual, unadjusted Closing Price, rather than an artificial value that may not correspond to any price at which the security actually traded or was reported. This promotes transparency and consistency between the Settlement Price used for ByRDs and the Closing Price used elsewhere for the same underlying security. Second, it would simplify the rule structure by resolving the at-the-money scenario through the proposed payout definitions of a Finish High ByRD and a Finish Low ByRD, rather than through a separate, purpose-built rounding mechanism layered on top of such rules. Lastly, it would eliminate any potential investor

confusion that could arise from a reported Settlement Price that differs by \$0.01 from the security's actual closing price for no economic reason other than avoiding a tie. For these reasons, the Exchange believes the proposed change is consistent with accurately and transparently determining ByRDs settlement outcomes and does not disadvantage either side of an expiring Finish High or Finish Low ByRDs option contract.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act²⁷ in general, and furthers the objectives of Section 6(b)(5) of the Act.²⁸ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

Specifically, the Exchange believes that adopting the Closing Price to determine the settlement price of an expiring ByRDs option contract would increase participation among investors to trade in binary options given the importance of the closing auction on primary listing markets and, as discussed above, would reduce the hedging friction and basis risk associated with the current full-day VWAP methodology by aligning ByRDs settlement with the closing-auction hedging practices already standard among listed options market participants, a benefit that also furthers the protection of investors by reducing the difficulty of explaining and managing settlement risk for ByRDs holders. The NYSE closing auction remains the largest liquidity event in the U.S. equity market. The closing price produced by these auctions reflects a deep concentration of institutional and retail order flow precisely calibrated to produce a single, authoritative reference price, and thereby remove any impediments to and perfect the mechanism of a free and open market.

The Exchange believes the proposal to adopt the Closing Price to determine the

settlement price of an expiring ByRDs option contract would remove impediments to and perfect the mechanism of a free and open market for several reasons. First, the Closing Price is considered the most carefully determined price of the day as it is determined by a call auction process run by the underlying security's primary listing exchange, which allows market participants to participate in real-time price discovery. Second, primary listing markets disseminate auction information frequently during a prescribed period of time, providing transparency to all market participants. This real-time flow of data gives all participants equal visibility in where the market is heading before the price is set. Third, closing prices (especially in highly-liquid securities such as those that qualify for ByRDs listings) are stable and not susceptible to manipulation. Because the Closing Price is set through a structured, transparent, rules-based auction aggregating broad order flow, it is far less susceptible to end-of-day price manipulation than other point-in-time benchmarks consistent with the Section 6(b)(5) requirement that exchange rules be designed to prevent fraudulent and manipulative acts and practices. By contrast, because VWAP is computed by aggregating trades reported to the Consolidated Tape across the entire trading day, it can be moved by coordinated trading at any point during the session in ways that are difficult to detect in real time, a vulnerability the proposed change eliminates by settling ByRDs against a single, supervised auction print instead. Closing auction mechanisms are designed to make Closing Prices more reliable and less vulnerable to manipulation, providing a more robust and manipulation-resistant closing price discovery mechanism that reflects true supply and demand. Lastly, closing auctions within U.S. equity markets have grown significantly. This concentration of liquidity makes closing auctions an especially efficient execution point, as large orders can be filled with minimal price impact.

The Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would determine the settlement price of a ByRDs option contract using the Closing Price of the underlying security at expiration, while also reinforcing the resistance of that settlement price to manipulation. The Closing Price is a carefully designed, rules-based reference anchored to a closing auction

process: transparent, liquidity-rich, resistant to manipulation, and widely trusted. Using it to settle an expiring ByRDs option contract further perfects the mechanism of a free and open market because it would yield a settlement price that reflects the most recent and reliable market information available. The proposed rule change also furthers the Act's objective of fostering cooperation and coordination among persons engaged in facilitating transactions in securities by relying directly on the auction process conducted by the underlying security's primary listing market rather than requiring the Exchange to independently construct a settlement value. The Exchange does not believe that using Closing Price to determine the settlement price of a ByRDs option contract at expiration would render the marketplace for such options more susceptible to manipulative practices. The Exchange notes that, as discussed above, the Commission has recognized the robustness of closing auction liquidity in an analogous context, granting the Chicago Mercantile Exchange conditional exemptive relief to use a closing, rather than opening, price to settle certain cash-settled single-stock futures based in part on the growth of closing auction volumes and the use of official closing prices in other products, which the Exchange believes further supports the reliability of the Closing Price as a settlement benchmark for ByRDs.

The Exchange believes that the trading of ByRDs would provide investors with a potentially useful investment choice, which aids in perfecting the mechanism of a free and open market and a national market system. In addition, and consistent with the Commission's findings when initially approving ByRDs for listing, listing ByRDs "will extend to certain binary options the benefits of a listed exchange market, which include: A centralized forum for price discovery; pre- and post-trade transparency; standardized contract specifications; and the guarantee of the OCC."²⁹ The Exchange believes those benefits are reinforced, rather than diminished, by a settlement price that is itself transparent and manipulation-resistant, since the value of a centralized, standardized, OCC-guaranteed market depends in part on the integrity of the price used to determine the payout of an auto-exercised contract.

The Exchange also believes that eliminating the settlement price rounding convention in favor of

²⁷ 15 U.S.C. 78f(b).

²⁸ 15 U.S.C. 78f(b)(5).

²⁹ See *supra* note 5 at 46524.

allowing the Finish High and Finish Low definitions to resolve the at-the-money scenario is consistent with Section 6(b)(5) and, in particular, promotes just and equitable principles of trade and protects investors and the public interest. The proposed change is intended to add clarity and transparency to Exchange rules making them easier to navigate and comprehend and does not change the outcome of a position in a ByRDs option contract under the current rules. Because Finish High ByRDs as proposed are defined to pay off whenever the underlying security closes at or above the strike price, the existing rounding convention is an unnecessary artificial adjustment to the reported Closing Price that is no longer needed to produce a definitive outcome for expiring at-the-money contracts. Removing this convention ensures that the settlement price used for ByRDs reflects the underlying security's actual, unadjusted Closing Price, consistent with the transparency and manipulation-resistance benefits described above, rather than a value adjusted for a purpose unrelated to the integrity of that price. The Exchange believes this promotes investor understanding of how ByRDs are settled and removes an impediment to a free and open market by eliminating a divergence between the settlement price used for ByRDs and the actual Closing Price of the underlying security.

The Exchange believes the proposed increase to the minimum market capitalization requirement coupled with the proposed addition of the new eligibility requirement for the initial and continued listing of a ByRDs option contract would remove impediments to and perfect the mechanism of a free and open market because only a select list of 100 underlying securities would meet the qualification requirement to have a ByRDs option contract listed on, which further ensures that a ByRDs option contract would only be listed on some of the most liquid and actively-traded underlying securities. Applying both the existing ByRDs listing liquidity thresholds, with an increased minimum market capitalization requirement, and the newly-proposed \$10 million average daily closing auction trading value threshold yields approximately 100 eligible ByRDs underliers, with a median closing auction value traded of \$92.5 million per day across those securities. At these liquidity levels, a participant seeking to move the Closing Price by a meaningful amount would need to commit substantial capital against prevailing order flow within a brief, closely observed window, and the

closing auction's real-time dissemination of indicative prices and imbalances would make such an attempt visible to the market and likely to draw offsetting liquidity, consistent with the Exchange's own recent enhancement moving publication of auction imbalance information earlier in the day.³⁰ The Exchange believes the proposed eligibility criteria to qualify the listing of a ByRDs option contract is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Section 6(b)(5), in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest because only large, well-capitalized, and highly liquid issuers would qualify. Securities with high market capitalization and liquid markets are generally less susceptible to manipulation because of the substantial capital required to artificially influence prices of those securities. The depth and breadth of trading activity for securities with significant market capitalization make it unlikely that a single market participant would be able to exert undue influence on the price of such a stock, as large volumes of buyers and sellers are what ultimately continuously reflect the true market value of the stock.

The proposed rule change to use the Closing Price to determine the settlement price on the 100 underlying securities is designed to promote just and equitable principles of trade in that the proposal would give market participants an alternative to trading similar products in the over-the-counter (OTC) market. By trading a product in an exchange-traded environment (that is currently traded in the OTC market or other platforms that trade binary options), the Exchange would be able to compete more effectively with the OTC market. The Exchange believes the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that it would lead to the migration of options currently trading in the OTC market and other platforms to trading on the Exchange, where such trading would become subject to the Exchange's surveillance, audit trail, and member conduct rules that do not apply to comparable OTC or other-platform trading today. Also, any

migration to the Exchange from such other markets would result in increased market transparency. Additionally, the Exchange believes the proposed rule change is designed to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest in that it should create greater trading and hedging opportunities and flexibility. The proposed rule change should also result in enhanced efficiency in initiating and closing out positions and heightened contra-party creditworthiness due to the role of OCC as issuer and guarantor of ByRDs option contracts. Further, the proposed rule change would result in increased competition by permitting the Exchange to offer products that are currently available for trading in the OTC market and other platforms.

The Exchange believes not requiring Market Makers to continuously enter quotations in their appointed ByRDs class is consistent with the Act, protects investors, and prevents fraudulent and manipulative acts because Market Maker appointments apply at the underlying security level, and a Market Maker appointed in an underlying security is therefore automatically appointed in that security's corresponding ByRDs option contract as well, regardless of whether the Market Maker has chosen to participate in that product. Given that an appointment occurs automatically rather than by a Market Maker's election, the Exchange does not believe it would be appropriate to enforce continuous quoting obligations in a ByRDs option contract absent some affirmative indication, such as entering a quote, that the Market Maker has chosen to participate in a particular series.

The Exchange believes the proposed amendments to Rule 928.1NYP promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system and protects investors, to not apply the Price Reasonability Checks to ByRDs is a reasonable and justified product-specific accommodation that promotes orderly trading and clear, consistent treatment of transactions in these contracts. Additionally, applying a maximum execution price protection for ByRDs on a class basis, pursuant to which any execution price for a ByRDs option contract above the Exchange-designated maximum execution price for that class would be rejected would promote just and equitable principles of trade and remove impediments to and perfects the mechanism of a free and

³⁰ See note 25, *supra*.

open market and a national market system and protects investors. This protection provides investors with an additional safeguard against executions at potential erroneous prices, which the Exchange believes protects investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because the proposed rule change to use the Closing Price to determine the settlement price of ByRDs option contracts will apply equally to all market participants who wish to trade such options on the same terms and in the same manner (including with respect to the payout terms and amount). All market participants will be subject to the same rules applicable to ByRDs option contracts, as described in this proposed rule change. Except as set forth in this proposed rule change, ByRDs option contracts will trade in the same manner as other options on the Exchange.

The Exchange does not believe the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because other options exchanges may propose similar binary options. Additionally, substantively similar products to ByRDs option contracts are available in the OTC market and various other trading platforms.

The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues who offer similar products. The Exchange believes the proposed rule change will provide investors with a comparable alternative to the OTC market and other trading venues. The Exchange believes it may be a more attractive alternative to the OTC market and these other venues, as market participants will benefit from being able to trade these options in an exchange environment, which provides, among other things: (1) enhanced efficiency in initiating and closing out positions; (2) increased market transparency; and (3) heightened contra-party creditworthiness. As a result, the Exchange believes that the proposed rule change may relieve any burden on, or otherwise promote, competition, as it

will allow the Exchange to offer a securities exchange-listed alternative to the products currently available in these other markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act³¹ and subparagraph (f)(6) of Rule 19b-4 thereunder.³²

A proposed rule change filed under Rule 19b-4(f)(6)³³ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),³⁴ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The proposed rule change is designed to provide market participants with additional trading and hedging opportunities that could be better tailored to their investment objectives. The Exchange has proposed heightened eligibility criteria that would limit the underlying equity securities on which the Exchange could list a ByRDs option contract to 100 highly-liquid securities. This limitation should help mitigate the impact (if any) of ByRDs on the closing process of the underlying equity securities and the concern that using an equity security's Closing Price to determine the settlement price at expiration for a ByRDs option contract overlying that equity security could

cause excessive volatility or an increased potential for manipulation at the close in the underlying security. For these reasons, the Commission finds that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposal operative upon filing.³⁵

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEAMER-2026-96 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSEAMER-2026-96. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish

³¹ 15 U.S.C. 78s(b)(3)(A).

³² 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

³³ 17 CFR 240.19b-4(f)(6).

³⁴ 17 CFR 240.19b-4(f)(6)(iii).

³⁵ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEAMER–2026–96 and should be submitted on or before November 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁶

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22132 Filed 10–29–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106744; File No. SR–CboeBYX–2026–039]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 11.1(a) To Adopt a Start Time Order Instruction

October 27, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on October 15, 2026, Cboe BYX Exchange, Inc. (the “Exchange” or “BYX”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a “non-controversial” proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b–4(f)(6) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

Cboe BYX Exchange, Inc. (“BYX” or the “Exchange”) is filing with the Securities and Exchange Commission (“Commission” or “SEC”) a proposed rule change to amend Rule 11.1(a) to adopt a Start Time order instruction, based on the Start Time instruction adopted by its affiliated exchange, Cboe EDGX Exchange, Inc. (“EDGX”). The

text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission’s website (<https://www.sec.gov/rules/sro.shtml>), the Exchange’s website (https://www.cboe.com/us/equities/regulation/rule_filings/byx/), and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 11.1(a) to adopt a “Start Time” order instruction that would permit a User to designate, in thirty-minute increments prior to the commencement of Regular Trading Hours,⁵ the time at which an order entered prior to Regular Trading Hours becomes eligible for execution. The proposed rule change is based on EDGX Rule 11.1(a)(2),⁶ but the Exchange is proposing to adopt only the Start Time instruction and related provisions. The Exchange intends to implement the proposed rule change on December 7, 2026, in coordination with the implementation of the Start Time instruction on EDGX, so that Members have access to consistent order handling functionality across the Cboe-affiliated equities exchanges.

Current Rule

Under current Rule 11.1(a), Users may enter orders into the System from 6:00 a.m. until 8:00 p.m. Eastern Time (“ET”).⁷ Orders entered between 6:00

a.m. and 7:00 a.m. are not eligible for execution until the start of the Early Trading Session,⁸ Pre-Opening Session,⁹ or Regular Trading Hours, depending on the Time in Force¹⁰ selected by the User. At the commencement of the Early Trading Session, orders entered between 6:00 a.m. and 7:00 a.m. are handled in time sequence, beginning with the order with the oldest time stamp, and are placed on the BYX Book, routed, cancelled, or executed in accordance with the terms of the order. The current rule therefore provides a single, fixed point (the commencement of the Early Trading Session at 7:00 a.m.) at which orders entered prior to the Early Trading Session become eligible for execution, and does not permit a User to designate a later point prior to Regular Trading Hours at which an order becomes eligible.

Current Rule 11.1(a) also provides that the Exchange will not accept the following orders prior to 7:00 a.m.: BYX Post Only Orders,¹¹ ISOs,¹² BYX Market Orders¹³ other than those with a Time in Force of Regular Hours Only or Stop Orders,¹⁴ Minimum Quantity Orders¹⁵ that also include a Time in Force of Regular Hours Only, RPI Orders,¹⁶ and all orders with a Time in Force of IOC¹⁷ or FOK.¹⁸

Proposed Start Time Instruction

The Exchange proposes to amend the time-sequencing provision so that it is no longer limited to orders entered between 6:00 a.m. and 7:00 a.m., and to adopt a flexible Start Time instruction. As proposed, in addition to the Time in Force, a User may also designate a start time for an order (“Start Time”). Start Times may be designated in thirty-minute increments and must be set to a time prior to the commencement of Regular Trading Hours; Start Times may not be designated during Regular Trading Hours. This language is substantively identical to the Start Time language in EDGX Rule 11.1(a)(2), which replaced EDGX’s 4:00 a.m. Start and 7:00 a.m. Start designations with the same flexible and uniform framework. Because orders on the Exchange are not eligible for execution prior to the commencement of the Early Trading Session at 7:00 a.m., the earliest

⁸ See Exchange Rule 1.5(ff).

⁹ See Exchange Rule 1.5(r).

¹⁰ See Exchange Rule 11.9(b).

¹¹ See Exchange Rule 11.9(c)(6).

¹² See Exchange Rule 11.9(d).

¹³ See Exchange Rule 11.9(a)(2).

¹⁴ See Exchange Rule 11.9(c)(16).

¹⁵ See Exchange Rule 11.9(c)(5).

¹⁶ See Exchange Rule 11.24(a)(3).

¹⁷ See Exchange Rule 11.9(b)(1).

¹⁸ See Exchange Rule 11.9(b)(6).

³⁶ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b–4(f)(6).

⁵ See Exchange Rule 1.5(w).

⁶ See Securities Exchange Act Release No. 105587 (May 29, 2026), 91 FR 33238 (June 3, 2026) (SR–CboeEDGX–2026–019) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Amended by Amendment No. 1, To Extend the Exchange’s Trading Hours to 23 Hours per Day, Five Days per Week) (“EDGX Approval Order”).

⁷ See Exchange Rule 11.1(a). All times stated herein are in ET.

Start Time that will have practical effect is 7:00 a.m., and the latest permissible Start Time is 9:00 a.m.

The Exchange also proposes to provide that, at the commencement of the Early Trading Session and at each Start Time, orders will be handled in time sequence, beginning with the order with the oldest time stamp, and will be placed on the BYX Book, routed, cancelled, or executed in accordance with the terms of the order. This provision is consistent with the sequencing provision adopted by EDGX, which provides that, at each Start Time, orders will be handled in time sequence beginning with the oldest time stamp.¹⁹ The Exchange proposes to retain the reference to the commencement of the Early Trading Session so that orders that are entered prior to the Early Trading Session without a Start Time designation continue to become eligible for execution, in time sequence, at the commencement of the Early Trading Session, as they do today.

For example, a User may enter an order at 6:15 a.m. with a Start Time of 8:00 a.m. That order would be accepted but would not be eligible for execution until 8:00 a.m., at which time it would be handled in time sequence with all other orders designated with an 8:00 a.m. Start Time, beginning with the order with the oldest time stamp, and would be placed on the BYX Book, routed, cancelled, or executed in accordance with its terms.

Order Acceptance Restrictions

The Exchange proposes to amend the order acceptance restrictions in Rule 11.1(a) so that they apply prior to 7:00 a.m. or, if later, prior to the order's designated Start Time. The Exchange is not proposing any change to the categories of orders subject to these restrictions, which will continue to be: BYX Post Only Orders, ISOs, BYX Market Orders other than those with a Time in Force of Regular Hours Only or Stop Orders, Minimum Quantity Orders that also include a Time in Force of Regular Hours Only, RPI Orders, and all orders with a Time in Force of IOC or FOK. The Exchange is also retaining the existing 7:00 a.m. threshold. Under the proposal, an order in one of these categories designated with a Start Time later than 7:00 a.m. will not be accepted prior to its Start Time. Today, the Exchange does not accept these orders before 7:00 a.m., when orders first become eligible for execution. Tying the restrictions to an order's designated Start Time applies the same approach to

the more flexible Start Time framework, so that these orders are not accepted before the point at which the order may execute. EDGX similarly ties its order acceptance restrictions to the period before orders become eligible for execution, which on EDGX is the Order Acceptance Queueing Time.²⁰

The Exchange is not proposing to change its order entry window, which will continue to begin at 6:00 a.m., or the Time in Force instructions available to Users. Orders entered prior to the Early Trading Session without a Start Time designation will continue to become eligible for execution at the start of the Early Trading Session, Pre-Opening Session, or Regular Trading Hours, depending on the Time in Force selected by the User. Use of the Start Time instruction is optional.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.²¹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)²² requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed Start Time instruction removes impediments to and perfects the mechanism of a free and open market and a national market system because it replaces the single fixed point at which orders entered prior to the Early Trading Session become eligible for execution with a flexible and uniform framework. Under that framework, Members may

control the time at which their orders become eligible for execution prior to Regular Trading Hours. The Commission approved the same Start Time framework for EDGX, which replaced EDGX's 4:00 a.m. Start and 7:00 a.m. Start construct.²³ The Start Time instruction provides Members with additional flexibility to manage the timing of their order flow in the period before Regular Trading Hours. This includes aligning order eligibility with anticipated market conditions or with their own trading strategies, without requiring Members to manually enter orders at a particular time.

The Exchange believes the proposed time-sequencing provision promotes just and equitable principles of trade and protects investors because orders that become eligible at the commencement of the Early Trading Session or at a given Start Time will be handled in a transparent and objective manner, in time sequence beginning with the order with the oldest time stamp. This is the same manner in which orders are handled today at the commencement of the Early Trading Session, and it is consistent with the sequencing provision approved for EDGX.

The Exchange believes that tying the existing order acceptance restrictions to the later of 7:00 a.m. or the order's designated Start Time protects investors and the public interest. The proposal preserves the existing categories of restricted orders and the existing 7:00 a.m. threshold. It applies those restrictions consistently to orders that will not be eligible for execution until a later Start Time, ensuring that order types that are not suitable for queueing are not accepted before the order may execute. The proposed rule change does not loosen any existing restriction.

The proposed rule change also promotes consistency across the Cboe-affiliated equities exchanges, which reduces complexity for Members that access multiple Cboe-affiliated exchanges and fosters cooperation and coordination with persons engaged in facilitating transactions in securities. The proposed rule change does not permit unfair discrimination because the Start Time instruction will be available to all Members on the same terms, and its use is optional.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance

¹⁹ See EDGX Rule 11.1(a)(2); EDGX Approval Order, *supra* note 6.

²⁰ See EDGX Rule 11.1(a)(3); EDGX Approval Order, *supra* note 6. Because the Exchange does not operate an Overnight Trading Session or an Order Acceptance Queueing Time, the Exchange proposes to tie the restrictions to the existing 7:00 a.m. threshold and the order's designated Start Time.

²¹ 15 U.S.C. 78f(b).

²² 15 U.S.C. 78f(b)(5).

²³ See EDGX Approval Order, *supra* note 6.

of the purposes of the Act. The Exchange does not believe the proposed rule change will impose any burden on intramarket competition because the Start Time instruction will be available to all Members on an equal and non-discriminatory basis, and its use is optional. The Exchange does not believe the proposed rule change will impose any burden on intermarket competition because it is based on a rule that the Commission approved for EDGX, and it is designed to provide Members with consistent order handling functionality across the Cboe-affiliated equities exchanges rather than to address any competitive issue. Other exchanges are free to adopt similar functionality.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act²⁴ and Rule 19b-4(f)(6)²⁵ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-CboeBYX-2026-039 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-CboeBYX-2026-039. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CboeBYX-2026-039 and should be submitted on or before November 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁶

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-22133 Filed 10-29-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-106741; File No. SR-IEX-2026-41]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Pursuant to IEX Rule 15.110(a) and (c) To Amend the Exchange's Fee Schedule To Adopt Transaction Fees and Routing Fees

October 27, 2026.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the "Act")² and Rule 19b-4 thereunder,³

notice is hereby given that, on October 14, 2026, the Investors Exchange LLC ("IEX" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,⁴ and Rule 19b-4 thereunder,⁵ the Exchange is filing with the Commission a proposed rule change to amend the Exchange's fee schedule applicable to Options Members⁶ ("Options Fee Schedule") pursuant to IEX Rules 15.110(a) and (c) to adopt transaction fees and routing fees, and to update the Preface and Definitions sections of the Options Fee Schedule. Changes to the Options Fee Schedule pursuant to this proposal are effective upon filing.⁷

The text of the proposed rule change is available at the Exchange's website at <https://www.iexexchange.io/resources/regulation/rule-filings> and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

In preparation for the October 2, 2026 commencement of trading options on IEX Options, IEX filed a proposed rule change to establish the transaction and routing fees it would charge Options

²⁴ 15 U.S.C. 78s(b)(3)(A).

²⁵ 17 CFR 240.19b-4(f)(6).

²⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ 15 U.S.C. 78s(b)(1).

⁵ 17 CFR 240.19b-4.

⁶ See Rule 17.100.

⁷ 15 U.S.C. 78s(b)(3)(A)(ii).

Members.⁸ On October 14, 2026, IEX concurrently withdrew the Initial Transaction Fee Filing and replaced it with this proposed rule change, which makes no changes to the fees and credits proposed in the Initial Transaction Fee Filing, but provides additional support and context for certain of the fees and credits. Thus, this filing also (i) defines terms in the Preface and Definitions Sections of the Options Fee Schedule that are used throughout the Options Fee Schedule; (ii) establishes transaction fees and credits applicable to all Options Members trading on IEX Options (“Transaction Fees and Credits”); and (iii) establishes routing fees applicable to all Options Members trading on IEX Options who route orders to away exchanges (“Linkage Routing Fees”).

Updates to Preface Section

The Options Fee Schedule has a Preface section that currently has one paragraph, which provides information about billing disputes. The Exchange proposes to add a new paragraph directly following the billing disputes paragraph, which describes the rounding of fees that the Exchange would calculate on the basis of transaction volume. Specifically, the Exchange proposes to add a paragraph with the heading “Rounding,” which explains that the Exchange would apply the applicable fee rate to the sum of an Option Member’s volume for the month and where a fractional cent occurs, the Exchange would round up to the nearest whole cent for purposes of computing the Option Member’s invoice. The proposed text reads in full:

All volume for the month will be summed and the applicable rate applied. In those cases where a fractional cent occurs, the Exchange will round up to the nearest whole cent for purposes of computing the invoice.

The Exchange believes that including this Rounding paragraph in the Preface to the Options Fee Schedule provides clarity about how the Exchange computes fees. The Exchange’s proposed language is consistent with similar language included in the fee schedule of one other exchange.⁹

⁸ See SR-IEX–2026–38 (filed September 30, 2026) (“Initial Transaction Fee Filing”).

⁹ See NYSE American Options Fee Schedule, effective September 17, 2026, available at https://www.nyse.com/publicdocs/nyse/markets/american-options/NYSE_American_Options_Fee_Schedule.pdf; Securities Exchange Act Rel. No. 74086 (January 16, 2015), 80 FR 3701 (January 23, 2015) (SR–NYSEMKT–2015–04) (proposing to add a description of the exchange’s rounding practices to the fee schedule).

Updates to Definitions Section

The Exchange includes a Definitions section at the beginning of the Options Fee Schedule for terms that are used throughout the Options Fee Schedule. The purpose of the Definitions section is to streamline the Options Fee Schedule by placing many of the defined terms used in the Options Fee Schedule in one location. For ease of reference and readability, the Exchange proposes adding several definitions to the Definitions section of the Options Fee Schedule, all of which relate to the Transaction Fees and Credits section of the Options Fee Schedule. Many of the defined terms are also defined in the IEX Options Rules, particularly in Rule 17.100. IEX proposes arranging the following definitions in alphabetical order with the previously defined terms in the Options Fee Schedule:¹⁰

- An “Away Market Maker” for the purposes of this fee schedule shall mean a non-IEX Market Maker.
- A “Broker-Dealer” means an individual or organization registered with the Commission in accordance with Section 15(b)(1) of the Exchange Act or a foreign broker or dealer exempt from such registration pursuant to Rule 15a-6 under the Exchange Act. See Rule 28.100.
- The “Exchange System” or “System” means the automated trading system used by IEX Options for the trading of options contracts. See Rule 22.100(a).
- A “Firm” means a Broker-Dealer that is not registered as a Market Maker that is an Options Member of the Exchange. See Rule 28.100.
- A “Non-Penny” option refers to option classes that do not participate in the Penny Interval Program, as described in Rule 22.140.
- A “Non-Priority Customer” means anyone who is not a “Priority Customer.”
- A “Penny” option refers to option classes that participate in the Penny Interval Program, as described in Rule 22.140.
- A “Priority Customer” means any person or entity that is not: (A) a broker or dealer in securities; or (B) a Professional.
- A “Professional” means any person or entity that (A) is not a broker or dealer in securities; and (B) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s).
- The “Step Up Mechanism” is a feature within the System that provides

¹⁰ Currently, the defined terms in the Options Fee Schedule are: “Clearing Member,” “Market Maker,” “MPID,” and “Order Entry Firms” (or “OEFs”).

automated order handling in designated classes trading for qualifying orders that are not automatically executed by the System. See Rule 22.270.

IEX notes that other exchanges similarly set forth certain definitions of terms used in their fee schedules in definitions sections in their respective fee schedules.¹¹

Transaction Fees and Credits

IEX Options generally operates a “Maker-Taker” model, whereby it provides credits to Options Members that provide liquidity and charges fees to those that remove liquidity. The proposed credits and fees vary depending on the capacity of the two sides to a transaction, whether the applicable options class participates in the Penny Interval Program (“Penny Classes”)¹² or does not participate in the Penny Interval Program (“Non-Penny Classes”),¹³ and whether the transaction adds or removes liquidity from the IEX Options Book.

Section I of the Options Fee Schedule, which is titled “Transaction Fees and Credits,” is currently “Reserved.” IEX proposes to delete the word “Reserved” and replace it with language describing the transaction fees and credits in this fee proposal. Specifically, IEX proposes to begin Section I with the words “The following transaction rates apply to all options classes. Listed rates are per contract.

Credits are indicated by parentheses (.)” This introductory text will be followed by Section I.A (“Options Transaction Fees and Credits”) that has two tables showing fees and credits for Penny Classes and for Non-Penny Classes followed by some additional text, which is followed by Section I.B (“Linkage Routing Fees”) that has a table showing fees for routing Penny Class and Non-Penny Class options.

¹¹ See, e.g., MIAX Sapphire Options Exchange Fee Schedule as of August 17, 2026 (“MIAX Sapphire Fee Schedule”), available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Sapphire_Fee_Schedule_08172026.pdf; MIAX Emerald Options Exchange Fee Schedule as of August 1, 2026 (“MIAX Emerald Fee Schedule”), available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Emerald_Fee_Schedule_08012026.pdf.

¹² Options trading pursuant to the Penny Interval Program have a minimum quoting increment of \$0.01 if the series is trading at less than \$3.00 per contract and \$0.05 if the series is trading at \$3.00 or higher per contract, except for QQQ, SPY, and IWM which always have \$0.01 quoting increments. See Rule 22.140(a)(3).

¹³ Options that do not trade pursuant to the Penny Interval Program have a minimum quoting increment of \$0.05 if the series is trading at less than \$3.00 per contract and \$0.10 if the series is trading at \$3.00 or higher per contract. See Rule 22.140(a)(1) & (2).

IEX's proposed transaction fees and credits for Penny Classes do not differentiate between the capacity of the counterparties to the transaction. The following fees shall apply to executions of Penny Classes:

- A Priority Customer that adds liquidity will receive a \$0.32 credit per contract, and a Priority Customer that removes liquidity will pay a \$0.34 fee per contract.
- A Professional that adds liquidity will receive a \$0.28 credit per contract, and a Professional that removes liquidity will pay a \$0.40 fee per contract.
- A Market Maker that adds liquidity will receive a \$0.26 credit per contract, and a Market Maker that removes liquidity will pay a \$0.43 fee per contract.
- An Away Market Maker that adds liquidity will receive a \$0.22 credit per contract, and an Away Market Maker that removes liquidity will pay a \$0.45 fee per contract.
- A Firm/Broker-Dealer that adds liquidity will receive a \$0.26 credit per contract, and a Firm/Broker-Dealer that removes liquidity will pay a \$0.40 fee per contract.

IEX's proposed transaction fees and credits for Non-Penny Classes differentiate between the capacity of the counterparties to the transaction, as described below. Specifically, IEX proposes to charge different transaction fees and credits to the Options Member depending on whether its counterparty in a transaction is a Priority Customer or a Non-Priority Customer. The following fees and credits shall apply to executions of Non-Penny Classes:

- A Priority Customer that adds liquidity will receive a \$0.70 credit per contract if the counterparty is a Non-Priority Customer and pay \$0.00 per contract if the counterparty is a Priority Customer; a Priority Customer that removes liquidity will receive an \$0.85 credit per contract if the counterparty is a Non-Priority Customer and pay \$0.00 per contract if the counterparty is a Priority Customer.
- A Professional that adds liquidity will pay \$0.00 per contract if the counterparty is a Non-Priority Customer and pay \$0.95 per contract if the counterparty is a Priority Customer; a Professional that removes liquidity will pay \$0.25 per contract if the counterparty is a Non-Priority Customer and pay \$0.95 per contract if the counterparty is a Priority Customer.
- A Market Maker that adds liquidity will receive a \$0.10 credit per contract if the counterparty is a Non-Priority Customer and pay \$0.95 per contract if the counterparty is a Priority Customer;

a Market Maker that removes liquidity will pay \$0.25 per contract if the counterparty is a Non-Priority Customer and pay \$0.95 per contract if the counterparty is a Priority Customer.

- An Away Market Maker that adds liquidity will pay \$0.00 per contract if the counterparty is a Non-Priority Customer and pay \$0.95 per contract if the counterparty is a Priority Customer; an Away Market Maker that removes liquidity will pay \$0.25 per contract if the counterparty is a Non-Priority Customer and pay \$0.95 per contract if the counterparty is a Priority Customer.
- A Firm/Broker-Dealer that adds liquidity will pay \$0.00 per contract if the counterparty is a Non-Priority Customer and pay \$0.95 per contract if the counterparty is a Priority Customer; a Firm/Broker-Dealer that removes liquidity will pay \$0.25 per contract if the counterparty is a Non-Priority Customer and pay \$0.95 per contract if the counterparty is a Priority Customer.

IEX proposes to add language immediately after the Options Transaction Fees and Credits section explaining that orders that are exposed and execute via the Step Up Mechanism will be assigned the applicable fee or credit associated with removing liquidity, while orders that execute against an order exposed via the Step Up Mechanism will be assigned the applicable fee or credit associated with adding liquidity.

IEX also proposes adding a second paragraph that explains that transaction fees and credits associated with executions that occur as part of the Opening Process described in Rule 22.160 are waived.

Linkage Routing Fees

The Exchange proposes to assess Linkage Routing Fees on orders routed to other options exchanges. The amount of the applicable fee will be based on whether the order is in a Penny Class or Non-Penny Class. The Exchange proposes to charge a fee of \$1.20 for Penny Class options routed to another options exchange and \$1.63 for Non-Penny Class options routed to another options exchange.

The purpose of the proposed Linkage Routing Fees is to offset costs incurred by IEX Options when routing orders to other options exchanges on behalf of Options Members. In determining its proposed Linkage Routing Fees, the Exchange took into account transaction fees and credits assessed by the away markets to which the Exchange routes orders, as well as the Exchange's clearing, administrative, regulatory, and technical costs associated with routing orders to an away market. The Exchange

will use unaffiliated routing brokers to route orders to the away markets; the costs associated with the use of these services are reflected in the Linkage Routing Fees specified in the Fee Schedule.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b) of the Act¹⁴ in general and furthers the objectives of Section 6(b)(4) of the Act,¹⁵ in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities. In addition, the Exchange believes that the proposed fees are consistent with the purposes of Section 6(b)(5)¹⁶ of the Act in that they are designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to a free and open market and national market system, and, in general, to protect investors and the public interest, and particularly, are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

IEX Options operates in a highly fragmented and competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient, and the Exchange represents only a small percentage of the overall market. Accordingly, competitive forces constrain the Exchange's transaction fees and credits, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange believes the proposal reflects a reasonable and competitive pricing structure which will promote price discovery and enhance liquidity and market quality on the Exchange to the benefit of all Options Members and market participants. Additionally, the Exchange believes these fees are reasonable, equitable and not designed to permit unfair discrimination because these fees will apply equally to similarly situated Options Members for transactions executed in the same capacity, options class, liquidity role and applicable counterparty category.

¹⁴ 15 U.S.C. 78f(b).

¹⁵ 15 U.S.C. 78f(b)(4).

¹⁶ 15 U.S.C. 78f(b)(5).

As a threshold matter, the Exchange notes that it has structured its options transaction fee structure to incentivize the types of order flow the Exchange believes will enhance liquidity on IEX Options overall, in a manner that is consistent with the maintenance of a fair and orderly market.

The Exchange believes that it is reasonable, equitable and not designed to permit unfair discrimination, to offer its highest credits and lowest fees for Penny Class transactions to Priority Customers (\$0.32 credit per contract to a Priority Customer that adds liquidity; \$0.34 fee per contract to a Priority Customer that removes liquidity) because the Exchange believes that Priority Customer order flow enhances liquidity on the Exchange for the benefit of all market participants.¹⁷ Moreover, the options industry has a long history of providing preferential pricing to Priority Customers.¹⁸ Additionally, the Exchange notes that these fees are comparable to the fees and credits other options exchanges apply to Priority Customers adding and removing liquidity in Penny Class options.¹⁹

The Exchange also believes that it is reasonable, equitable and not designed to permit unfair discrimination, in a transaction in a Penny Class option, to offer a \$0.28 credit per contract to a Professional that adds liquidity, and to

charge a \$0.40 fee per contract to a Professional that removes liquidity. Specifically, the Exchange does not believe it is inequitable or unfairly discriminatory to assess lower credits and higher fees to Professionals, compared to Priority Customers, because there is a greater level of proficiency associated with Professionals due to the frequency upon which they access the market. Additionally, IEX notes that other exchanges also have a similar fee structure in Penny Class options where Priority Customers and Professionals (*i.e.*, customers) are subject to preferential rates compared to other types of market participants.²⁰ Thus, the Exchange does not believe it is inequitable or unfairly discriminatory to offer a lower fee or higher credit to Priority Customers and Professionals than it offers to other market participants.

The Exchange believes that it is reasonable, equitable and not designed to permit unfair discrimination for the Exchange, in a transaction in a Penny Class option, to offer a \$0.26 credit per contract to a Firm/Broker-Dealer that adds liquidity, and to charge a \$0.40 fee per contract to a Firm/Broker-Dealer that removes liquidity. IEX notes that it is not uncommon for options exchanges to charge different rates to different non-customers based upon their trading capacity, such as the proposed fees (credits) which are higher (lower) than those charged to customers but lower (higher) than those charged to other non-customer type market participants.²¹ Additionally, IEX notes that these fees are comparable to the fees and credits other options exchanges apply to Firms/Broker-Dealers adding and removing liquidity in Penny Class options.²²

The Exchange also believes that it is reasonable, equitable and not designed to permit unfair discrimination for the Exchange, in a transaction in a Penny Class option, to offer a \$0.26 credit per contract to a Market Maker that adds

liquidity, and to charge a \$0.43 fee per contract to a Market Maker that removes liquidity. The Exchange believes that the proposed fee structure is consistent with the Act because it is designed to incentivize Market Makers to provide competitively priced liquidity on IEX Options. The Exchange further believes that the differences in fees and credits for Market Makers, as compared to Professionals and Firms/Broker-Dealers, is reasonable, equitable and not designed to permit unfair discrimination because it reflects each type of market participant's level of sophistication and typical liquidity adding or removing role. More specifically, the proposed credit for Market Makers and Firms/Broker-Dealers is designed to incentivize these professional market participants to provide tight and deep quotes in Penny Class options. Similarly, the proposed fees for removing liquidity reflect the trading activity in which the Exchange expects such market participants to generally engage. Specifically, Market Makers are sophisticated market participants, and their role is generally to provide rather than take liquidity, while Professionals and Firms/Broker-Dealers often seek to take liquidity provided by Market Makers. Additionally, the Exchange notes that these proposed rates are comparable to the fees and credits other options exchanges apply to Market Makers adding and removing liquidity in Penny Class options.²³

The Exchange also believes that it is reasonable, equitable and not designed to permit unfair discrimination, in a transaction in a Penny Class option, to offer its least attractive fees and credits to Away Market Makers. The Exchange understands that Away Market Makers are generally as sophisticated as Market Makers but are not subject to Market Makers' obligations.²⁴ Thus the Exchange believes it is consistent with the Act to assess Away Market Makers its lowest credits and highest fees for Penny Class transactions. IEX notes that an Away Market Maker could register with IEX Options as a Market Maker, which would make it eligible for Market Maker fees and credits. Additionally, IEX notes that its Away Market Maker fees are comparable to the fees and credits other options exchanges apply to Away Market Makers for adding and

¹⁷ Other exchanges that offer pricing incentives to Priority Customers also charge higher fees for Non-Priority Customers to transact with Priority Customers. For example, BOX charges \$0.00 to public customers adding liquidity against non-public customers (Penny and Non-Penny Classes), and offers credits of \$0.20 (Penny Classes) to \$0.50 (Non-Penny Classes) to public customers taking liquidity against non-public customers, while it charges \$0.50 to a non-public customer adding or removing liquidity against a public customer in a Penny Class option and charges \$0.95 to a non-public customer adding or removing liquidity against a public customer in a Non-Penny Class option. See BOX Exchange Fee Schedule, effective October 1, 2026, available at <https://boxoptions.com/resources/fee-schedule/>.

¹⁸ See, e.g., Securities Exchange Act Release No. 95885 (September 22, 2022), 87 FR 58856 (September 28, 2022) (SR-EMERALD-2022-29) ("Priority Customer liquidity benefits all market participants by providing more trading opportunities. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants."); Securities Exchange Act Release No. 78421 (July 26, 2016), 81 FR 50580 (August 1, 2016) (SR-C2-2016-013) (giving enhanced credits to "public customers", noting that there is a long history of options exchanges providing preferential pricing to such customers).

¹⁹ For example, IEX's proposed fees and credits are comparable to the fees and credits NYSE Arca charges for the same transaction in a Penny Class option (\$0.25 credit to add; \$0.49 fee to remove). See NYSE Arca Options Fee Schedule, effective September 17, 2026, available at https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_Fee_Schedule.pdf.

²⁰ See e.g., Nasdaq Options 7, Section 2 (charging \$0.49 for Priority Customers and Professionals to remove liquidity in Penny Class options, and charging all other market participants \$0.50 for the same transactions).

²¹ See, e.g., BOX Exchange Fee Schedule, *supra*, note 17 (for Penny Class options, offering free trades or providing credits to Priority Customers adding or removing liquidity, while charging between \$0.00 and \$0.50 for liquidity adding and removing trades by market makers, professionals, and broker-dealers).

²² For example, IEX's fees and credits are comparable to the fees and credits MIAx Emerald charges for the same transaction in a Penny Class option (\$0.25 credit to add; \$0.50 fee to remove). See MIAx Emerald Options Fee Schedule, *supra*, note 11.

²³ For example, IEX's fees and credits are comparable to the fees and credits NYSE Arca charges for the same transaction in a Penny Class option (\$0.28 credit to add; \$0.50 fee to remove). See NYSE Arca Options Fee Schedule, *supra*, note 19.

²⁴ See Rule 23.140 (Obligations of Market Makers).

removing liquidity in Penny Class options.²⁵

The Exchange also believes that it is reasonable, equitable and not designed to permit unfair discrimination for the Exchange, in a transaction in a Non-Penny Class option, to offer a \$0.70 credit per contract to a Priority Customer that adds liquidity with a Non-Priority Customer counterparty; charge \$0.00 per contract to a Priority Customer that adds liquidity in a transaction with a Priority Customer counterparty; offer an \$0.85 credit per contract to a Priority Customer that removes liquidity in a transaction with a Non-Priority Customer counterparty; and charge \$0.00 per contract to a Priority Customer that removes liquidity in a transaction with a Priority Customer counterparty, because these fees are comparable to the fees and credits other options exchanges apply to Priority Customers adding and removing liquidity in Non-Penny Class options.²⁶

Additionally, the Exchange believes that providing relatively higher credits for Priority Customer trades²⁷ with Non-Priority Customer counterparties in Non-Penny Class options and charging relatively higher fees to the Non-Priority Customer counterparties²⁸ is consistent with the purposes of the Act because, as described above, the Exchange believes that Priority Customer liquidity benefits all market participants by providing more trading opportunities, which can attract Market Makers and other market participants.²⁹ IEX also believes that an increase in the activity of Priority

Customers would in turn facilitate tighter spreads, which may cause an additional corresponding increase in order flow from Market Makers and other market participants. Moreover, as discussed above, the options industry has a long history of providing preferential pricing to Priority Customers.³⁰ Finally, all fee and credit amounts proposed to apply to Priority Customers will be applied equally to all Priority Customers. Thus, the Exchange believes that it is reasonable, equitable and not designed to permit unfair discrimination for the Exchange to incentivize Priority Customer orders with the higher credits and lower fees contained in this proposal.

The Exchange also believes that it is reasonable, equitable and not designed to permit unfair discrimination for the Exchange, in a transaction in a Non-Penny Class option, to charge \$0.00 per contract to a Professional that adds liquidity in a transaction with a Non-Priority Customer counterparty; charge \$0.95 per contract to a Professional that adds liquidity in a transaction with a Priority Customer counterparty; charge \$0.25 per contract to a Professional that removes liquidity in a transaction with a Non-Priority Customer counterparty; and charge \$0.95 per contract to a Professional that removes liquidity in a transaction with a Priority Customer counterparty, because these fees are comparable to the fees and credits other options exchanges apply to Professionals adding and removing liquidity in Non-Penny Class options.³¹

The Exchange also believes that it is reasonable, equitable and not designed to permit unfair discrimination for the Exchange, in a transaction in a Non-Penny Class option, to offer a \$0.10 credit per contract to a Market Maker that adds liquidity in a transaction with a Non-Priority Customer counterparty; charge \$0.95 per contract to a Market Maker that adds liquidity in a transaction with a Priority Customer counterparty; charge \$0.25 per contract to a Market Maker that removes liquidity in a transaction with a Non-Priority Customer counterparty and charge \$0.95 per contract to a Market Maker that removes liquidity in a transaction with a Priority Customer counterparty, because these fees are comparable to the fees and credits other

options exchanges apply to Market Makers adding and removing liquidity in Non-Penny Class options.³²

The Exchange also believes that it is reasonable, equitable and not designed to permit unfair discrimination for the Exchange, in a transaction in a Non-Penny Class option, to charge \$0.00 per contract to an Away Market Maker that adds liquidity in a transaction with a Non-Priority Customer counterparty; charge \$0.95 per contract to an Away Market Maker that adds liquidity in a transaction with a Priority Customer counterparty; charge \$0.25 per contract to an Away Market Maker that removes liquidity in a transaction with a Non-Priority Customer counterparty; and charge \$0.95 per contract to an Away Market Maker that removes liquidity in a transaction with a Priority Customer counterparty, because these fees are comparable to the fees and credits other options exchanges apply to Away Market Makers adding and removing liquidity in Non-Penny Class options.³³

The Exchange also believes that it is reasonable, equitable and not designed to permit unfair discrimination for the Exchange, in a transaction in a Non-Penny Class option, to charge \$0.00 per contract to a Firm/Broker-Dealer that adds liquidity in a transaction with a Non-Priority Customer counterparty; charge \$0.95 per contract to a Firm/Broker-Dealer that adds liquidity in a transaction with a Priority Customer counterparty; charge \$0.25 per contract to a Firm/Broker-Dealer that removes liquidity in a transaction with a Non-Priority Customer counterparty; and charge \$0.95 per contract to a Firm/Broker-Dealer that removes liquidity in a transaction with a Priority Customer counterparty, because these fees are comparable to the fees and credits other options exchanges apply to Firm/Broker-Dealers adding and removing liquidity in Non-Penny Class options.³⁴

²⁵ For example, IEX's fees and credits are comparable to the fees and credits MIAX Emerald charges for the same transaction in a Penny Class option (\$0.25 credit to add; \$0.50 fee to remove). See MIAX Emerald Options Fee Schedule, effective August 1, 2026, available at https://www.miaxglobal.com/sites/default/files/fee-schedule-files/MIAX_Emerald_Fee_Schedule_08012026.pdf.

²⁶ For example, IEX's fees and credits are comparable to the fees and credits BOX Exchange charges for the same transaction in a Non-Penny Class option, in particular BOX and IEX both offer credits to Priority Customers (called "public customers" by BOX) that remove liquidity against a Non-Priority Customer. Although BOX does not offer a similar credit to a public customer that adds liquidity against a non-public customer, it charges less for that transaction (\$0.00 fee) than it would if the trade was executed in any other capacity with the exception of some market maker trades (fees ranging from \$0.15 to \$0.95). And BOX, like IEX, charges a fee of \$0.00 for Priority Customer trades executed against other Priority Customers. See BOX Exchange Fee Schedule, *supra*, note 17.

²⁷ The proposed credits are \$0.70 for Priority Customers adding liquidity against a Non-Priority Customer and \$0.85 for a Priority Customer taking liquidity against a Non-Priority Customer in a Non-Penny Class option.

²⁸ The proposed fees are \$0.95 for Non-Priority Customer adding or removing liquidity against a Priority Customer in a Non-Penny Class option.

²⁹ See *supra*, note 17.

³⁰ See *supra*, note 18.

³¹ For example, IEX's proposed fees are either lower than, or comparable to, the fees BOX charges for the same transaction in a Non-Penny Class option (\$0.95 fee for a Professional to add or remove liquidity against a public customer; \$0.15 fee for a Professional to add and \$0.85 fee to remove liquidity against a non-public customer). See BOX Exchange Fee Schedule, *supra*, note 17.

³² For example, IEX's fees and credits are either lower than (or with respect to credits, higher than), or comparable to, the fees and credits BOX charges for the same transaction in a Non-Penny Class option (\$0.95 fee for a market maker to add or remove liquidity against a public customer; \$0.00 fee for a market maker to add and \$0.75 fee to remove liquidity against a non-public customer). See BOX Exchange Fee Schedule, *supra*, note 17.

³³ For example, IEX's fees and credits are comparable to the fees and credits Nasdaq Options Market charges for the same transaction in a Non-Penny Class option (\$0.45 fee for an away market maker to add liquidity against any counterparty; \$1.25 fee for an away market maker to take liquidity against any counterparty). See Nasdaq Options 7, Section 2(1).

³⁴ For example, IEX's fees and credits are comparable to the fees and credits BOX charges for the same transaction in a Non-Penny Class option (\$0.95 fee for a firm/broker-dealer to add or remove liquidity against a public customer; \$0.15 fee for a

Further, the Exchange believes it is appropriate, reasonable, and consistent with the Act to specify in its Fee Schedule that orders that are exposed and execute via the Step Up Mechanism will be assigned the applicable fee or credit associated with removing liquidity, while orders that execute against an order exposed via the Step Up Mechanism will be assigned the applicable fee or credit associated with adding liquidity, because other options exchanges specify in their fee schedules that they treat executions that occurred within their step up mechanisms in the identical manner.³⁵

Furthermore, the Exchange believes it is appropriate, reasonable, and consistent with the Act to waive any transaction fees and credits associated with executions that occur as part of the Opening Process, because other options exchanges also waive transaction fees and credits associated with executions that occur as part of their opening processes.³⁶

The Exchange also believes that the Exchange's proposed Linkage Routing Fees for orders routed to other options exchanges (\$1.20 for Penny Class option contracts and \$1.63 for Non-Penny Class option contracts) are appropriate, reasonable, and consistent with the Act. As discussed in the Purpose section, the proposed Linkage Routing Fees are designed to offset costs incurred by IEX Options when routing orders to other options exchanges on behalf of Options Members. In determining its proposed Linkage Routing Fees, the Exchange took into account transaction fees and credits assessed by the away markets to which the Exchange routes orders, as well as the Exchange's clearing, administrative, regulatory, and technical costs associated with routing orders to an away market, and the costs associated with the use of unaffiliated routing brokers to route orders to the away markets. Further, the Exchange notes that its Linkage Routing Fees are identical to the fees charged by MEMX

firm/broker-dealer to add and \$0.85 fee to remove liquidity against a non-public customer). See BOX Exchange Fee Schedule, *supra*, note 17.

³⁵ For example, IEX's language is functionally identical to language in the C2 Options Fee Schedule, which states "For executions that occur within the Step Up Mechanism ("SUM") auctions, the incoming order will receive applicable Remove rates, and auction responses and unrelated orders will receive applicable Add rates." See C2 Options Fee Schedule, effective September 11, 2026, available at https://www.cboe.com/us/options/membership/fee_schedule/ctwo/.

³⁶ For example, IEX's waiver of fees and credits is identical to the practice of NYSE Arca, which states in its fee schedule that "Transaction fees do not apply to executions occurring during the Opening Auction." See NYSE Arca Options Fee Schedule, *supra*, note 19.

for routing Penny and Non-Penny Classes to away exchanges.³⁷

Finally, the Exchange believes that it is reasonable to update the Preface and Definitions sections of the Options Fee Schedule, because the additional language will clearly set forth the terms used in the Transaction Fees portion of the Options Fee Schedule. Further, the Exchange believes this section is equitable and not unfairly discriminatory because the definitions section (as part of the Options Fee Schedule) will be distributed to all Options Members, so that all Options Members will have equal clarity on fees charged and credits provided.

For the reasons discussed above, the Exchange believes that its proposed changes to the Options Fee Schedule satisfy the requirements of Sections 6(b)(4)³⁸ and 6(b)(5)³⁹ of the Act in that they provide for the equitable allocation of reasonable dues, fees and other charges among Options Members and other persons using its facilities and are not designed to unfairly discriminate between customers, issuers, brokers, or dealers. As described more fully below in the Exchange's statement regarding the burden on competition, the Exchange believes that its transaction pricing is subject to significant competitive forces, and that the proposed fees and credits described herein are appropriate to address such forces.

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

As a new entrant in the already highly competitive environment for options trading, the Exchange believes that the proposed changes would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Options Members. IEX Options proposes transaction fees, credits, and routing fees that are comparable to transaction fees, credits and routing fees assessed by other options exchanges. As a result, the Exchange believes that the proposal will have a positive effect on competition.

³⁷ See MEMX Options Fee Schedule, effective September 1, 2026, available at <https://info.memxtrading.com/memx-options-fee-schedule-memx/>.

³⁸ 15 U.S.C. 78f(b)(4).

³⁹ 15 U.S.C. 78f(b)(5).

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed fees and credits will apply equally to similarly situated Options Members for transactions executed in the same capacity, options class, liquidity role and applicable counterparty category. The proposed pricing structure is intended to encourage participants to trade on IEX Options by providing credits that are comparable to those offered by other exchanges as well as providing competitive fees. The Exchange believes that the proposed credits and fees will help to encourage Options Members to send orders to the Exchange to the benefit of all Exchange participants. As the proposed fees and credits are equally applicable to all similarly situated market participants, the Exchange does not believe there is any burden on intramarket competition. Further, as discussed in the Statutory Basis section, while different fees are assessed to different market participants based upon the market participant's capacity (or in the case of Non-Penny Classes, based upon the capacities of both parties to the transaction), these different market participants have different obligations to the Exchange. Additionally, as discussed in the Statutory Basis, the fees are designed to incentivize market participants to engage in the trading activity that is most common for each type of market participant.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that the proposed pricing structure will increase competition and is intended to draw volume to the Exchange as it commences operations. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue or reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and credits, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. Currently, no single registered options exchange has more than approximately 19% of the total market share of

executed volume of listed options trading.⁴⁰ As a new exchange, the Exchange expects to face intense competition from existing exchanges. The proposed pricing structure is intended to encourage market participants to trade on the Exchange by providing credits and assessing fees that are comparable to those offered by other exchanges, which the Exchange believes will help to encourage Options Members to send orders to the Exchange to the benefit of all Exchange participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act⁴¹ and Rule 19b-4(f)(2) thereunder.⁴²

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)⁴³ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-IEX-2026-41 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-IEX-2026-41. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-IEX-2026-41 and should be submitted on or before November 20, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁴

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-22130 Filed 10-29-26; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21997 and #21998; CALIFORNIA Disaster Number CA-20051]

Administrative Declaration of a Disaster for the State of California

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is notice of an Administrative declaration of a disaster for the state of California dated October 27, 2026.

Incident: East Oakland Apartment Fire.

DATES: Issued on October 27, 2026.
Incident Period: September 25, 2026.
Physical Loan Application Deadline Date: December 28, 2026.

Economic Injury (EIDL) Loan Application Deadline Date: July 27, 2027.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Jennifer Talarico, Office of Disaster

Recovery, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given as a result of the Administrator's disaster declaration, applications for disaster loans may be submitted online using the MySBA Loan Portal <https://lending.sba.gov> or in person at other locally announced locations. For further assistance please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1-800-659-2955. If you are deaf, hard of hearing, or have a speech disability, please dial 7-1-1 to access telecommunications relay services.

The following areas have been determined to be adversely affected by the disaster:

Primary County: Alameda.

Contiguous Counties:

California: Contra Costa, San Francisco, San Joaquin, San Mateo, Santa Clara, Stanislaus.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	6.000
Homeowners without Credit Available Elsewhere	3.000
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Private Non-Profit Organizations with Credit Available Elsewhere	3.625
Private Non-Profit Organizations without Credit Available Elsewhere	3.625
<i>For Economic Injury:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Private Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 219975 and for economic injury is 219980.

The state which received an SBA Administrative declaration is California. (Catalog of Federal Domestic Assistance Number 59008) (Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery.

[FR Doc. 2026-22172 Filed 10-29-26; 8:45 am]

BILLING CODE 8026-09-P

⁴⁰ See Options Clearing Corporation Options Volume by Exchange, available at <https://www.theocc.com/market-data/market-data-reports/volume-and-open-interest/volume-by-exchange>.

⁴¹ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴² 17 CFR 240.19b-4(f)(2).

⁴³ 15 U.S.C. 78s(b)(2)(B).

⁴⁴ 17 CFR 200.30-3(a)(12).

SMALL BUSINESS ADMINISTRATION

Surety Bond Guarantee Program Fees

AGENCY: U.S. Small Business Administration.

ACTION: Notification of Prior Approval Surety Bond Guarantee Program Fee Changes.

SUMMARY: This document announces a change in the guarantee fees that the U.S. Small Business Administration (SBA) charges all Prior Approval (Plan A) Surety companies and Principals on each guaranteed bond (other than a bid bond) issued in SBA's Surety Bond Guarantee (SBG) Program; with the exception of projects under NAICS Code 31, 32, 33: Manufacturing.

DATES: *Applicability Date:* The fee change described in this document will apply to all SBA surety bond guarantees approved on or after November 30, 2026.

FOR FURTHER INFORMATION CONTACT: Jermaine Perry, Director, Office of Surety Guarantees, (202) 401-8275; jermaine.perry@sba.gov.

SUPPLEMENTARY INFORMATION: Under its SBG Program, the SBA guarantees bid, payment and performance bonds for small and emerging contractors who cannot obtain surety bonds through regular commercial channels. SBA's guarantee gives participating Sureties an incentive to provide bonding for small businesses and, thereby, assist small businesses in obtaining greater access to contracting opportunities. SBA's guarantee is an agreement between a Surety and SBA that SBA will assume a certain percentage of the Surety's loss should a contractor default on the underlying contract. Pursuant to its statutory authority "to establish such fee or fees for small business concerns and premium or premiums for sureties as it deems reasonable and necessary," and to administer the SBG Program "on a prudent and economically justifiable basis," 15 U.S.C. 694b(h), SBA assesses a guarantee fee against both the small business concern (the Principal) and the Surety and deposits these fees into a revolving fund to cover the program's liabilities and certain program expenses.

SBA last changed the fees October 1, 2018, when the fee charged to the Sureties was decreased from 26 percent to 20 percent of the bond premium and the fee charged to Principals decreased from \$7.29 per thousand dollars of the contract amount to \$6.00 per thousand dollars of the contract amount. At that time, SBA determined the program's revolving fund was sufficient to cover projected, unfunded liabilities. *See* 83

FR 36658 (July 30, 2018) and 85 FR 62362 (October 2, 2020). SBA decreased the guarantee fees temporarily to evaluate the effects of a fee reduction and the implications for participating Sureties and SBA. Since implementation, the Prior Approval program has operated at a funding deficit while the Preferred Surety Bond program has operated at a marginal funding surplus.

SBA's regulations 13 CFR 115.32(b) and (c), and 13 CFR 115.66 provide that the amount of the fees to be paid by the Surety and the Principal "will be determined by SBA and published in Notices in the **Federal Register** from time to time." SBA is announcing the SBA fees required for an SBA surety bond guarantee will be the following:

1. Prior Approval Program

Under 13 CFR 115.32, SBA's Surety fee on guarantees will increase from 20 percent of the bond premium to 26 percent of the bond premium and the Contractor fee on guarantees will increase from \$6.00 per thousand dollars of the contract amount to \$7.29 per thousand dollars of the contract amount. Except for bond guarantees on projects under NAICS Code 31, 32, 33 "Manufacturing" which will receive the following rates: SBA's Surety fee on guarantees will remain 20 percent of the bond premium and the Principal fee on guarantees will remain \$6.00 per thousand dollars of the contract amount.

2. Preferred Surety Bond Program

Under 13 CFR 115.66, SBA's Surety fee on guarantees will remain 20 percent of the bond premium and the Principal fee on guarantees will remain \$6.00 per thousand dollars of the contract amount.

Authority: 15 U.S.C. 694b(h), 13 CFR 115.32(b) and (c), and 115.66.

Thomas Kimsey,
Associate Administrator, Office of Capital Access.
[FR Doc. 2026-22177 Filed 10-29-26; 8:45 am]
BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #22000 and #22001; NEBRASKA Disaster Number NE-20031]

Administrative Declaration of a Disaster for the State of Nebraska

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is notice of an Administrative declaration of a disaster for the state of Nebraska dated October 27, 2026.

Incident: Remnants of Hurricane Polo.

DATES: Issued on October 27, 2026.

Incident Period: September 30, 2026 through October 1, 2026.

Physical Loan Application Deadline Date: December 28, 2026.

Economic Injury (EIDL) Loan Application Deadline Date: July 26, 2027.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Shaquille Lewis, Office of Disaster Recovery, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given as a result of the Administrator's disaster declaration, applications for disaster loans may be submitted online using the MySBA Loan Portal <https://lending.sba.gov> or in person at other locally announced locations. For further assistance please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1-800-659-2955. If you are deaf, hard of hearing, or have a speech disability, please dial 7-1-1 to access telecommunications relay services.

The following areas have been determined to be adversely affected by the disaster:

Primary County: Douglas.

Contiguous Counties:
Nebraska: Dodge, Sarpy, Saunders, Washington.
Iowa: Pottawattamie.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	6.000
Homeowners without Credit Available Elsewhere	3.000
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Private Non-Profit Organizations with Credit Available Elsewhere	3.625
Private Non-Profit Organizations without Credit Available Elsewhere	3.625
<i>For Economic Injury:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Private Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 220006 and for economic injury is 220010.

The states which received an SBA Administrative declaration are Iowa and Nebraska.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery.

[FR Doc. 2026–22184 Filed 10–29–26; 8:45 am]

BILLING CODE 8026–09–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2025–0030]

Privacy Act of 1974; System of Records

AGENCY: Social Security Administration (SSA).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, we are issuing public notice of our intent to establish a new system of records entitled, Client Data System (60–0392). We will use the information in this system of records to track data fields that are used across multiple agency systems to help ensure consistent and up-to-date information is maintained to effectively and efficiently communicate with customers and administer Social Security programs, as detailed in the PURPOSE section. This notice publishes details of the new system as set forth under the caption, **SUPPLEMENTARY INFORMATION.**

DATES: The system of records notice (SORN) is applicable upon its publication in today's **Federal Register**, with the exception of the new routine uses, which are effective November 30, 2026.

We invite public comment on the routine uses or other aspects of this SORN. In accordance with the Privacy Act of 1974, we are providing the public a 30-day period in which to submit comments. Therefore, please submit any comments by November 30, 2026.

ADDRESSES: The public, Office of Management and Budget (OMB), and Congress may comment on this publication by writing to the Head of Privacy and Disclosure Policy, Law and Policy, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, or through the Federal e-Rulemaking Portal at <https://www.regulations.gov>. Please reference docket number SSA–2025–0030. All comments we receive will be available for public inspection at the above address and we will post them to <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Tristin Dorsey, Government Information Specialist, Disclosure and Data Support Division, Privacy and Disclosure Policy, Law and Policy, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, telephone: (410) 965–1727, email: LP.PDP.SORN@ssa.gov.

SUPPLEMENTARY INFORMATION: We are establishing the Client Data System to track and manage information about a customer including personal information and customer interactions, which will support SSA's business processes and administration of Social Security programs, including but not limited to, pre-claims, claims processing, and post-entitlement situations. This system will be used to track data fields that are maintained in multiple SSA systems to help ensure consistent information across systems. With this system, SSA employees will be able to serve SSA customers more efficiently and effectively by providing one main location to view information concerning the customer.

In accordance with 5 U.S.C. 552a(r), we have provided a report to OMB and Congress on this new system of records.

Matthew Ramsey,

Head of Privacy and Disclosure Policy, Law and Policy.

SYSTEM NAME AND NUMBER:

Client Data System, 60–0392.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Social Security Administration, Chief Information Officer, Shared IT & Enterprise Services, 6401 Security Boulevard, Baltimore, Maryland 21235.

Information is also located in additional locations in connection with cloud-based services and kept at an additional location as backup for business continuity purposes.

SYSTEM MANAGER(S):

Social Security Administration, Chief Information Officer, Shared IT & Enterprise Services, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–1727.

Social Security Administration, Chief, Digital Services, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–1727.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 202–205, 223, 226, 228, 1602, 1611–1616, 1631, 1633, 1634, 1818, 1836, and 1840 and Title VIII of the Social Security Act, as amended;

and the Internal Revenue Code (26 U.S.C. 6103(l)(1)(A)).

PURPOSE(S) OF THE SYSTEM:

We will use the information in this system of records to track data fields that are used across multiple agency systems to help ensure consistent and up-to-date information is maintained to effectively and efficiently communicate with customers and administer Social Security programs. We will also use the information in this system of records to:

- provide a centralized location to view the covered customer data;
- determine and manage customer preferences, such as methods of communication;
- track and manage customer interactions;
- track applicable customer authorization, e.g., consent for disclosure for in-person identity proofing purposes, consent to text;
- complete customer transactions such as pre-claims, claims processing, and post-entitlement situations;
- make informed decisions about priority workloads, staffing needs, and equipment needs;
- form agency strategic goals and funding decisions;
- determine agency operating plans and public service indicators; and
- to assist in the administration of Social Security programs, such as identity verification of SSA customers, prevention of fraud in the Social Security program, research that relates to the Social Security program, and other uses that help administer the Social Security program.

We may also use contact information (e.g., email addresses) provided by individuals who conduct business with SSA for program outreach (e.g., notification about our programs, online services, SSA events, and surveys) and other purposes related to our administration of the Social Security Act.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system maintains information on individuals who have been issued a Social Security number (SSN), including those who have conducted business with SSA beyond enumeration.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system maintains records on customers including, but not limited to:

- *Identity Information:* This information may include name; SSN; sex; date of birth; parent name(s); and place of birth.
- *Citizenship Information:* This information may include country of citizenship.

- *Contact Information:* This information may include mailing address; email address; written and spoken language; telephone number; opt-in and opt-out of electronic messaging selections; applicable customer authorizations; contact's relationship with number holder, *i.e.*, parental or marriage; customer interaction history, including notes or remarks entered by technicians; and details of customer contact and verification history.
- *Representative Payee Information:* This information may include names, SSNs, telephone number(s), and address of current representative payee and relationship with the beneficiary.
- *Appointed Representative Information:* This information may include name and telephone number(s) of current appointed representatives; and fee agreement information including whether the fee has been waived and/or whether direct payment has been waived.
- *Benefits Information:* This information may include title II benefit and title XVI payment amounts; effective dates of benefit and payment amounts; and claim number.
- *Earnings Information:* This information may include yearly earnings and quarters of coverage; and voluntary tax withholding rates.
- *Accommodation Information:* This information may include special notice formats for individuals that may be blind or visually impaired, *e.g.*, Braille or large-print; language interpreter needs; and accommodations for individuals that may be deaf or hard of hearing, *e.g.*, passing notes or use of a hearing loop.
- *Marriage Information:* This information may include spouse's SSN, name and date of birth; marriage start and end dates; reason for marriage end; place of marriage; marriage type, *e.g.*, whether marriage conducted by clergyman/public official, common law or other ceremony; whether spouse is deceased, disabled, or blind; and address.
- *Warning or Alert Information:* This information may include electronic block, high-risk, and special indicator warnings.
- *Military Service Information:* This includes indicators for Department of Defense Wounded Warrior and Department of Veterans Affairs 100% Permanent and Total Disability Compensation Rating.

RECORD SOURCE CATEGORIES:

We obtain information in this system of records primarily from existing SSA systems of records such as the Master

Files of SSN Holders and SSN Applications, 60–0058; Earnings Recording and Self-Employment Income System, 60–0059; Claims Folders System, 60–0089; Master Beneficiary Record, 60–0090; Supplemental Security Income Record and Special Veterans Benefits, 60–0103; Master Representative Payee File, 60–0222; Medicare Database File, 60–0321; Appointed Representative File, 60–0325; Appointments, Visitor Information, and Customer Service Record System, 60–0350; Digital Identity File System, 60–0373; Requests for Accommodation from Members of the Public, 60–0378; and Customer Engagement Tools Record System, 60–0383.

We also obtain information from the number holder; appointed representatives; representative payees; third parties such as a contractor or vendor; and Federal, State, and local agencies.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

We will disclose records pursuant to the following routine uses; however, we will not disclose any information defined as “return or return information” under 26 U.S.C. 6103 of the Internal Revenue Code (IRC), unless authorized by statute, the Internal Revenue Service (IRS), or IRS regulations.

1. To a congressional office in response to an inquiry from that office made on behalf of, and at the request of, the subject of the record or a third party acting on the subject's behalf.

2. To the Office of the President, in response to an inquiry received from that office made on behalf of, and at the request of, the subject of the record or a third party acting on the subject's behalf.

3. To the National Archives and Records Administration (NARA) under 44 U.S.C. 2904 and 2906.

4. To appropriate agencies, entities, and persons when:

(a) SSA suspects or has confirmed that there has been a breach of the system of records;

(b) SSA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, SSA (including its information systems, programs, and operations), the Federal Government, or national security; and

(c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connections with SSA's efforts to respond to the suspected or confirmed

breach or to prevent, minimize, or remedy such harm.

5. To another Federal agency or Federal entity, when SSA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in:

(a) responding to a suspected or confirmed breach; or

(b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

6. To the Department of Justice (DOJ), a court or other tribunal, or another party before such court or tribunal, when:

(a) SSA, or any component thereof; or

(b) any SSA employee in the employee's official capacity; or

(c) any SSA employee in the employee's individual capacity where DOJ (or SSA where it is authorized to do so) has agreed to represent the employee; or

(d) the United States or any agency thereof, where SSA determines the litigation is likely to affect SSA or any of its components, is a party to the litigation or has an interest in such litigation, and we determine that the use of such records by DOJ, a court or other tribunal, or another party before the tribunal is relevant and necessary to the litigation, provided, however, that in each case, we determine that such disclosure is compatible with the purpose for which the records were collected.

7. To Federal, State, and local law enforcement agencies and private security contractors, as appropriate, information necessary:

(a) to enable them to ensure the safety of our employees and customers, the security of our workplace, and the operation of our facilities, or

(b) to assist investigations or prosecutions with respect to activities that affect such safety and security or activities that disrupt the operations of our facilities.

8. To contractors and other Federal agencies, as necessary, for assisting SSA in the efficient administration of its programs. We will disclose information under this routine use only in situations in which we may enter into a contractual or similar agreement to obtain assistance in accomplishing an agency function relating to this system of records.

9. To student volunteers, individuals working under a personal services contract, and other workers who

technically do not have the status of Federal employees, when they are performing work for us, as authorized by law, and they need access to personally identifiable information (PII) in our records in order to perform their assigned agency functions.

10. To contractors, cooperative agreement awardees, State agencies, Federal agencies, and Federal congressional support agencies for research and statistical activities that are designed to increase knowledge about present or alternative Social Security programs; are of importance to the Social Security program or the Social Security beneficiaries; or are for an epidemiological project that relates to the Social Security program or beneficiaries. We will disclose information under this routine use pursuant only to a written agreement with SSA.

11. Tax return information to the Department of the Treasury, IRS, for the purpose of auditing SSA's compliance with the safeguard provisions of the IRC of 1986, as amended.

12. To third parties when an individual involved with a request needs assistance to communicate because of a hearing impairment or a language barrier (*e.g.*, to interpreters, telecommunications relay system operators).

13. To the Secretary of Health and Human Services (HHS) or to any State, the Commissioner shall disclose any record or information requested in writing by the Secretary, for the purpose of administering a program administered by the Secretary, if records of information of such type were so disclosed under applicable rules, regulations, and procedures in effect before the date of enactment of the Social Security Independence and Program Improvements Act of 1994.

14. To Federal, State, or local agencies (or agents on their behalf), for administering income or health maintenance programs including programs under the Social Security Act. Such disclosures include the release of information to the following agencies, but are not limited to:

(a) Railroad Retirement Board (RRB), for administering provisions of the Railroad Retirement Act and Social Security Act, relating to railroad employment, and for administering provisions of the Railroad Unemployment Insurance Act;

(b) Department of Veterans Affairs (VA), for administering 38 U.S.C. 1312, and upon request, for determining eligibility for, or amount of, veterans' benefits or for verifying other

information with respect thereto pursuant to 38 U.S.C. 5106;

(c) Department of Labor for administering provisions of Title IV of the Federal Coal Mine Health and Safety Act, as amended by the Black Lung Benefits Act;

(d) State welfare departments, for administering sections 205(c)(2)(B)(i)(II) and 402 of the Social Security Act, which require information about assigned SSNs for Temporary Assistance for Needy Families (TANF) program purposes, and for determining a beneficiary's eligibility under the TANF program;

(e) State agencies for administering the Medicaid program; and

(f) State agencies for making determinations of food stamp eligibility under the food stamp program.

15. To third party contacts (*e.g.*, employers and private pension plans) in situations where an individual's whereabouts are unknown or the party to be contacted has, or is expected to have, information relating to the individual's capability to manage their benefits or payments, or their eligibility for or entitlement to benefits or eligibility for payments, under the Social Security program when:

(a) The individual is unable to provide information being sought. An individual is considered to be unable to provide certain types of information when:

- i. they are incapable or is of questionable mental capability;
- ii. they cannot afford the cost of obtaining the information; or
- iii. the custodian of the information will not, as a matter of policy, provide it to the individual; or

(b) the data is necessary to establish the validity of evidence or to verify the accuracy of information presented by the individual, and it concerns one or more of the following:

- i. their entitlement to or eligibility for benefits under the Social Security program;
- ii. the amount of their benefit or payment; or
- iii. any case in which the evidence is being reviewed, as a result of suspected abuse or fraud or concern for program integrity, quality appraisal or evaluation and measurement activities.

16. To the Department of State, for administration of the Social Security Act in foreign countries through services and facilities of that agency.

17. To Department of Homeland Security, upon request, to identify and locate aliens in the United States pursuant to section 290(b) of the Immigration and Nationality Act (8 U.S.C. 1360(b)).

18. To third party contacts (*e.g.*, State bureaus of vital statistics) that issue documents or confer a specific status to a person, when the third party has, or is expected to have, information that will verify the document/status.

19. To an individual, when information about themselves or others, which is filed under someone else's Social Security number, affects the individual's entitlement to Social Security benefits or the amount of those benefits (*e.g.*, relevant records to an adversely affected beneficiary).

20. To Federal, State, and local law enforcement agencies, with jurisdiction to investigate or prosecute criminal violations of the Social Security Act, or other applicable statutes to which criminal penalties attach, when the agency determines that the information is relevant and necessary to the investigation or prosecution.

21. To the American Institute, a private corporation under contract to the Department of State, for administering the Social Security Act in Taiwan through facilities and services of that agency.

22. To the VA, Regional Office, Manila, Philippines, for the administration of the Social Security Act in the Philippines and other parts of the Asia-Pacific region through services and facilities of that agency.

23. To the Department of Interior and its agents, for the purpose of administering the Social Security Act in the Northern Mariana Islands through facilities and services of that agency.

24. To claimants, prospective claimants (other than the data subject), and their appointed representatives and those working with such representatives (including, but not limited to, partners, associates, and contractors) when the information pertains to the individuals whom the appointed representative is representing; and to representative payees, when the information pertains to individuals for whom they serve as representative payees, for the purpose of assisting us in administering representative payment responsibilities under the Social Security Act, to the extent necessary to pursue Social Security claims, and for the purpose of assisting them in performing their duties as payees, including receiving and accounting for benefits for individuals for whom they serve as payees.

25. To specified business and other community members and Federal, State, and local agencies for verification of eligibility for benefits under section 1631(e) of the Social Security Act.

26. To third party contacts (including private collection under contract with

us), for the purpose of their assisting us in recovering overpayments.

27. To State and local government agencies, in situations involving suspected abuse, neglect, or exploitation of minor children or vulnerable adults, to report suspected abuse or determine a victim's eligibility for services.

28. To HHS, Office of Child Support Enforcement, as required by section 453(e)(2) and (j)(1) of the Social Security Act for the administration of the Federal Parent Locator System.

29. Limited information to third parties as necessary to reach claimants, beneficiaries, and others SSA has a business need to reach related to records in this system.

30. To the U.S. Department of the Treasury, when disclosure of the information is relevant to review SSA's payment and award eligibility through the Do Not Pay Working System for the purposes of identifying, preventing, or recouping improper payments to an applicant for, or recipient of, Federal funds, including funds disbursed by a state (meaning a state of the United States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian tribe) in a state-administered, federally funded program. This routine use will be applied when disclosure meets the requirements in 20 CFR 401.150(c).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

We will maintain records in this system in electronic form.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

We will retrieve records in this system by the number holder's SSN.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

In accordance with NARA rules codified at 36 CFR 1225.16, we maintain records in accordance with approved NARA General Records Schedule (GRS) 3.1, item 011; GRS 3.2, item 020; GRS 4.2, item 170; and GRS 5.2, items 010 and 020; and agency-specific records schedule, N1-047-05-001.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

We retain electronic files containing personal identifiers in secure storage areas accessible only by our authorized individuals, including our employees and contractors, who have a need for the information when performing their official duties. Security measures include, but are not limited to, the use of codes and profiles, personal identification numbers and passwords, and personal identification verification

cards. We restrict access to specific correspondence within the system based on assigned roles and authorized users. We use audit mechanisms to record sensitive transactions as an additional measure to protect information from unauthorized disclosure or modification.

We annually provide authorized individuals, including our employees and contractors, with appropriate security awareness training that includes reminders about the need to protect PII and the criminal penalties that apply to unauthorized access to, or disclosure of, PII (5 U.S.C. 552a(i)(1)). Furthermore, authorized individuals with access to databases maintaining PII must annually sign a sanctions document that acknowledges their accountability for inappropriately accessing or disclosing such information.

RECORD ACCESS PROCEDURES:

Individuals may submit requests for information about whether this system contains a record about them by submitting a written request to the system manager at the above address, which includes their name, SSN, or other information that may be in this system of records that will identify them. Individuals requesting notification of, or access to, a record by mail must include: (1) a notarized statement to us to verify their identity; or (2) must certify in the request that they are the individual they claim to be and that they understand that the knowing and willful request for, or acquisition of, a record pertaining to another individual under false pretenses is a criminal offense.

Individuals requesting notification of, or access to, records in person must provide their name, SSN, or other information that may be in this system of records that will identify them, as well as provide an identity document, preferably with a photograph, such as a driver's license. Individuals lacking identification documents sufficient to establish their identity must certify in writing that they are the individual they claim to be and that they understand that the knowing and willful request for, or acquisition of, a record pertaining to another individual under false pretenses is a criminal offense.

Under 20 CFR 401.35, you are only entitled to seek access to records about yourself. Thus, when providing access, we may need to redact or otherwise withhold information about third parties in a record retrieved by your identifier. To the extent you seek access to a record with information about more than one individual, under 20 CFR

401.60, you may only receive access to information about you, the fact of entitlement, and the amount of benefits payable to other persons based on your record.

These procedures are in accordance with our regulations at 20 CFR 401.40 and 401.45.

CONTESTING RECORD PROCEDURES:

Same as record access procedures. Individuals should also reasonably identify the record, specify the information they are contesting, and state the corrective action sought and the reasons for the correction with supporting justification showing how the record is incomplete, untimely, inaccurate, or irrelevant.

As recognized under the "Records Source Categories" information maintained in this system may be sourced from other agency systems of records. Dependent on the information the individual is seeking to contest, the individual may need to identify each system of records in which the individual seeks to correct or amend the record and follow the procedures for contesting records within the applicable system of records notice.

These procedures are in accordance with our regulations at 20 CFR 401.65(a).

NOTIFICATION PROCEDURES:

Same as records access procedures. These procedures are in accordance with our regulations at 20 CFR 401.40 and 401.45.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2026-22173 Filed 10-29-26; 8:45 am]

BILLING CODE 4191-02-P

DEPARTMENT OF STATE

[Public Notice: 13159]

Notice of Public Meeting To Prepare for International Maritime Organization MEPC 85 Session

The Department of State will conduct a public meeting at 10:00 a.m. on Friday, November 13th, 2026, by teleconference. The primary purpose of the meeting is to prepare for the 85th session of the International Maritime Organization's (IMO) Marine Environment Protection Committee (MEPC 85), to be held at IMO Headquarters in London, United Kingdom from Monday, November 30th, 2026, to Friday, December 3rd, 2026.

The agenda items to be considered include:

- Adoption of the agenda
- Decisions of other bodies
- Consideration and adoption of amendments to mandatory instruments
- Harmful aquatic organisms in ballast water
- Air pollution prevention
- Energy efficiency of ships
- Reduction of GHG emissions from ships
- Follow-up work emanating from the action plan to address marine plastic litter from ships
- Experience-building phase for the reduction of underwater radiated noise from shipping
- Reports of other sub-committees
- Identification and protection of Special Areas, ECAs and PSSAs
- Application of the Committees' method of work
- Work programme of the Committee and subsidiary bodies
- Election of the Chair and Vice-Chair
- Any other business
- Consideration of the report of the Committee

Please note: The IMO may, on short notice, adjust the MEPC 85 agenda to accommodate any constraints associated with the meeting. Although no changes to the agenda are anticipated, if any are necessary, they will be provided to those who RSVP.

Those who plan to participate may contact the meeting coordinator, LT Justus Martin, by email at Justus.D.Martin@uscg.mil, by phone at (571) 610-0444, or in writing at ATTN: LT Justus Martin, 2703 Martin Luther King Jr. Ave. SE, Stop 7509, Washington, DC 20593-7509, by November 8th, 2026. Members of the public needing reasonable accommodation should advise LT Justus Martin no later than November 8th, 2026. Requests made after that date will be considered but might not be possible to fulfill.

Additional information regarding this and other IMO public meetings may be found at: <https://www.dco.uscg.mil/IMO>.

(Authority: 22 U.S.C. 2656 and 5 U.S.C. 552)

Emily M. Gibbons,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, U.S. Department of State.

[FR Doc. 2026-22214 Filed 10-29-26; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Public Notice: 13160]

Notice of Department of State Sanctions Actions

ACTION: Notice of Designation.

SUMMARY: The Department of State is publishing the names of one or more persons that have been placed on the Department of the Treasury's List of Specially Designated Nationals and Blocked Persons (SDN List) administered by the Office of Foreign Assets Control (OFAC) based on the Department of State's determination, in consultation with other departments, as appropriate, that one or more applicable legal criteria of the following Executive Orders (E.O.) were satisfied: the E.O. regarding blocking property of weapons of mass destruction proliferators and their supporters; the E.O. regarding blocking property of certain persons with respect to the conventional arms activities of Iran; the E.O. regarding blocking property with respect to specified harmful foreign activities of the Government of Russia; and the E.O. regarding imposing sanctions on those responsible for repression in Cuba and for threats to United States national security and foreign policy. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT:

Office of Counterproliferation Initiatives, Bureau of Arms Control and Nonproliferation, Department of State, Washington, DC 20520, tel.: (202) 647-5193, email: ACN_Sanctions@state.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning sanctions programs are available on OFAC's website (<https://ofac.treasury.gov/>).

Notice of Department of State Actions

On September 29, 2026, the Department of State, in consultation with other departments, as appropriate, determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Entities

1. JOINT STOCK COMPANY
EXPERIMENTAL DESIGN BUREAU

NAMED AFTER A.S. YAKOVLEV (a.k.a. JOINT STOCK COMPANY OKB NAMED AFTER A.S. YAKOVLEV; a.k.a. JOINT-STOCK COMPANY A.S. YAKOVLEV DESIGN BUREAU; a.k.a. JSC A.S. YAKOVLEV DB; a.k.a. OJSC OPYTNO-KONSTRUKTORSKOYE BYURO IM. A.S. YAKOVLEVA), 68 Leningradsky Ave, Moscow 125315, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 31 Aug 1993; Tax ID No. 7714039849 (Russia); Registration Number 1027739252298 (Russia) [IRAN-CON-ARMS-E.O.] [RUSSIA-EO14024] (Linked To: PUBLIC JOINT STOCK COMPANY YAKOVLEV).

Designated pursuant to section 1(a)(iii) of E.O. 13949 of September 21, 2020 "Blocking Property of Certain Persons With Respect to the Conventional Arms Activities of Iran," (E.O. 13949) for having engaged, or attempted to engage, in any activity that materially contributes to, or poses a risk of materially contributing to, the proliferation of arms or related materiel or items intended for military end-uses or military end-users, including any efforts to manufacture, acquire, possess, develop, transport, transfer, or use such items, by the Government of Iran (including persons owned or controlled by, or acting for or on behalf of the Government of Iran) or paramilitary organizations financially or militarily supported by the Government of Iran.

2. MG-FLOT LIMITED LIABILITY COMPANY (a.k.a. MG-FLOT LLC (Cyrillic: ООО МГ-ФЛОТ); a.k.a. MG-FLOT ООО; a.k.a. TRANSMORFLOT LLC; a.k.a. TRANSMORFLOT SHIPPING COMPANY; a.k.a. TRANSMORPORT ООО), House 18 D Premise 1, Lenina Street, Akhtynskiy District, Republic of Dagestan 368730, Russia; ul. Chkalova, D. 27, Olya, Astrakhan Oblast 416425, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 17 Feb 2005; Tax ID No. 3017041900 (Russia); Identification Number IMO 6330601; alt. Identification Number IMO 6016988; Government Gazette Number 75191644 (Russia); Business Registration Number 1053001124483 (Russia) [IRAN-CON-ARMS-E.O.] [RUSSIA-EO14024].

Designated pursuant to section 1(a)(iii) of E.O. 13949 for having engaged, or attempted to engage, in any activity that materially contributes to, or poses a risk of materially contributing to, the proliferation of arms or related materiel or items intended for military end-uses or military end-users, including any efforts to manufacture,

acquire, possess, develop, transport, transfer, or use such items, by the Government of Iran (including persons owned or controlled by, or acting for or on behalf of the Government of Iran) or paramilitary organizations financially or militarily supported by the Government of Iran.

3. SAHA AIRLINES (a.k.a. ARMED FORCES AIR TRANSPORT SERVICE; a.k.a. SAHA AIRLINES PJSC; a.k.a. SERVICE ERTEBAATAAT-E HAVAAEE ARTESH), Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Organization Established Date 01 Jan 1989; Organization Type: Passenger air transport; alt. Organization Type: Freight air transport; Registration Number 6327 (Iran) [IFSR] [IRAN–EO13902] [IRAN–CON–ARMS–E.O.].

Designated pursuant to section 1(a)(iii) of E.O. 13949 for having engaged, or attempted to engage, in any activity that materially contributes to, or poses a risk of materially contributing to, the proliferation of arms or related materiel or items intended for military end-uses or military end-users, including any efforts to manufacture, acquire, possess, develop, transport, transfer, or use such items, by the Government of Iran (including persons owned or controlled by, or acting for or on behalf of the Government of Iran) or paramilitary organizations financially or militarily supported by the Government of Iran.

Notice of Department of State Actions

On September 17, 2026, the Department of State, in consultation with other departments, as appropriate, determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Entities

1. CENTRO DE INVESTIGACION Y DESARROLLO DE ARMAMENTO DE INFANTERIA (a.k.a. “CIDAI”), Circunvalacion Norte, Km 8½, Camaguey, Cuba; Organization Established Date 11 Apr 2010; Organization Type: Research and experimental development on natural sciences and engineering; alt. Organization Type: Defense activities; Target Type State-Owned Enterprise; Entity Code 14124 (Cuba) [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(A) of E.O. 14404 of May 1, 2026 “Imposing Sanctions on Those Responsible for Repression in Cuba and for Threats to United States National Security and Foreign Policy,” (E.O.

14404) for operating in or having operated in the defense and related materiel sector of the Cuban economy.

2. CENTRO DE INVESTIGACION Y DESARROLLO DE SIMULADORES (a.k.a. EMPRESA DE CIENCIA Y TECNOLOGIA SIMULADORES; a.k.a. “CID–SIM”; a.k.a. “ECTSIM”; a.k.a. “SIMPRO”), Loma S/N, Entre Santa Ana Y Conill, Nuevo Vedado, Plaza De La Revolucion, Havana, Cuba; Organization Established Date 09 Jul 2009; Organization Type: Research and experimental development on natural sciences and engineering; alt. Organization Type: Defense activities; Target Type State-Owned Enterprise; Entity Code 14032 (Cuba) [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(A) of E.O. 14404 for operating in or having operated in the defense and related materiel sector of the Cuban economy.

3. CENTRO DE INVESTIGACION Y DESARROLLO NAVAL (a.k.a. CIDNAV), Estrada Palma No. 13, Casablanca, Regla, Havana, Cuba; Organization Established Date 09 Jul 2009; Organization Type: Research and experimental development on natural sciences and engineering; alt. Organization Type: Defense activities; Target Type State-Owned Enterprise; Entity Code 14034 (Cuba) [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(A) of E.O. 14404 for operating in or having operated in the defense and related materiel sector of the Cuban economy.

4. CENTRO DE INVESTIGACION, DESARROLLO Y PRODUCCION GRITO DE BAIRE (a.k.a. CENTRO DE INVESTIGACION Y DESARROLLO GRITO DE BAIRE; a.k.a. CIDP GRITO DE BAIRE; a.k.a. GRITO DE BAIRE CENTER FOR RESEARCH AND DEVELOPMENT AND PRODUCTION; a.k.a. “CIDP–GB”; a.k.a. “GELCOM”; a.k.a. “GRUPO DE LA ELECTRONICA DE COMUNICACIONES”), Santa Ana S/N, Entre 47 Y Reforma, Nuevo Vedado, Plaza De La Revolucion, Havana, Cuba; Organization Established Date 11 Apr 2010; Organization Type: Research and experimental development on natural sciences and engineering; alt. Organization Type: Defense activities; Target Type State-Owned Enterprise; Entity Code 14123 (Cuba) [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(A) of E.O. 14404 for operating in or having operated in the defense and related materiel sector of the Cuban economy.

Individuals

1. CANCIO MONTEAGUDO, Joaquin Francisco, 58 #2906 Eyrpto, Playa, Havana, Cuba; DOB 16 Sep 1945; nationality Cuba; Gender Male; Passport E493203 (Cuba) expires 20 May 2031 (individual) [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(E) of E.O. 14404 for being or having been a leader, official, senior executive officer, or member of the board of directors of the Government of Cuba or an entity whose property or interests in property are blocked pursuant to E.O. 14404.

2. HURTADO BETANCOURT, Julio, Cuba; DOB 04 Nov 1962; nationality Cuba; Gender Male; Passport E459994 (Cuba) expires 29 Apr 2031 (individual) [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(E) of E.O. 14404 for being or having been a leader, official, senior executive officer, or member of the board of directors of the Government of Cuba or an entity whose property or interests in property are blocked pursuant to E.O. 14404.

3. PEDRERA ARGUELLO, Dioglis, Cuba; Calle 186 No 311531 Y 33, Playa, Havana, Cuba; DOB 13 Jun 1963; nationality Cuba; Gender Male; Passport A010659 (Cuba) expires 13 Aug 2030 (individual) [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(E) of E.O. 14404 for being or having been a leader, official, senior executive officer, or member of the board of directors of the Government of Cuba or an entity whose property or interests in property are blocked pursuant to E.O. 14404.

Notice of Department of State Actions

On August 24, 2026, the Department of State, in consultation with other departments, as appropriate, determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Entities

1. DADENEGAR STARTUP STUDIO, Fereydownkhani Street, South Dibaji, Tehran, Iran; Heravi Hossein Abad, Tehran, Iran; 6743 W 75th St, Al Fallujah, Al Anbar Governorate 31002, Iraq; Scharmberg 109, Assen 9407 EA, Netherlands; website <https://dadenegarco.com>; Email Address dadenegarcompany@gmail.com; alt. Email Address dadenegarhr@gmail.com; alt. Email Address dn.bi.api@gmail.com; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization

Established Date 2021; Organization Type: Computer programming activities [SDGT] [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(iii) of E.O. 13949 for having engaged, or attempted to engage, in any activity that materially contributes to, or poses a risk of materially contributing to, the proliferation of arms or related materiel or items intended for military end-uses or military end-users, including any efforts to manufacture, acquire, possess, develop, transport, transfer, or use such items, by the Government of Iran (including persons owned or controlled by, or acting for or on behalf of the Government of Iran) or paramilitary organizations financially or

militarily supported by the Government of Iran.

2. IRANIAN ISLAMIC REVOLUTIONARY GUARD CORPS CYBER-ELECTRONIC COMMAND (a.k.a. IRGC JANGAL ORGANIZATION; a.k.a. IRGC-CEC; a.k.a. ISLAMIC REVOLUTIONARY GUARD CORPS ELECTRONIC WARFARE AND CYBER DEFENSE ORGANIZATION), Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 [SDGT] [IRGC] [IFSR] [HRIT-IR] [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(iii) of E.O. 13949 for having

engaged, or attempted to engage, in any activity that materially contributes to, or poses a risk of materially contributing to, the proliferation of arms or related materiel or items intended for military end-uses or military end-users, including any efforts to manufacture, acquire, possess, develop, transport, transfer, or use such items, by the Government of Iran (including persons owned or controlled by, or acting for or on behalf of the Government of Iran) or paramilitary organizations financially or militarily supported by the Government of Iran.

BILLING CODE 4710-05-P

Individuals

1. TALAEI NIK, Reza (Arabic: رضا طلائی نیک), Iran; DOB 1963; POB Hamadan, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male (individual) [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(i) of E.O. 13949 for engaging in any activity that materially contributes to the supply, sale, or transfer, directly or indirectly, to or from Iran, or for the use in or benefit of Iran, of arms or related materiel, including spare parts.

2. FARAHI, Seyyed Mahdi (a.k.a. FARAHI, Seyyed Mehdi; a.k.a. FARAJZADEH, Seyyed Hadi), Iran; DOB 21 Mar 1962; alt. DOB 30 Sep 1960; POB Qom, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport G9321488 (Iran) expires 10 Oct 2016 (individual) [NPWMD] [IFSR] [IRAN-CON-ARMS-EO] (Linked To: MINISTRY OF DEFENSE AND ARMED FORCES LOGISTICS).

Designated pursuant to section 1(a)(ii) of E.O. 13949 for providing to Iran any technical training, financial resources or services, advice, other services, or assistance related to the supply, sale, transfer, manufacture, maintenance, or use of arms and related materiel described in subsection (a)(i) of E.O. 13949.

3. HATAMI, Amir (Arabic: امیر حاتمی), Iran; DOB 1966; POB Zanjan, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male (individual) [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(ii) of E.O. 13949 for providing to Iran any technical training, financial resources or services, advice, other services, or assistance related to the supply, sale, transfer, manufacture, maintenance, or use of arms and related materiel described in subsection (a)(i) of E.O. 13949.

4. EFTEKHARI, Sayyed Hosein Majid Musavi (a.k.a. IFTIKHARI, Sayyid Husayn Musawi; a.k.a. MOUSAVI, Majid; a.k.a. MOUSAVI, Sayid Majid), Iran; DOB 17 Feb 1965; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0040158721 (Iran) (individual) [NPWMD] [IRGC] [IFSR] [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(ii) of E.O. 13949 for providing to Iran any technical training, financial resources or services, advice, other services, or assistance related to the supply, sale, transfer, manufacture, maintenance, or use of arms and related materiel described in subsection (a)(i) of E.O. 13949.

5. ABDOLLAHI, Ali (a.k.a. ABDOLLAHI ALI ABADI, Ali; a.k.a. ABDOLLAHI ALIABADI, Ali (Arabic: علی عبداللهی علیآبادی)), Iran; DOB 1959; POB Aliabad, Rudbar County, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male (individual) [IRAN-EO13876] [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(ii) of E.O. 13949 for providing to Iran any technical training, financial resources or services, advice, other services, or

assistance related to the supply, sale, transfer, manufacture, maintenance, or use of arms and related materiel described in subsection (a)(i) of E.O. 13949.

6. VAHIDI, Ahmad (Arabic: احمد وحيدى) (a.k.a. CHERAGHI, Ahmad Shah), Tehran, Iran; DOB 27 Jun 1958; POB Shiraz, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Brigadier General (individual) [NPWMD] [IFSR] [IRAN-HR] [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(ii) of E.O. 13949 for providing to Iran any technical training, financial resources or services, advice, other services, or assistance related to the supply, sale, transfer, manufacture, maintenance, or use of arms and related materiel described in subsection (a)(i) of E.O. 13949.

7. ZOLQADR, Mohammad Baqer (Arabic: محمد باقر زو القدر) (a.k.a. ZOLGHADR, Mohammad Baqer; a.k.a. ZULQADER, Mohammad Baqer), Iran; DOB 1954; POB Faixa, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male (individual) [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(iii) of E.O. 13949 for having engaged, or attempted to engage, in any activity that materially contributes to, or poses a risk of materially contributing to, the proliferation of arms or related materiel or items intended for military end-uses or military end-users, including any efforts to manufacture, acquire, possess, develop, transport, transfer, or use such items, by the Government of Iran (including persons owned or controlled by, or acting for or on behalf of the Government of Iran) or paramilitary organizations financially or militarily supported by the Government of Iran.

BILLING CODE 4710-05-C

Notice of Department of State Actions

On August 6, 2026, the Department of State, in consultation with other departments, as appropriate, determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Entities

1. EMPRESA CUBANA IMPORTADA Y EXPORTADA DE PRODUCTOS TECNICOS (a.k.a. IMPORT AND EXPORT CUBAN COMPANY OF TECHNICAL PRODUCTS; a.k.a. STATE ENTERPRISE TECHNOIMPORT; a.k.a. TECHNOIMPORT; a.k.a. TECNOIMPORT), Havana, Cuba; Organization Established Date 01 Jan 1995; Organization Type: Wholesale of other machinery and equipment; Target Type State-Owned Enterprise [CUBA-EO14404].

Designated pursuant to section 2(a)(i)(A) of E.O. 14404 for operating in or having operated in the defense and related materiel sector of the Cuban economy.

2. SOCIEDAD MERCANTIL DUNA SA (a.k.a. "DUNA SA"), Havana, Cuba; Organization Established Date 11 Nov 2022; Organization Type: Non-specialized wholesale trade [CUBA-EO14404].

Designated pursuant to section 2(a)(i)(A) of E.O. 14404 for operating in or having operated in the defense and related materiel sector of the Cuban economy.

3. EMPRESA MILITAR INDUSTRIAL YURI GAGARIN (a.k.a. EMI YURI GAGARIN; a.k.a. YURI GAGARIN MILITARY INDUSTRIAL ENTERPRISE), Havana, Cuba; Organization Established Date 10 May 1966; Organization Type: Maintenance and repair of motor vehicles; Target Type State-Owned Enterprise [CUBA-EO14404].

Designated pursuant to section 2(a)(i)(A) of E.O. 14404 for operating in or having operated in the defense and related materiel sector of the Cuban economy.

4. UNION DE INDUSTRIA MILITAR (a.k.a. LA UNION DE INDUSTRIAS MILITARES; a.k.a. MILITARY INDUSTRIES UNION; a.k.a. UNION OF WAR INDUSTRY; a.k.a. "UIM"), Havana, Cuba; Organization Established

Date 1988; Organization Type: Defense activities; Target Type State-Owned Enterprise [CUBA-EO14404].

Designated pursuant to section 2(a)(i)(A) of E.O. 14404 for operating in or having operated in the defense and related materiel sector of the Cuban economy.

5. EMPRESA CUBANA EXPORTADORA E IMPORTADORA DE SERVICIOS, ARTICULOS Y PRODUCTOS TECNICOS ESPECIALIZADOS SA (a.k.a. TECNOTEX SA), Havana, Cuba; Organization Established Date 13 Sep 1983; Organization Type: Wholesale of other machinery and equipment; Target Type State-Owned Enterprise [CUBA-EO14404].

Designated pursuant to section 2(a)(i)(B) of E.O. 14404 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the Government of Cuba.

Individuals

1. VICIANA MOUSSET, Roberto Jesus, Havana, Cuba; DOB 26 Dec 1963; nationality Cuba; Gender Male (individual) [CUBA-EO14404].

Designated pursuant to section 2(a)(i)(E) of E.O. 14404 for being or having been a leader, official, senior executive officer, or member of the board of directors of UNION DE INDUSTRIA MILITAR, an entity whose property or interests in property are blocked pursuant to this order.

2. SANCHEZ ALLEYNE, Heriberto, Havana, Cuba; DOB 22 Aug 1966; POB Havana, Cuba; nationality Cuba; Gender Male; Passport I103675 (Cuba); alt. Passport E452433 (Cuba) issued 24 Mar 2023 expires 24 Mar 2029; National ID No. 66082217669 (Cuba) (individual) [CUBA–EO14404] (Linked To: EMPRESA CUBANA IMPORTADA Y EXPORTADA DE PRODUCTOS TECNICOS).

Designated pursuant to section 2(a)(i)(E) of E.O. 14404 for being or having been a leader, official, senior executive officer, or member of the board of directors of EMPRESA CUBANA IMPORTADORA Y EXPORTADORA DE PRODUCTOS TECNICOS, an entity whose property or interests in property are blocked pursuant to this order.

3. LOPEZ MIERA, Alvaro Victoriano, Cuba; DOB 26 Dec 1943; POB Havana, Cuba; nationality Cuba; Gender Male (individual) [GLOMAG] [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(E) of E.O. 14404 for being or

having been a leader, official, senior executive officer, or member of the board of directors of the Government of Cuba.

4. LEGRA SOTOLONGO, Roberto, Havana, Cuba; DOB 05 Jun 1954; POB Baracoa, Cuba; nationality Cuba; Gender Male; Passport A008444 (Cuba) expires 18 Jun 2027 (individual) [GLOMAG] [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(E) of E.O. 14404 for being or having been a leader, official, senior executive officer, or member of the board of directors of the Government of Cuba.

5. REMON RODRIGUEZ, Jose Antonio, Cuba; DOB 03 Oct 1960; nationality Cuba; Gender Male; Passport A011900 (Cuba) expires 04 Jan 2030 (individual) [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(E) of E.O. 14404 for being or having been a leader, official, senior executive officer, or member of the board of directors of the Government of Cuba.

6. BIOSCA GALLEG0, Oscar Enrique, Cuba; DOB 01 Jul 1958; POB Holguin, Cuba; nationality Cuba; Gender Male; Passport A011514 (Cuba) expires 14 Sep 2029 (individual) [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(E) of E.O. 14404 for being or having been a leader, official, senior executive officer, or member of the

board of directors of the Government of Cuba.

7. MILIAN GOMEZ, Monica, Moscow, Russia; DOB 13 Dec 1963; POB Havana, Cuba; nationality Cuba; Gender Female (individual) [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(E) of E.O. 14404 for being or having been a leader, official, senior executive officer, or member of the board of directors of the Government of Cuba.

8. PEREZ CORTES, Waldo, Beijing, China; DOB 13 Oct 1964; nationality Cuba; Gender Male; Passport A014056 (Cuba) (individual) [CUBA–EO14404].

Designated pursuant to section 2(a)(i)(E) of E.O. 14404 for being or having been a leader, official, senior executive officer, or member of the board of directors of the Government of Cuba.

Notice of Department of State Actions

On June 10, 2026, the Department of State, in consultation with other departments, as appropriate, determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

BILLING CODE 4710–05–P

Entities

1. CENTER FOR INNOVATION AND TECHNOLOGY COOPERATION (a.k.a. CENTER FOR PROGRESS AND DEVELOPMENT OF IRAN; a.k.a. OFFICE OF SCIENTIFIC AND INDUSTRIAL STUDIES; a.k.a. OFFICE OF SCIENTIFIC AND TECHNICAL COOPERATION; a.k.a. PRESIDENCY OFFICE OF SCIENTIFIC AND INDUSTRIAL STUDIES; a.k.a. TECHNOLOGY COOPERATION OFFICE; a.k.a. “CITC”; a.k.a. “CPDI”; a.k.a. “OSIS”; a.k.a. “POSIS”; a.k.a. “TCO”), No 7 East Avesta Rd, Sheykh Bahaie Street, Sheykh Bahaie Sq, Tehran 1995859611, Iran; PO Box 141554671, Tehran, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 01 Jan 1983 to 31 Dec 1984; Target Type Government Entity; National ID No. 14002821290 (Iran) [NPWMD] [IFSR] [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(ii) of E.O. 13949 for having provided to Iran any technical training, financial resources or services, advice, other services, or assistance related to the supply, sale, transfer, manufacture, maintenance, or use of arms and related materiel described in subsection (a)(i) of section 1 of E.O. 13949.

2. ARMORY ALLIANCE LLC (Cyrillic: ООО АРМОРИ АЛІЯНЦ), Building 33, Section 14, 13A, Tarkhanova St, Minsk 220035, Belarus; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 20 Oct 2021; Tax ID No. 193596647 (Belarus) [NPWMD] [IFSR] [IRAN-CON-ARMS-EO] (Linked To: CENTER FOR INNOVATION AND TECHNOLOGY COOPERATION).

Designated pursuant to section 1(a)(i) of E.O. 13949 for engaging in any activity that materially contributes to the supply, sale, or transfer, directly or indirectly, to or from Iran, or for the use in or benefit of Iran, of arms or related materiel, including spare parts.

BILLING CODE 4710-05-C

Individuals

1. MALEKI, Mohammadmahdi (a.k.a. MALEKI, Mohammad Mahdi), Belarus; DOB 26 Apr 1995; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; Passport I67689026 (Iran) expires 09 Mar 2029 (individual) [NPWMD] [IFSR] [IRAN-CON-ARMS-EO] (Linked To: CENTER FOR INNOVATION AND TECHNOLOGY COOPERATION).

Designated pursuant to section 1(a)(i) of E.O. 13949 for engaging in any activity that materially contributes to the supply, sale, or transfer, directly or indirectly, to or from Iran, or for the use in or benefit of Iran, of arms or related materiel, including spare parts.

2. AHADZADEH, Sajjad, Tehran, Iran; DOB 26 Mar 1983; POB Tehran, Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; Passport D10006855 (Iran); National ID No. 0072094400 (Iran) (individual) [IFSR] [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(iii) of E.O. 13949 for having engaged, or attempted to engage, in any activity that materially contributes to, or poses a risk of materially contributing to, the proliferation of arms or related materiel or items intended for military end-uses or military end-users, including any efforts to manufacture, acquire, possess, develop, transport, transfer, or use such items, by the

Government of Iran (including persons owned or controlled by, or acting for or on behalf of the Government of Iran) or paramilitary organizations financially or militarily supported by the Government of Iran.

Notice of Department of State Actions

On May 8, 2026, the Department of State, in consultation with other departments, as appropriate, determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

BILLING CODE 4710-05-P

Entities

1. MEENTROPY TECHNOLOGY HANGZHOU CO LTD (Chinese Simplified: 冕熵科技 杭州 有限公司) (a.k.a. MIZARVISION), No. 501, 2nd Street, Baiyang Street, 6-1103, Hangzhou, Zhejiang, China; Organization Established Date 03 Dec 2021; Registration Number 310141000638093 (China); Unified Social Credit Code (USCC) 91310115MA1K4Q0G00 (China) [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(ii) of E.O. 13949 for having provided to Iran any technical training, financial resources or services, advice, other services, or assistance related to the supply, sale, transfer, manufacture, maintenance, or use of arms and related materiel described in section (1)(a)(i) of E.O. 13949.

2. THE EARTH EYE CO (a.k.a. BEIJING MUMEI STARRY SKY TECHNOLOGY CO LTD; a.k.a. BEIJING MUMEI XINGKONG TECHNOLOGY CO LTD), No. Jia 21-120, Beizhuanghu Village, Machikou Town, Changping District, Beijing, China; Website <https://www.teesat.com>; Organization Established Date 10 Nov 2021; Unified Social Credit Code (USCC) 91110105MA04H61R7D (China) [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(ii) of E.O. 13949 for having provided to Iran any technical training, financial resources or services, advice, other services, or assistance related to the supply, sale, transfer, manufacture, maintenance, or use of arms and related materiel described in section (1)(a)(i) of E.O. 13949.

3. CHANG GUANG SATELLITE TECHNOLOGY CO., LTD. (Chinese Simplified: 长光卫星科技有限公司) (a.k.a. CHANGGUANG SATELLITE CO., LTD.; a.k.a. "CGSTC"; a.k.a. "CGSTL"; a.k.a. "CHARMING GLOBE"), No. 1299, Mingxi Road, Beihu Science Technology Development District, Changchun, Jilin, China; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 2014; Unified Social Credit Code (USCC) 91220101310012867G (China) [IRAN-CON-ARMS-EO] [RUSSIA-EO14024].

Designated pursuant to section 1(a)(iii) of E.O. 13949 for having engaged, or attempted to engage, in any activity that materially contributes to, or poses a risk of materially contributing to, the proliferation of arms or related materiel or items intended for military end-uses or military end-users, including any efforts to manufacture, acquire, possess, develop, transport, transfer, or use such items, by the Government of Iran (including persons owned or controlled by, or acting for or on behalf of the Government of Iran) or paramilitary organizations financially or militarily supported by the Government of Iran.

4. MINISTRY OF DEFENCE EXPORT CENTER (a.k.a. MINISTRY OF DEFENSE LEGION EXPORT; a.k.a. MINISTRY OF DEFENSE LOGISTICS EXPORT; a.k.a. "MINDEX"; a.k.a. "MINDEX CENTER"; a.k.a. "MODLEX"), PO Box 16315-189, Tehran, Iran, located on the west side of Dabestan Street, Abbas Abad District, Tehran, Iran; PO Box 19315-189, Pasdaran Street, South Noubonyand Square, Tehran, Iran; Additional Sanctions Information - Subject to Secondary Sanctions [NPWMD] [IFSR] [IRAN-CON-ARMS-EO].

Designated pursuant to section 1(a)(iii) of E.O. 13949 for having engaged, or attempted to engage, in any activity that materially contributes to, or poses a risk of materially contributing to, the proliferation of arms or related materiel or items intended for military end-uses or military end-users, including any efforts to manufacture, acquire, possess, develop, transport, transfer, or use such items, by the Government of Iran (including persons owned or controlled by, or acting for or on behalf of the Government of Iran) or paramilitary organizations financially or militarily supported by the Government of Iran.

BILLING CODE 4710-05-C

Notice of Department of State Actions

On August 20, 2021, the Department of State, in consultation with other departments, as appropriate, determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Entities

1. 27TH SCIENTIFIC CENTER (a.k.a. 27TH NTS; a.k.a. FEDERAL STATE BUDGETARY ESTABLISHMENT 27 SCIENTIFIC CENTER OF THE MINISTRY OF DEFENSE OF THE RUSSIAN FEDERATION), Brigadirskiy Pereulok 13, Moscow, 105005, Russia; Additional Sanctions Information—Subject to Secondary Sanctions [RUSSIA—EO14024] [NPWMD].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

2. 33RD SCIENTIFIC RESEARCH AND TESTING INSTITUTE (a.k.a. 33RD TSNII; a.k.a. FEDERAL STATE BUDGETARY ESTABLISHMENT 33 CENTRAL SCIENTIFIC RESEARCH TEST INSTITUTE OF THE MINISTRY OF DEFENSE OF THE RUSSIAN FEDERATION), 1 Ulitsa Krasnoznamennaya Volsk-18/Shikhany, Saratov Oblast, Russia; Krasnoznamennaya Street 1, Volsk-18, Saratov, 41218, Russia; Additional Sanctions Information—Subject to Secondary Sanctions [RUSSIA—EO14024] [NPWMD].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector of the Russian Federation economy.

Notice of Department of State Actions

Effective June 8, 2020, the Department of State, in consultation with other departments, as appropriate, determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Entities

1. ESAIL SHIPPING LIMITED (a.k.a. E-SAIL SHIPPING COMPANY LTD; f.k.a. SANTEX LINES), Building 1088, Suite 1501, Pudong South Road (Shanghai Zhong Rong Plaza), Shanghai 200122, China; Additional Sanctions Information—Subject to Secondary Sanctions; Trade License No. 1429927 (Hong Kong) [IRAN]. -to- ESAIL

SHIPPING LIMITED (a.k.a. E-SAIL SHIPPING COMPANY LTD; f.k.a. SANTEX LINES), Building 1088, Suite 1501, Pudong South Road (Shanghai Zhong Rong Plaza), Shanghai 200122, China; Additional Sanctions Information—Subject to Secondary Sanctions; Trade License No. 1429927 (Hong Kong) [IRAN] [NPWMD] [IFSR].

Designated pursuant to section 1(a)(ii) of Executive Order 13382 of June 28, 2005 “Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters,” (E.O. 13382) for having engaged, or attempted to engage, in activities or transactions that have materially contributed to, or pose a risk of materially contributing to, the proliferation of weapons of mass destruction or their means of delivery (including missiles capable of delivering such weapons), including any efforts to manufacture, acquire, possess, develop, transport, transfer or use such items, by any person or foreign country of proliferation concern.

2. ISLAMIC REPUBLIC OF IRAN SHIPPING LINES (a.k.a. IRISL), Asseman Tower, Pasdaran Street, Tehran, Iran; P.O. Box 19395-177, Tehran, Iran; P.O. Box 1957614114, Tehran, Iran; No 523, Al Seman Tower Building, No 8: Narenjestan, Laveitani Street, Sayya Shirazi Square, Pasdaran Street, Tehran 1957617114, Iran; No 37 Aseman Tower Sayyade Shirazee Square, Pasdaran Avenue, PO Box 19395-1311, Tehran, Iran; website www.irisl.net; IFCA Determination—Involved in the Shipping Sector; Additional Sanctions Information—Subject to Secondary Sanctions; Trade License No. 11670 (Iran); All Offices Worldwide [IRAN] [NPWMD] [IFSR] [IFCA].

Designated pursuant to section 1(a)(ii) of E.O. 13382 for having engaged, or attempted to engage, in activities or transactions that have materially contributed to, or pose a risk of materially contributing to, the proliferation of weapons of mass destruction or their means of delivery (including missiles capable of delivering such weapons), including any efforts to manufacture, acquire, possess, develop, transport, transfer or use such items, by any person or foreign country of proliferation concern.

Notice of Department of State Actions

On July 18, 2017, the Department of State, in consultation with other departments, as appropriate, determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Entities

1. ISLAMIC REVOLUTIONARY GUARD CORPS AEROSPACE FORCE SELF SUFFICIENCY JIHAD ORGANIZATION (a.k.a. ISLAMIC REVOLUTIONARY GUARD CORPS AEROSPACE FORCE RESEARCH AND SELF SUFFICIENCY JEHAD ORGANIZATION; a.k.a. ISLAMIC REVOLUTIONARY GUARD CORPS AEROSPACE FORCE SELF-SUFFICIENCY JEHAD ORGANIZATION), Iran; Additional Sanctions Information—Subject to Secondary Sanctions [NPWMD] [IRGC] [IFSR].

Designated pursuant to section 1(a)(ii) of E.O. 13382 for having engaged, or attempted to engage, in activities or transactions that have materially contributed to, or pose a risk of materially contributing to, the proliferation of weapons of mass destruction or their means of delivery (including missiles capable of delivering such weapons), including any efforts to manufacture, acquire, possess, develop, transport, transfer or use such items, by any person or foreign country of proliferation concern.

2. ISLAMIC REVOLUTIONARY GUARD CORPS RESEARCH AND SELF-SUFFICIENCY JEHAD ORGANIZATION (a.k.a. ISLAMIC REVOLUTIONARY GUARD CORPS RESEARCH AND SELF-SUFFICIENCY JIHAD ORGANIZATION; a.k.a. ISLAMIC REVOLUTIONARY GUARD CORPS SELF-SUFFICIENCY JEHAD ORGANIZATION), Iran; Additional Sanctions Information—Subject to Secondary Sanctions [NPWMD] [IRGC] [IFSR].

Designated pursuant to section 1(a)(ii) of E.O. 13382 for having engaged, or attempted to engage, in activities or transactions that have materially contributed to, or pose a risk of materially contributing to, the proliferation of weapons of mass destruction or their means of delivery (including missiles capable of delivering such weapons), including any efforts to manufacture, acquire, possess, develop, transport, transfer or use such items, by any person or foreign country of proliferation concern.

Gonzalo O. Suarez,

Deputy Assistant Secretary, Bureau of Arms Control and Nonproliferation, U.S. Department of State.

[FR Doc. 2026-22187 Filed 10-29-26; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Public Notice: 13145]

Determination Pursuant to Section 451 of the Foreign Assistance Act of 1961

Pursuant to section 451 of the Foreign Assistance Act of 1961 (the “Act”) (22 U.S.C. 2261) and section 1–100(a)(I) of E.O. 12163, I hereby authorize, notwithstanding any other provision of law, the use of up to \$125,000,000 made available to carry out provisions of the Act (other than the provisions of chapter 1 of part I of the Act) to provide assistance authorized by part I of the Act to support exigent energy security needs for partners facing coercive supply cutoffs, market disruptions, and inflated costs.

This Determination and the accompanying Memorandum of Justification shall be promptly reported to the Congress. This Determination shall be published in the **Federal Register**.

Dated: September 25, 2026.

Marco Rubio,

Secretary of State, U.S. Department of State.

[FR Doc. 2026–22252 Filed 10–29–26; 8:45 am]

BILLING CODE 1470–05–P

SURFACE TRANSPORTATION BOARD**Release of Waybill Data**

The Surface Transportation Board has received a request from Georgetown University, (WB26–50–09/16/26) for permission to use all fields in the Unmasked Carload Waybill Sample data from 1984 through 2026 inclusive. A copy of this request may be obtained from the Board’s website under docket no. WB26–50.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board’s Office of Economics within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

Any inquiries on this request should be directed to waybill@stb.gov.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2026–22232 Filed 10–29–26; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****Notice of Meeting of the National Parks Overflights Advisory Group**

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of meeting.

SUMMARY: The Federal Aviation Administration (FAA) and the National Park Service (NPS), in accordance with the National Parks Air Tour Management Act of 2000 (NPATMA), announce the next meeting of the National Parks Overflights Advisory Group (NPOAG). This notification provides the date, location, and agenda for the meeting.

DATES: The NPOAG will meet on November 3, 2026, from 10:00 a.m. ET–3:30 p.m. ET.

ADDRESSES: The meeting will take place at the Department of Transportation Volpe Center, 220 Binney St., Cambridge, MA 02142. This NPOAG meeting is open to the public.

FOR FURTHER INFORMATION CONTACT: Sandra Fox, sandra.y.fox@faa.gov; (202) 267–0928; 400 N 8th St., Suite 750, Richmond, VA 23219.

SUPPLEMENTARY INFORMATION:**I. Background**

NPATMA, enacted on April 5, 2000, as Public Law 106–181, required the establishment of the NPOAG within one year after its enactment. NPATMA requires that the NPOAG be a balanced group of representatives of general aviation, commercial air tour operations, environmental concerns, and Native American tribes. The Administrator of the FAA and the Director of NPS (or their designees) serve as ex officio members of the group. Representatives of the Administrator and Director serve alternating 1-year terms as chairperson of the advisory group.

The duties of the NPOAG include providing advice, information, and recommendations to the FAA Administrator and the NPS Director on implementation of Public Law 106–181; quiet aircraft technology; other measures that might accommodate interests to visitors of national parks; and at the request of the Administrator and the Director, on safety, environmental, and other issues related to commercial air tour operations over national parks or tribal lands.

II. Agenda for November 3, 2026, NPOAG Meeting

The agenda for the meeting will include, but is not limited to, air tour reporting, competitive bidding, and quiet technology.

III. Attendance at the Meeting and Submission of Written Comments

Although this is not a public meeting, interested persons may attend. Because seating is limited, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** no later than Nov 2, 2026, if you plan to attend so that meeting space may be made to accommodate all attendees. Written comments regarding the meeting will be accepted directly from attendees or may be sent to the person listed under **FOR FURTHER INFORMATION CONTACT**.

IV. Record of the Meeting

If you cannot attend the NPOAG meeting, a summary of the meeting will be made available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Issued in Washington, DC, on October 28, 2026.

Eric Elmore,

Senior Policy Advisor, Federal Aviation Administration—Office of Environment and Energy.

[FR Doc. 2026–22242 Filed 10–29–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Transit Administration****Safety Advisory 26–01 Overhead Catenary System (OCS) and Pantograph Reliability**

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Notice of Safety Advisory.

SUMMARY: The Federal Transit Administration (FTA) is issuing Safety Advisory 26–01 to recommend State Safety Oversight Agencies (SSOAs) direct Rail Transit Agencies (RTAs) within their jurisdiction to use their Safety Management System (SMS) to identify hazards and mitigate risks related to Overhead Catenary System (OCS) and pantograph failures.

FOR FURTHER INFORMATION CONTACT: Isaiah Garcia, Senior Accident Investigator, Office of Transit Safety and Oversight, at Isaiah.Garcia@dot.gov, phone: 202–695–9765.

SUPPLEMENTARY INFORMATION: The FTA is issuing Safety Advisory 26–01 in response to recent OCS and pantograph-

related events that highlight emerging systemic risks across rail transit systems, including structural failures, pantograph entanglements, and downed live wires.

FTA recommends that State Safety Oversight Agencies (SSOAs) direct Rail Transit Agencies (RTAs) within their jurisdiction to use the RTA's Safety Management System (SMS) to review and analyze safety performance data to identify hazards related to OCS and pantograph failures, conduct safety risk assessments, identify new or modified safety risk mitigations as necessary to reduce the associated safety risks, and monitor the effectiveness of those mitigations as part of the RTA's Safety Assurance process.

FTA recommends SSOAs obtain any documentation related to the recommended actions outlined above from their RTAs.

FTA recommends that SSOAs that receive such documentation submit it to the State Safety Oversight Reporting (SSOR) system within 180 days from the issuance of this Safety Advisory.

FTA's Safety Advisory 26–01, "Overhead Catenary System (OCS) and Pantograph Reliability," will be available in its entirety on the agency's public website: <https://www.transit.dot.gov/regulations-and-guidance/safety/fta-safety-advisories>.

Authority: 49 U.S.C. 5329; 49 CFR 1.91 and 670.29.

Jamie D. Pfister,
Acting Executive Director.

[FR Doc. 2026–22168 Filed 10–29–26; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2026–1321]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Request for Comment; State Data Transfer (SDT)

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for renewal with modification of a currently approved information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) summarized below will be submitted to

the Office of Management and Budget (OMB) for review and approval. The ICR describes the nature of the information collection and its expected burden. This document describes a collection of information for which NHTSA intends to seek OMB approval on the State Data Transfer (SDT) program for Vehicle Crash Information. A **Federal Register** Notice with a 60-day comment period soliciting comments on this information collection was published on June 25, 2026. NHTSA received one public comment.

DATES: Comments must be submitted on or before November 30, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection, including suggestions for reducing burden, should be submitted to the Office of Management and Budget at www.reginfo.gov/public/do/PRAMain. To find this particular information collection, select "Currently under Review—Open for Public Comment" or use the search function.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Liza Lemaster-Sandbank, Office of State Data Reporting System Division (NSA–0120), telephone (202) 744–5942, National Highway Traffic Safety Administration, W43–481, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Please identify the relevant collection of information by referring to its OMB Control Number, 2127–0753.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), a Federal agency must receive approval from the Office of Management and Budget (OMB) before it collects certain information from the public, and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. In compliance with these requirements, this notice announces that the following information collection request will be submitted to OMB.

Title: State Data Transfer (SDT).

OMB Control Number: 2127–0753.

Form Number(s): N/A.

Type of Request: Renewal with modification of a currently approved information collection.

Type of Review Requested: Regular.

Length of Approval Requested: Three years from date of approval.

Summary of the Collection of Information: The State Data Transfer (SDT) program is a voluntary collection of motor vehicle crash data.

Participating States electronically transfer Police Crash Report (PCR) data, supplemental crash reports, and crash images to NHTSA using automated electronic data transfer (EDT) protocols. Transfers typically occur nightly in Extensible Markup Language (XML) or JavaScript Object Notation (JSON) formats via web services. This information collection updates the burden estimates and removes the legacy State Data System (SDS) protocol, which is being sunsetted, leaving only the automated EDT protocol in place. The program includes Non-SEDC States that voluntarily transmit data under the terms of a memorandum of understanding, as well as SEDC States participating under the State Electronic Data Collection (SEDC) discretionary grant program, which requires states to modernize their crash data repositories, align with Model Minimum Uniform Crash Criteria (MMUCC) Sixth Edition standards, and transfer data electronically.

Description of the Need for the Information and Proposed Use of the Information: NHTSA uses SDT data to identify existing and emerging highway safety trends, evaluate the effectiveness of motor vehicle safety standards, and develop countermeasures to reduce deaths and injuries from motor vehicle crashes. The data allows NHTSA to study the effectiveness of emerging technologies, such as advanced driver assistance systems (ADAS), and supplies critical volume to support cost-benefit analyses for Corporate Average Fuel Economy (CAFE) rulemakings regarding vehicle mass and fatality rates. Furthermore, automated SDT data pre-populates several NHTSA systems and special studies, including the Fatality Analysis Reporting System (FARS), Crash Report Sampling System (CRSS), and Crash Investigation Sampling System (CISS). This electronic transfer significantly reduces the administrative and technical burden on States by eliminating manual, redundant data entry into Federal databases.

60-Day Notice: NHTSA published a 60-day notice on June 25, 2026, requesting comment on NHTSA's intention to submit this ICR to OMB for approval (91 FR 38472). During the comment period, NHTSA received one comment from Mr. Eric Hein.

Mr. Hein's comment supported the renewal of the State Data Transfer (SDT) program but was critical of how underride crashes are currently captured and transferred into NHTSA's national crash databases (such as FARS, CRSS, and CISS). He argued that underreporting and misclassification of

underride crashes is a practical utility issue under the Paperwork Reduction Act (PRA). To resolve these data deficiencies at the source, Mr. Hein urged NHTSA to use its existing authorities under the SDT program, specifically by adding a dedicated underride data element to the State Electronic Data Collection (SEDC) discretionary grant requirements and Non-SEDC States, operating under a Memoranda of Understanding (MOUs) and data mapping. This would require participating States to capture and transfer a discrete underride field electronically. He also requested that NHTSA establishes adoption of timelines and completeness benchmarks for underride reporting, track vulnerable road user underride events separately from passenger-vehicle crashes, and report on progress in the administrative record.

NHTSA remains committed to improving its crash data collections wherever possible, because accurate and reliable data is essential to the agency's lifesaving mission. In response to Mr. Hein's comments, NHTSA has taken several significant steps to enhance the quality, utility, and accuracy of underride data collections, while ensuring consistency with the agency's statutory authorities:

1. **Model Minimum Uniform Crash Criteria (MMUCC) Sixth Edition Alignment:** In February 2023, NHTSA published a draft 6th edition of MMUCC for public comment. The 6th edition of MMUCC was finalized and published in January 2024, formally incorporating the standardized "Vehicle Underride or Override" data element (with attributes: None or Not Applicable, Underride, Override, and Unknown) along with an Initial Contact Point clock points element. Under the SEDC discretionary grant program, participating States are required to align their centralized statewide crash repositories with the latest MMUCC 6th Edition standards at a minimum of 25 to 34 percent. While achieving 100 percent alignment is voluntary, the grant program offers a direct, funded pathway, whereas alignment remains fully voluntary for non-SEDC States.

2. **Standardization of Definition and Database Integration:** NHTSA has implemented this standardized MMUCC definition of underride and override across both the Fatality Analysis Reporting System (FARS) and the Crash Report Sampling System (CRSS) data collection programs and related documentation.

3. **Statutory Limitations on Mandating Crash Reports:** While Mr. Hein requested that NHTSA mandate an

underride/override "checkbox" on all State police crash reports, NHTSA published a denial of a related request in April 2025, explaining that the agency lacks the statutory authority to mandate specific data fields, formats, or modifications to individual State crash report forms. Participation in SDT, FARS, the SEDC grant program, and the non-SEDC electronic data transfer (EDT) protocol by States is voluntary. However, NHTSA continues to actively encourage and support States in adopting the MMUCC 6th Edition. Once a State implements the MMUCC underride data element, the SDT automated (EDT) protocol automatically maps and transfers this data nightly to NHTSA's databases.

4. **Improved Database Coding and Quality Checks:** Based on a 2020 internal study, NHTSA has implemented multiple updates to improve the accuracy of vehicle underride/override reporting in its crash databases starting in 2021. These updates include:

a. Simplified underride/override coding (assessed for each vehicle in every vehicle-to-vehicle collision),

b. Replaced coding guidance in manuals,

c. Enhanced training for analysts and coders to note the difference in procedures with the combination of underride and override crashes versus a single occurrence for the vehicle performing the action.

d. Developed new automated edit checks to verify coding accuracy by recording the action of both vehicles.

5. **GAO Recommendations Addressed:** NHTSA has successfully addressed and closed three March 2019 Government Accountability Office (GAO) recommendations (Report GAO-19-264) regarding improved underride data collection and research. This included developing and distributing an underride training pamphlet to State and local law enforcement.

6. **Vulnerable Road User Tracking:** Regarding separate tracking of vulnerable road users, researchers can currently determine underride or override details in FARS and CRSS by combining the standardized Vehicle Underride or Override data element with Sequence of Events, Initial Contact Point, Damaged Areas, and other crash-level elements.

Affected Public: State governments, the District of Columbia government, U.S. Territory governments (generically referred to as "States").

Estimated Number of Respondents: 35.

Frequency: Nightly/daily automated electronic feeds, with some respondents submitting weekly or monthly.

Estimated Total Annual Burden

Hours: 14,389 hours.

The SDT Program receives crash data from States in two ways: (1) the Non-SEDC protocol, under a voluntary MOU between NHTSA and each State, of which there are currently 22 participating States, and (2) the SEDC grant, which imposes specific grant requirements; there are 18 SEDC grantees. Of the 22 Non-SEDC States, 10 have been awarded SEDC grants and will transition to SEDC transmission requirements by January 2030. The remaining eight participating SEDC grantees are actively developing their capabilities to implement electronic data transmission under the SEDC requirements by that same deadline.

This ICR is being modified to remove the legacy SDS protocol and to reflect the ongoing EDT participation by both Non-SEDC States and SEDC grantees. As a result, NHTSA projects a total of 33 annual respondents by January 2030: 12 Non-SEDC States (the 22 original States minus the 10 transitioning to SEDC) and 18 SEDC grantees (the 10 transitioning EDT States plus the 8 SEDC-only States). The transition to the SEDC transmission will happen gradually, with approximately three States migrating per year until all 10 complete the shift by January 2030. The eight SEDC-only States will also begin their SEDC transmissions over this period. Because the transmission requirements differ for Non-SEDC and SEDC grantees, the annual burden for each group is detailed separately below.

States Using SDS Protocol

SDS information was previously obtained using a traditional method via electronic media through secured mail or a Secure File Transfer Protocol (SFTP) from participating States on an annual basis. However, this collection has been sunset, removing the associated State burden.

Non-SEDC EDT Protocol

The State burden associated with the EDT protocol varies between Non-SEDC States and SEDC grantees. This difference is driven by the distinct requirements placed on each group, such as mutually agreed upon data sharing memorandum of understanding for Non-SEDC States or mandatory data standardization and MMUCC alignment for SEDC grantees.

The burden estimate for Non-SEDC States is derived from the actual level of effort reported by states currently using the Non-SEDC EDT protocol. NHTSA

projects that each year, one additional state will implement the protocol, while several existing SEDC grantees will transition from Non-SEDC to SEDC requirements annually. Consequently,

NHTSA anticipates an average of 17 active Non-SEDC states annually over the next three years (22 in Year 1, 20 in Year 2, and 18 in Year 3) as shown in Table 1. For these states, the burden is

limited to annual maintenance, apart from the newly added state, which also includes implementation costs.

TABLE 1—NUMBER OF NON-SEDC PROTOCOL STATES

Non-SEDC protocol State	Number of Non-SEDC State each year	Number of Non-SEDC State to SEDC State conversion	Newly added Non-SEDC States
Current Year	22	0	0
Current + 1	22	1	1
Current + 2	20	3	1
Current + 3	18	3	1
Average Per Year for Next Three Years	20	3	1

Maintenance Burden Calculation for Non-SEDC States

Non-SEDC States report an annual maintenance burden of five (5) hours per respondent, primarily dedicated to troubleshooting connections and refining data mapping protocols. To calculate the economic impact, NHTSA utilizes the May 2024 BLS mean wage for Software and Web Developers (\$71.54/hour¹). Adjusting for total compensation, where wages comprise 61.7%² of the package, the fully loaded hourly rate is \$115.95. Consequently, the annual maintenance cost per state is approximately \$579.75. Based on a projected average of 20 participating Non-SEDC States, the total annual collective burden is estimated at 100 hours and \$11,595.00 in labor costs.

Implementation Burden Calculation for Non-SEDC States

States report an initial implementation burden of 150 hours per respondent. To calculate the economic impact, NHTSA utilizes the May 2024 BLS mean wage for Software and Web Developers (\$71.54/hour). Adjusting for total compensation, where wages comprise 61.7% of the package, the fully loaded hourly rate is \$115.95. Consequently, the implementation cost for a new Non-SEDC EDT State is approximately \$17,392.50 in labor costs. Based on the addition of one new participating State, the total collective implementation burden is estimated at 150 hours and \$17,392.50 in labor costs.

SEDC EDT Protocol

On January 31, 2024, NHTSA issued a Notice of Funding Opportunity (NOFO) to modernize state crash data systems and facilitate electronic data transfer to NHTSA, which is the SEDC program. Twenty-six jurisdictions, including States, Territories, and the Bureau of Indian Affairs, applied for the SEDC grant. Nineteen applicants were awarded the SEDC Grant. There are currently eighteen active SEDC grantees, with one grantee terminating their agreement in the first year of the project.

SEDC grantees must commit to electronically transferring standardized crash data to NHTSA within five years of the award. Key implementation actions and funding uses were identified from each State's workplan and budget for the following three goals:

- (i) equipment to upgrade a statewide crash data repository;
- (ii) adoption of electronic crash reporting by law enforcement agencies; and
- (iii) increasing alignment of State crash data with the latest Model Minimum Uniform Crash Criteria.

Under the SEDC grant, States (excluding American Samoa) are required to provide a 20% non-federal match of the total grant award. Because grant applications required total budget commitments rather than granular labor categories, NHTSA's State burden estimates are derived directly from these matching funds committed. These costs cover both the initial development

effort, such as repository updates and MMUCC alignment, and the ongoing implementation of standardized data transmissions. The SEDC grant does not allow operation and maintenance costs, therefore, the same Non-SEDC State calculations are used to estimate the maintenance burden cost for the SEDC grantees.

NHTSA anticipates that during the first two (2) years of the grant, *i.e.*, the past and current year, all States will be in the development and implementation phase, meaning no data transmission is expected. Beginning next year (Current+1), States will gradually begin transmitting data using the SEDC protocol, either by converting from an existing Non-SEDC EDT system or joining as a brand-new SEDC state. Specifically, NHTSA estimates that two states will begin transmitting in Year (Current+1), five in Year (Current+2), and five in Year (Current+3), averaging four states per year. Over these final three years, an average of seven states per year will be actively transmitting data. Concurrently, for the next three years, the number of states in the maintenance phase will scale from zero Year (Current+1) to two Year (Current+2), and seven Year (Current+3), averaging three states per year. Meanwhile, the number of states remaining in the implementation phase will decrease from 16 Year (Current+1) to 11 Year (Current+2), and six (Current+3), averaging 11 states per year. The details are shown in Table 2.

¹ May 2024 National Occupational Employment and Wage Estimates United States, Occupational Employment Statistics, Bureau of Labor Statistics, U.S. Department of Labor, <https://www.bls.gov/>

[news.release/ecec.t01.htm](https://www.bls.gov/news.release/ecec.t01.htm), last accessed April 29, 2026).

² See Table 1, Employer Costs for Employee Compensation by ownership (Dec. 2025), available

at <https://www.bls.gov/news.release/ecec.t01.htm> (accessed April 29, 2026).

TABLE 2—NUMBER OF SEDC PROTOCOL STATES

SEDC protocol	States finish implementation	Total number of SEDC State under implementation	Number of States for maintenance
Current Year	0	18	0
Current + 1	2	16	0
Current + 2	5	11	2
Current + 3	5	6	7
Average Per Year for Next Three Years	4	11	3

Implementation Burden Calculation for SEDC States

The collective burden calculation for the 17 SEDC States based on the State’s matching fund, except for American Samoa which is not required to provide matching fund. These matching funds represent eligible expenses such as state employee labor, contractual services, IT, and equipment costs. Because this comprehensive project inherently demands a mix of contractual services, IT or equipment needs, in addition to State’s personnel costs, some States agreed to a flat 20% match under personnel, contractual or a combination of eligible cost categories rather than calculating an exact mathematical breakdown for each individual line item.

Out of the eighteen SEDC States, 15 committed matching funds for State personnel costs. Among these, only four States itemized their actual labor costs and burden hours, while the remaining 11 committed to a flat percentage. Based on the four states that explicitly provided estimated burden hours for their matching personnel costs, the

baseline average per State is 1,284 burden hours annually, with a corresponding average labor cost of \$198,512.65. Applying these averages to the 11 states projected to be in the implementation phase each year, the total labor burden hours and cost are 14,121 hours and \$2,183,639.15.

Nine out of these fifteen States also committed a percentage of their State-match to contractual costs, which may be used for contractor, IT, or equipment activity costs. The remaining three States committed their entire matching requirement to the contractual cost category without exact breakdowns for contractual services, IT and equipment costs.

Maintenance Burden Calculation for SEDC States

Non-SEDC States report an annual maintenance burden of five (5) hours per respondent, primarily dedicated to troubleshooting connections and refining data mapping protocols. NHTSA will apply this same annual maintenance burden to the SEDC grantees. To calculate the economic

impact, NHTSA utilizes the May 2024 BLS mean wage for Software and Web Developers (\$71.54/hour³). Adjusting for total compensation, where wages comprise 61.7%⁴ of the package, the fully loaded hourly rate is \$115.95. Consequently, the annual maintenance cost per state is approximately \$579.75. Based on a projected average of 3 participating SEDC States under maintenance phase, the total annual collective burden is estimated at 15 hours and \$1,739.25 in labor costs.

Table 3 is a representation of implementation and maintenance burden. The breakdown is based on information received from every SEDC grantees’ workplan and budget descriptions. NHTSA estimates burden for development and implementation using actual labor hour and cost breakdowns when available, percent cost commitment, or actual monetary figures provided. Maintenance costs are based on known State maintenance burden reported by Non-SEDC EDT States currently maintaining the EDT protocol.

TABLE 3—TOTAL ANNUAL STATE IMPLEMENTATION AND MAINTENANCE BURDEN

Category	Annual respondents (states)	Burden per respondent (hours)	Annual total burden hours (hours)	Labor rate w/o overhead (\$)	Overhead rate (%)	Labor rate w/overhead (\$)	Burden cost per respondent (\$)	Total labor cost (\$)
Non-SEDC Implementation	1	150	150	\$71.54	61.70	\$115.95	\$17,392.50	\$17,392.50
Non-SEDC Maintenance	20	5	100	71.54	61.70	115.95	579.75	11,595.00
SEDC Implementation	11	1,284	14,124	NA	NA	NA	198,512.65	2,183,639.15
SEDC Maintenance	3	5	15	71.54	61.70	115.95	579.75	1,739.25
Total	35	1,444	14,389					2,214,365.90

Estimated Total Annual Burden Cost: \$ 6,262,231.02.

The SEDC grant, in compliance with IJA, requires a 20% match from participating State respondents. Based on information provided by the SEDC grantees, as part of the required 20% match from each grantee with the

exception of American Samoa, NHTSA estimates the annual average per State burden cost for the SEDC program (beyond the labor costs discussed above) will be about \$569,293.73 for the non-labor burdens, which includes contracts, equipment, IT cost and other miscellaneous burdens. For the eleven

states under implementation, the total burden cost is \$6,262,231.02.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the

³ May 2024 National Occupational Employment and Wage Estimates United States, Occupational Employment Statistics, Bureau of Labor Statistics,

U.S. Department of Labor, <http://www.bls.gov/soc/home.htm>, last accessed April 29, 2026).

⁴ Employer Costs for Employee Compensation by ownership (Dec. 2025), available at <https://www.bls.gov/news.release/eccec.t01.htm> (accessed April 29, 2026).

agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29A.

Rajesh Subramanian,

Acting Associate Administrator, National Center for Statistics and Analysis.

[FR Doc. 2026–22226 Filed 10–29–26; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2026–2377]

Denial of Motor Vehicle Defect Petition, DP26–009

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Denial of a petition as moot with Recall 26V525.

SUMMARY: This notice sets forth the reasons for the denial of defect petition (DP26–009) submitted by Mr. Jason Rund (petitioner) to NHTSA's Administrator. The petition requests NHTSA (the Agency) to initiate a defect investigation to determine if an issue with the rear differential (final drive) assembly of 2022 BMW 540i vehicles is causing the rear wheels to decouple from the drivetrain. Following a technical review of the petition and other information, NHTSA's Office of Defects Investigation (ODI) concluded that that the issues raised do not warrant a defect investigation at this time. Accordingly, the Agency has denied the petition.

FOR FURTHER INFORMATION CONTACT: Roy Nelson, Vehicle Defects Division D, Office of Defects Investigation, NHTSA, 1200 New Jersey Avenue SE, Washington, DC 20590. Telephone: 202–940–7086. Email: roy.nelson@dot.gov.

SUPPLEMENTARY INFORMATION:

Introduction

Interested persons may petition NHTSA requesting that the Agency initiate an investigation to determine whether a motor vehicle or an item of replacement equipment does not comply with an applicable motor vehicle safety standard or contains a defect that relates to motor vehicle safety. 49 U.S.C. 30162(a)(2); 49 CFR 552.1. Upon receipt of a properly filed petition, the Agency conducts a technical review of the petition, material submitted with the petition and any additional information. 49 U.S.C. 30162(a)(2); 49 CFR 552.6. The technical review may consist solely of a review of information already in the possession of the Agency or it may include the collection of information from a motor vehicle manufacturer and/or other sources. After conducting the technical review and considering appropriate factors, which may include, but are not limited to, the nature of the complaint, allocation of Agency resources, Agency priorities, the likelihood of uncovering sufficient evidence to establish the existence of a defect, and the likelihood of success in any necessary enforcement litigation, the Agency will grant or deny the petition. *See* 49 U.S.C. 30162(a)(2); 49 CFR 552.8.

Background Information

On September 1, 2026, The Office of Defects Investigation (ODI) received a petition dated August 5, 2026, requesting a defect investigation into an alleged defect of the “rear differential” on the Model Year (MY) 2022 BMW 540i. The petition itself can be reviewed at [NHTSA.gov](https://www.nhtsa.gov) under ODI number 11761650.

Summary of Petition

The petition cites allegations of loss of motive power and inability to hold the vehicle stationary, originating from a severed drive connection between the driveshaft and the rear wheels.

Office of Defects Investigation Analysis

On August 12, 2026, BMW filed Safety Recall 26V525 which addresses the same condition raised in Petitioner's submission and covers certain 2022–2026 840i, 840i xDrive, 2021–2023 540i, 540i xDrive, M550i xDrive, and 2024–2026 750e xDrive vehicles. The subject of recall 26V525 addresses progressive wear leading to potential failure of the connection between the rear driveshaft and the rear differential. Petitioner's Vehicle Identification Number (VIN) falls within BMW's recall scope and is subject to BMW's reimbursement program.

Consequently, Recall 26V525 renders the petition moot. Therefore, ODI is denying this petition. The agency reserves the right to take additional action if warranted by future circumstances. To review the reports cited in the Closing Resume ODI Report Identification Number document, go to [NHTSA.gov](https://www.nhtsa.gov).

Authority: 49 U.S.C. 30162(d) and 49 CFR part 552; delegation of authority at 49 CFR 1.95(a).¹

Eileen Sullivan,

Associate Administrator for Enforcement.

[FR Doc. 2026–22125 Filed 10–29–26; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

[Docket No. CDFI–2026–0232]

Agency Information Collection Activities; Proposed Collection; Comment Request; CDFI Program and NACA Program Financial Assistance and Technical Assistance Applications

ACTION: Notice of information collection; request for public comment.

SUMMARY: The U.S. Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the Community Development Financial Institutions Fund (CDFI Fund), U.S. Department of the Treasury, is soliciting comments concerning the Community Development Financial Institutions Program (CDFI Program) and the Native American CDFI Assistance Program (NACA Program) Financial Assistance (FA) and Technical Assistance (TA) Applications (hereafter, the Application or Applications). The FA Application includes optional questions that addresses Persistent Poverty Counties—Financial Assistance (PPC–FA), Disability Funds—Financial Assistance (DF–FA), and Healthy Food Financing Initiative—Financial Assistance (HFFI–FA). Changes were made to ensure that the Applications are aligned with the Administration's Executive Orders and efforts to reduce waste, fraud, and abuse within federal programs.

¹ The authority to determine whether to approve or deny defect petitions under 49 U.S.C. 30162(d) and 49 CFR part 552 has been further delegated to the Associate Administrator for Enforcement.

DATES: Written comments must be received on or before December 29, 2026, to be assured of consideration.

ADDRESSES: The Applications will be available for review and public comment on the Federal eRulemaking Portal at www.regulations.gov, under Docket Number CDFI–2026–0232.

Follow the instructions on the Regulations.gov website to submit comments. All comments submitted through Regulations.gov—including any personal information you provide—will be posted publicly on the site.

Comments, including attachments and other supporting materials, become part of the public record. Do not submit any information you consider confidential or inappropriate for public disclosure.

Do not submit comments by email. All comments must be submitted through Regulations.gov. Commenters with visual, auditory, or mobility impairments that prevent them from using Regulations.gov, or who require reasonable accommodation under Section 504 of the Rehabilitation Act, should contact 504support@cdfi.treas.gov or (202) 653–0326 (not a toll-free number) for assistance.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Pooja Patel, Program Manager, CDFI Program and Native Initiatives, CDFI Fund, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220, (202) 653–0423 (not a toll-free number). Other information regarding the CDFI Fund and its programs may be obtained on the CDFI Fund website at <https://www.cdfifund.gov>.

SUPPLEMENTARY INFORMATION:

Title: CDFI Program and NACA Program Financial Assistance and Technical Assistance Applications.

OMB Control Number: 1559–0021.

Abstract: The CDFI Program and NACA Program provide (i) FA awards to Certified Community Development Financial Institutions (CDFIs) to build their financial capacity to lend to Eligible Markets and/or their Target Markets, and (ii) TA awards to Certified and Emerging CDFIs to build their organizational capacity to serve Eligible Markets and/or their Target Markets. CDFI Program and NACA Program award Recipients will be selected after the CDFI Fund's careful review of their applications. The Applications presented for public comment request the required information collection for the CDFI Fund to evaluate Applicants and select award Recipients.

Current Actions: Renewal of Existing Information Collection with no material

or substantive changes to a currently approved collection.

Type of Review: Regular.

Affected Public: Businesses or other for-profit institutions, non-profit entities, and State, local and Tribal entities participating in CDFI Fund programs.

Estimated Number of Respondents: 795.

Frequency of Responses: Annually.

Estimated Total Number of Annual Responses for FA Application: 495.

Estimated Total Number of Annual Responses for TA Application: 300.

Estimated Annual Time per Respondent for FA Application including optional questions: 140.

Estimated Annual Time per Respondent for TA Application: 90.

Estimated Total Annual Burden Hours for FA Application: 69,300.

Estimated Total Annual Burden Hours for TA Application: 27,000.

Requests for Comments: The CDFI Fund is requesting comments on CDFI Program and NACA Program Financial Assistance and Technical Assistance Applications. Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the agency's functions, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) the accuracy of the estimates of the burden of the information collections.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. Potential commenters can review the proposed CDFI Program and NACA Program Financial Assistance and Technical Assistance Applications on the CDFI Fund website at <https://www.cdfifund.gov/requests-for-comments>.

(Authority: Pub. L. 103–325; 12 U.S.C. 4703, 4703 note, 4710, 4717; 31 U.S.C. 321; 12 CFR part 1805.)

Christopher Miller,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2026–22241 Filed 10–29–26; 8:45 am]

BILLING CODE 4810–05–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

[Docket No. CDFI–2026–0201]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Markets Tax Credit Program Community Development Entity (CDE) Certification Application

ACTION: Notice of information collection; and request for public comment.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the Community Development Financial Institutions Fund (CDFI Fund), Department of the Treasury, is soliciting comments concerning the New Markets Tax Credit Program (NMTCP) Community Development Entity (CDE) Certification Application, which Applicants will submit through the CDFI Fund's Awards Management Information System (AMIS).

DATES: Written comments must be received on or before December 29, 2026 to be assured of consideration.

ADDRESSES: You may submit comments via the Federal eRulemaking Portal at www.regulations.gov Docket No. CDFI–2026–0201. Follow the instructions on the website for the submission of comments. In general, all comments will be available for inspection at www.regulations.gov. Comments, including attachments and other supporting materials, are part of the public record. Do not submit any information in your comments or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to Shannon McKay, Acting Program Manager for the Office of Certification Policy and Evaluation, CDFI Fund, U.S. Department of the Treasury, 1500 Pennsylvania Ave. NW, Washington, DC 20220 or by phone at (202) 653–0300. Other information regarding the CDFI Fund and its programs may be obtained through the CDFI Fund's website at <http://www.cdfifund.gov>.

SUPPLEMENTARY INFORMATION:

Title: New Markets Tax Credit Program Community Development Entity (CDE) Certification Application.
OMB Control Number: 1559–0014.

Abstract: Title I, subtitle C, section 121 of the Community Renewal Tax Relief Act of 2000 (the Act), as enacted in the Consolidated Appropriations Act, 2001 (Pub. L. 106–554, December 21, 2000), amended the Internal Revenue Code (IRC) by adding IRC 45D and created the NMTC Program. The Department of the Treasury, through the CDFI Fund, administers the NMTC Program, which provides an incentive to investors in the form of tax credits over seven years, expected to stimulate the provision of private investment capital that, in turn, will facilitate economic and community development in low-income communities. In order to qualify for an allocation of tax credits through the NMTC Program, an entity must be certified as a qualified CDE and submit an allocation application to the CDFI Fund. Nonprofit entities and for-profit entities may be certified as CDEs by the CDFI Fund. In order to be certified as a CDE, an entity must be a domestic corporation or partnership, that: (1) has a primary mission of serving or providing investment capital for low-income communities or low-income persons; and (2) maintains accountability to residents of low-income communities through their representation on any governing or advisory board of the entity.

The CDE Certification Application is being updated to ensure that Applicants are meeting the statutory and regulatory disclosure requirements as well as protecting government resources in alignment with Administration priorities where appropriate. The specific changes include: (1) removal of references to “Minority-Owned or Controlled” in terms of Applicant’s structure; (2) addition of a new subsection on “Affiliate Information” to gather information about ownership, control, and foreign interests for affiliates; (3) addition of a new subsection on “Government Investigations and Enforcement” to gather more information on government investigations, enforcement actions and related matters; and (4) additional detailed language for federal anti-discrimination, alignment with specific Executive Orders, and prevention of fraud, waste, and abuse.

Current Actions: Revision of currently approved collection.

Type of Review: Regular.

Form: CDE Certification Application.

Affected Public: CDEs and entities seeking CDE certification, including business or other for-profit institutions,

nonprofit entities, and State, local and Tribal entities.

Estimated Number of Respondents: 150.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 150.

Estimated Annual Time per Respondent: 4 hours.

Estimated Total Annual Burden Hours: 600 hours.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record at <http://www.cdfifund.gov>. The CDFI Fund is seeking input on the content of the revised CDE Certification Application. The application and related guidance may be obtained on the CDFI Fund’s website at <https://www.cdfifund.gov/programs-training/certification/cde>. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the CDFI Fund, including whether the information shall have practical utility; (b) the accuracy of the CDFI Fund’s estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) the accuracy of the estimates of the burden of the information collections.

(Authority: 26 U.S.C. 45D; 31 U.S.C. 321; 26 CFR 1.45D–1.)

Christopher Miller,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2026–22240 Filed 10–29–26; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

[Docket No. CDFI–2026–0202]

Agency Information Collection Activities; Proposed Collection; Comment Request; Performance Progress Report and Financial Statement Audit Report Form

ACTION: Notice and request for public comment.

SUMMARY: The U.S. Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other

Federal agencies to take this opportunity to comment on proposed information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Community Development Financial Institutions Fund (CDFI Fund), the Department of the Treasury, is soliciting comments concerning the Performance Progress Report and Financial Statement Audit Report Form. The Performance Progress Report and Financial Statement Audit Report Form are online forms submitted through the CDFI Fund’s Awards Management Information System (AMIS).

DATES: Written comments must be received on or before December 29, 2026 to be assured of consideration.

ADDRESSES: You may submit comments via the Federal eRulemaking Portal at www.regulations.gov via Docket No. CDFI–2026–0202. Follow the instructions on the website for the submission of comments. In general, all comments will be available for inspection at www.regulations.gov. Comments, including attachments and other supporting materials, are part of the public record. Do not submit any information in your comments or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to Trefor Henry, Acting Program Manager, CDFI Fund, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220, (202) 653–0423 (not a toll-free number). Other information regarding the CDFI Fund and its programs may be obtained on the CDFI Fund website at <https://www.cdfifund.gov>.

SUPPLEMENTARY INFORMATION:

Title: Performance Progress Report and Financial Statement Audit Report Form.

OMB Number: 1559–0050.

Abstract: Recipients of the Community Development Financial Institutions Program (CDFI Program), the Native American CDFI Assistance Program (NACA Program), CDFI Equitable Recovery Program (CDFI ERP) and the Small Dollar Loan Program (SDL Program) submit the Performance Progress Report via the CDFI Fund’s AMIS once a year, three (3) months after their Period of Performance end date or fiscal year end, and the Financial Statement Audit Report via the CDFI Fund’s AMIS once a year, six (6) months after their Period of Performance end date or fiscal year end. Recipients

respond to the questions below by providing numerical figures, “yes” or “no” answers, or narrative responses, as appropriate. These reports are used to determine Recipient compliance with their Assistance Agreement. There are no significant content changes to the forms.

Current Actions: Extension without change of currently approved collection.

Type of Review: Regular.

Affected Public: Businesses or other for-profit institutions, non-profit entities, and State, local and Tribal entities participating in the CDFI Fund programs.

Estimated Number of Respondents: 1,114.

Frequency of Responses: Annually.

Estimated Total Number of Annual Responses: 2,228.

Estimated Annual Time per

Respondent: 0.75 hours.

Estimated Total Annual Burden

Hours: 1,671 hours.

Requests for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record

and may be published on the CDFI Fund website at <http://www.cdfifund.gov>.

Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) the accuracy of the estimates of the burden of the information collections.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

(Authority: 12 U.S.C. 4704, 4713, 4719; 12 CFR parts 1805, 1806, 1815.)

Christopher Miller,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2026–22239 Filed 10–29–26; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Quarterly Publication of Individuals, Who Have Chosen To Expatriate

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

This notice is provided in accordance with IRC section 6039G of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, as amended. This listing contains the name of each individual losing United States citizenship (within the meaning of section 877(a) or 877A) with respect to whom the Secretary received information during the quarter ending September 30, 2026. For purposes of this listing, long-term residents, as defined in section 877(e)(2), are treated as if they were citizens of the United States who lost citizenship.

Last name	First name	Middle name or initials
ABBOTT	ANDREW	ROBERT
ABBOTT	MATTHEW	
ABBOTT	MELANIE	RAE
ABBOTT-DEANE	JACQUELINE	DOROTHY
ACKERMANN	HORST	
AGUSTIN KADER	CONNIE	CONCHITA
AHLBERG KLEITERP	NOELLE	MISCHELLE
AHRENS	BRADLEY	JAMES
AHRENS	PETRA	MARINNA
AKDIS	EMIN	
AKENS	MAYUKO	
AL BARWANI	RAHMA	MOHAMMED
AL SHARIF	DIANA	NABEEL
ALAJEEL	SALWA	M
ALBALBISI	FEDA	FUAD
ALEMANN	KATE	BEATRIZ
ALEXANDER	SHIRLEY	ANN
AL-FULAIJ	DANA	ADNAN
ALI	ROBLEH	DAUD
ALKHALIFAH	ARWA	ABDULAZIZ
ALLEN	SHARLA	CLAIRE
ALNATOUR	SHARIF	S
AL-REFAI	ASMAA	MAJID
AL-SHAikh	FAHED	MOHAMMED
AMBROISE	AURELIEN	
AMEDT-LYON	NANCY	BETH
AMMANN	NOEMIE	CRISTINA
AMMENTORP	EVA	JUTTAN ANKER
AMSTAD	TANYA	JESSICA
ANDERS	CATHERINE	ELIZABETH
ANDRESEN	PER	ARNE
ANDREWS	JAMES	NORMAN LAMONT
AQDAS	NADIA	
ARAKI	CHIE	
ARNDT	KRYSTAL	JESSALIN
ARNOLD	LEYA-ANNE	
ASH	PETER	JAMES
ASLET	EMILY	PAIGE TARRANT
ASPLE	FIONA	ELIZABETH
ASTOLFO	LISA	CHAMA

Last name	First name	Middle name or initials
ATKIN	MAX	ROBERT
AVEDIAN	PAUL	ANDREW
AW	YUIN	YING
AWADAH	MISHAL	EMAD
AYOUB	MATTA	
BABIC	CLAUDIO	ANTONAS
BACHMANN	STEFAN	LEOPOLD
BAILAK	RACHEL	ELENA
BAILEY	JOHN	ROBERT PEMBERTON
BAKI	MICHELE	ANNE
BAKKER	JELTE	LUBERTUS
BALCH	LESA	CHERYL
BALLARD	HYRAM	RILEY
BALLARD	NEIL	ANDREW
BANKS	JAMES	RICHARD
BARBATI	FRANCESCO	
BARBER	ROSALIND	CLAIRE
BARGE	JUDITH	ANN
BARKER	MARTHA	CLARA NICKERSON VAIL
BARNEOND	ANA	EUGENIA
BARNETT	COURTNEY	BRIANNE
BARRETO	MAXINE	XENIA
BARRONS	JEFFREY	BROOKS
BARTH	MARGIT	
BARTH	MICHAEL	RENE
BARTLETT	GEORGIA	KATE
BARTLETT	JAMES	DOUGLAS
BATCHELOR	REBECCA	LEE
BATLER	BRUCE	CONSTANTIN
BATRICK	BRICE	CHARLES
BAUER	AMANDA	JANE
BAUER	KAI	HAGEN
BAXTER	ANDREW	
BEAMES	ELEANOR	SUSAN
BEAUDOUIN	NANCY	MICHELE
BEAUMONT	CALLUM	LOUIS
BEAUMONT	DAREN	JOHN
BEAVAN	LIAM	THOMAS
BECK	CHRISTA	NICOLE
BEDDOES	JENNIFER	CAROLYN
BEDNAR	DAVID	ELIZABETH
BEEKE JR	JOHN	RICHARD
BEINLICH	INGO	ALBERT
BELANGER	MAXIME	
BELL-PETER	AUDREY	LYNN
BENDER	BEATRICE	PATRIZIA FLAVIA
BENGOA	ENEKO	
BENJAMIN	ZACH	
BENNDORF	ROLF	RAINER
BENNETT	DECLAN	WILLIAM
BENTZEN	ILKA	URSULA
BENTZEN	PEER	
BERGEN	PIETER	KINSLEY
BERGERON	MICHEL	
BERTSCHINGER	TOBIAS	FRANCIS
BESHEVA	DIMITRINA	HRISTOVA
BHALALA	NIRALI	BHARAT
BIBER	MADELEINE	VERENA
BIEDENKOPF	KONRAD	KARL
BILLICK	NOA	
BILLING	ELLA	EMILIA
BINDLER	RICHARD	EUGENE
BIONDI	FRANCESCO	
BJORND AHL	ASA	MARIE
BJORND AHL	NILS	SIXTEN
BLAIR	LORA	LYN
BLATTMANN	FRANZISKA	REGULA
BLEILER	LYNETTE	RHONA
BLUM	KATHARINA	ALICIA
BLUM	SARAH	ISABEL
BOEL	GREGORY	PIERRE BERNARD
BOLEY	NILS	OLIVER
BOLGER	KAREN	VALERIE
BOLLIGER	MARK	ALFRED

Last name	First name	Middle name or initials
BOMBA	SINEAD	
BONAZZI	SIMONE	
BONGIORNI	PETER	MICHAEL
BONNER	MICHAEL	JOSEPH
BORG	ALICIA	MAY
BORG	JULIAN	MARIAN
BORLAND	EDWARD	ROSS
BORRA	JILL	ALEXANDRA
BOSCHITZ	ANGELIKA	LEONORE
BOTHUM	CHERITH	BROOK
BOUCHARD	FREDERIQUE	
BOULOS	FADY	GEORGE GHOBRIAL
BOU-MANSOUR	ANTHONY	MATTHEW
BOUREY	NANCY	ANN
BOUSQUET	PAUL	
BOWMAN	WILLIAM	JAMES
BOYARCHUK	TEA	CECILIA
BOYLE	KELLY	CHRISTOPHER
BRAATEN	NAOKO	
BRACHT	THOMAS	KENNETH
BRAGANZA	CHRISTINE	MARIE
BRAMWALL	BENJAMIN	
BRANDLI	MONIKA	
BRAUEN	ELIZABETH	ANN
BRAUNEIS	SHELLEY	LYNN
BRAYNE	SOPHIE	JOANNA
BRECKMAN	GILLIAN	F
BREEN	CHARLES	EDWARD PITT
BRENNAN	MICHAEL	JAMES
BRIGGS	CAMILLA	ANNE
BROAD	DAVID	NEVILLE
BROCATO	SASHA	
BROCK	ALISON	JUNE
BROCKMANN-GOHL	ALICE	
BRODE	DAVID	LELAND
BRODERICK	DYLAN	IAN
BROUGHTON	CHRISTOPHER	MICHAEL
BROWN	MARIE-EVE	
BROWN	OLIVIA	O'NEILL
BROWN	STEPHEN	JOHN
BRUCE	KAREN	ANN
BRUNNER	JACOB	STEPHEN
BUCHER	CELINE	GENEVIEVE LUCIE
BUCHER	MATHIAS	ADRIAN
BUETLER	NICOLAS	
BUKHAMSEEN	DALYA	EMAD
BULSUK	KARN	GIL
BURKERT	ROBERTO	GARBIELE
BURTON	ANDREW	NICHOLAS
BURTON	JAMES	
BUTZER	ANDRE	
BYER	PHILIP	HOWARD
BYER	SANDRA	
CADY	CAROL	JEAN
CAHILL	PETER	TIMOTHY
CAI	HAOWEN	
CALI	LOUIS	SEBASTIAN
CALLBECK	MELISSA	JANE
CAMACHO	JOSHUA	
CAMPBELL	GIULIA	
CAMPBELL	HELEN	MARGARET
CAMPBELL	KRISTINA	
CANEL	ROMAIN	PIERRE NICOLAS
CANEZIN	CYRIL	RENE LOUIS
CARBALLIDO	MIGUEL	JOSE
CARLOS	VERONIQUE	
CARMEL	DENISE	
CARR	SUSAN	GENNESS
CARRIER-COTE	VINCENT	
CARROLL	EOIN	
CARROLL	MICHAEL	WILLIAM
CARROLL	PERCIVAL	JAMES
CARRUTHERS	JAMES	MALCOLM
CARSON	DAVID	BRUCE

Last name	First name	Middle name or initials
CARSON	MARGOT	
CARSON	NEIL	ALEXANDER
CARSTENSEN	ELISABETH	ROSE
CASE	PAUL	BRETT
CASE	SANDRA	LYNN
CASE	STEVEN	JAMES
CASTANOS	ANTONIO	BELTRAN
CASTIGLIONE	EVA	ANDREA
CATELLANI	ANDREA	KRISTEN
CATELLANI	JENNIFER	VICK
CATELLANI	LUCAS	ALESSIO
CATENACCI	FRANCA	MARIA
CAVANAGH	RACHAEL	SARAH
CAVIGELLI	LUKAS	GIERI
CERLIENCO	CHRISTIAN	PIETRO RICCARDO
CHANEL	THIERRY	MARIE
CHANG	DAVINA	TWAN GIA
CHARNY	DANIEL	
CHARTOUNI	TATIANA	MARIA
CHASSE	JOHANNE	
CHATELAIN	ANDRE	LUC
CHEN	MING	Y
CHEN	RICHARD	YI
CHEN	SHANGSHANG	
CHEN	XI	
CHEN	ZHIJIAN	
CHEONG	CHRISTINA	YOKE KEEN
CHIANTORE	PAOLO	VINCENZO
CHIN	DANIEL	PENG YAN
CHIU	KIN-CHUNG	RAY
CHO	JUN	YEON
CHOW	JASON	BRYAN
CHRISTOFFERSEN	CHRISTINA	LEE
CHUNG	HYO	GU
CHUNG	PAMELA	ELIZABETH
CHUNG	RAYMOND	ABRAHAM
CHUNG	SZU	NAN
CIMICATA	CAROL	ANN
CLARK	CARMEN	MARIE
CLARK	KELLY	GRANT
CLARK	NATHANIEL	DAVID
CLARK	NOAH	GEORGE JOHN
CLARKSON	RODNEY	MARK
CLIFFORD	DISA	NICOLE
CLIFFORD	JULIAN	MICHAEL
CLIFFORD	TIMOTHY	CARTER
COALDRAKE	GUY	ALLEN
COHEN	OMER	
COLEMAN	KATHY	ELIZABETH
COMEAU	STEPHANE	J
CONRAD	LAWRENCE	GEORGE
CONRAD	LEANNE	FRANCES
CONSTABLE	RYAN	AIDAN
CONVERY	JANET	BRAZIER
COOK	ALISON	
COOPER	TAMMY	LENORA
COQUARD-PATRY	LAURA	MARIE SANTINA
CORCORAN	MICHAEL	EDWARD
CORDIER	CAROLINE	JEANNINE
CORKILL	GARTH	WILLIAM
CORKILL	SHELLY	TSUI LI
CORREIA	ALEX	R
CORTEZ	ALIVIA	EARTH
COTE	WILLIAM	RUSSELL
COURTRIGHT	TIMOTHY	RAHT
COUSINEAU	AMY	ELIZABETH
COUTURE	JEAN	CLAUDE
COVENTRY	KIRSTY	LEIGH
COWAN-YOUNG	MICHAEL	WILLIAM
COX	FIELDEN	
COX	KATHARINE	HARRIS
COX	POLLY	JEAN
COX	SARAH	ELIZABETH
COX	STEPHEN	PETER

Last name	First name	Middle name or initials
COX	ZAHARA	ISABELLE
CRAIG	ANN	MARIE
CRAIK	PERSIS	ANNE
CREECH	LAURA	REBECCA
CREWE	BENJAMIN	JAMES
CROOKER	SUSANNE	
CROPPER	SUSAN	
CROSBY	CHRISTINE	ERIN
CROTTY	VICTORIA	JANE
CRUZ	JACQUELYN	FRANCIS
CU	MARTIN	ANGELO VILLANUEVA
CUNNINGHAM	SASHA	ELISABETH
CURRAN	BENJAMIN	MICHAEL
CURRAN	KEVIN	DAVID
CURRAN	PETA	LOUISE
DACEY ARIANI	FRANCESCA	MARIE
DALEY	ANGELA	LEAH
DALEY	KILEY	LUKE PETER
DALLY	JESSICA	SHANNON
DAMEN	ROBERT	GERARD
D'ANTONIO	SABINA	
DARCY	NIAMH	MARY
DAVIDSON	BRUCE	
D'COSTA	ALEXANDER	MARTIN
DE FREITAS PEREIRA	BRUNO	ALEXANDRE
DE JAGER	MICHELLE	LYNN
DEGE	LINDA	LEE
DEGE	NICHOLAS	JOHN SEBASTIAN
DEHNE	URSULA	AGNES
DEL GIUDICE	DANIELA	LILIANA
D'ELIA	DARIO	HARALD
DEMIRDERE	OZTURK	
DENMEADE	ALEXANDRA	ELIZABETH
DENNEWALD	FRANCOIS	ROBERT
DENNIFORD	ANNIKA	ELISABETH WILSON
DENOMEY	SARAH	STEPHANIE
DESCHAMPS	SHAUNA	RAE
DEUTSCH	NOAM	
DEVEAU	KATHERINE	ELIZABETH
DI BIASO	OLIVIA	LINNEA LOUISE
DI STEFANO	JOHN	
DIDERIKSEN	THOMAS	LUND
DIMOFTE	ANDREA	MARIA
DION	JEAN	MAURICE
DITLEV-SIMONSEN	OLAF	I
DIX	LAURE	
DOBMAYER GAUTHIER	ALYSSA	SHALANE
DODD	STEPHEN	GEORGE
DONALD	PAUL	DAVID
DONNELLY	HAROLD	MALCOLM
DONNELLY	MYSTELI	MICHELLE
DORBERT	KERSTIN	UTE MARIANNE
DOUMET	BEATRICE	MIRANDA
DOVE-MCFALLS	SAMUEL	JOHN
DRESSLER	LUZIUS	STEPHAN
DU BOIS	KYM	MICHELLE
DUAN	MINGLEI	
DUBALD	MANUEL	MARCEL
DUBAY	JOSEPH	L
DUBOURDEAU	FRANCOIS	
DUCHARME	CONNIE	JO
DUCHARME	JENNIFER	LESLIE
DURAFORG	ROBERT	JEAN
DURKSEN	JAMES	DAVID
DWYER	MICHAEL	JOSEPH
DYSLI	SANDRA	PENDLETON
DYVIK	TROND	GISLE
EINFELD	LAUREN	CARA
ELLIOTT	CATHERINE	ISABELLA
ELLIOTT	MATTHEW	DONALD
ELLIOTT	WADE	
ELVE	BARBARA	MARIE
ENGELBERT	JONATHAN	PATRICK
ENGLANDER	KAREN	

Last name	First name	Middle name or initials
ENOMOTO	KIMIE	
ENOMOTO	YOSHIHIDE	
ESMAY	REBECCA	
ESSERS	JENNY	ANN
ESTERS	AMANDA	
ETERMAN	LINDA	ANN
FADDERSBOELL	MARIANNE	
FAIVRE	CYRIELLE	MARIE PERRINE
FALQUIER	RENE	MARCEL
FALTJHANS	ROLAND	MICHAEL
FARHI	BAHARAK	
FARRELL	KEVIN	
FARRELL	MARK	ARTHUR
FASSETT	HUNTER	JAMES
FELDMAN	GREGORY	MARK
FELLENZ	JUSTIN	RIOME
FENG	RONGJIE	
FENN-MORLEY	TRACY	JANE
FENWICK	KRISTEN	JAYNE
FENWICK	MATTHEW	DANIEL
FERAGEN	KAYLA	CORINNE
FERRAN CARRION	ISABEL	DEVORA
FIGG	SARAH	PORTER CRANE
FILIPOVIC	TALINE	MANDA
FINEGAN	ANNA	RAYENA
FISCHER	ROBERT	FRANCIS
FISCHER	SUSAN	BARBARA
FISHER	ROBERT	EDWARD
FISKER	SIMON	KRISTOFFER
FITZGERALD	CHARLOTTE	DOMINIQUE LOUISE
FLEMING	CYNTHIA	LOUISE
FLURI	CORNELIA	JOY
FLUXGOLD	BEVERLY	
FOERSTER-ADKISSON	CHARLES	OSCAR
FOLDSCHACK	DANIEL	JAMES CLARIDGE
FORREST	ALEAH	BREAWN
FORSTNER	GORDON	KENNETH
FORTE	RICHARD	EDGAR
FOX	VALERIE	JILL
FRAEFEL	ANNA-SOPHIA	THI KIM
FRANK	CLAUDIA	
FREIMAN	ANNA	SARAH
FREUDENSTEIN	JANE	ELIZABETH
FREY	CHRISTIAN	OSKAR
FRIBERG	JUNE	METTE
FRICKEY	MORGAN	REBECCA
FRIGINAL	ERICSON	VILLAS
FU	TSUN	WAI
FUJII	HISAKO	
FUKUI	HANA	
FUKUMOTO	JUTARO	ALLEN
FULLER	STEPHEN	PATRICK
GAIA	ASPEN	AP
GALE	SARAH	KATHRYN
GALLANT	GREGORY	JOANNE
GALLANT	KATHLEEN	ANNE
GAUCHER	KIMBERLEY	
GAUDET	MINNETTE	HELEN
GAUER	CHRISTOPHER	MICHAEL
GAUGLITZ	STEFFEN	
GAUTAM	ARPAN	
GEIGER	BENITA	EVELINE ERIKA
GEORGE	RONALD	ALAN
GERRING	GEOFFREY	ROBERT
GIBBS	DAVID	CHARLES
GIBSON	DONALD	EUGENE
GIBSON	DONNA	
GIESE	SANDRA	LEE
GINGRAS	YANNICK	
GLADMAN	JENNIFER	LYNN
GLANVILLE	RANULF	DAMIAN NIAL
GLASER	STUART	ROBERT
GOETZ	BENEDIKT	MANFRED
GOLDBLATT	AVIHU	

Last name	First name	Middle name or initials
GOLDSCHMIDT	JUDITH	EVELYN
GOLLER	VERONIKA	FRANZISKA ANNE SOPHIE
GOLUSH	PRISCILLA	ANNE
GOOLEY	SEAN	MICHAEL
GOSSELIN	MARC-ANDRE	
GOTTLANDER	MAGDALENA	ANNA EVA
GRAHAM	CHRISTINE	ANN
GRANT	JULIA	PATRICIA
GRASSHAM	ABIGAIL	MICHELLE
GRBIC	ALEXANDER	
GRBIC	GORDANA	
GREAVES	SERENA	RACHEL
GREENE	ANGELA	WENDY
GREENHALGH	JESSICA	FAY
GREGG-SMITH	AUSTIN	THEODORE
GREGG-SMITH	CELESTE	AMELIA
GREGOLETTO	GIOVANNI	
GREGSON	CLIVE	JAMES
GRETHMANN	IRIS	
GRIEDER	CEDRIC	BECKETT
GRIFFIN	BRIAN	DOUGLAS
GRIMES	JOEL	THOMAS
GRITZ	MAXIMILIAN	OLIVER KLEE
GROB	LIAM	JACK
GROMADKA	JAROSLAW	TADEUSZ
GROSKY	MITCHELL	SEAN
GROSSMAN	MARTIN	BARRETT
GU	JIA	
GU	JIN	WEI
GUARDIA	FERNANDO	
GUBBELS	PETER	ANTHONY HUBERT
GUBE	JAN	BERTIL
GUECEM-DRAHORAD	HEIDI	ALENKA
GUO	KUANFU	
GUO	LINGLING	
GUTSCHE	KEVIN	MARCEL
HABIB	SAYEDA	RAFIQ
HACKMAN	MICHAEL	GUNNAR WOLDEMAR
HAHN HALBHEER	KATHERINE	LOUISE
HAIDER	MASOOM	ABBAS
HALL	JENNIFER	LOUISE
HAMEL	SUSAN	FRANCES
HAN	KIWON	
HAN	SANGJIN	
HAN	XIAOYIN	
HANAZUKA	MARIKO	
HANKO	CATHARINA	MADELEINE
HANNA	CLAUDIA	MAGDY
HANNAH	SUSAN	JOYCE
HANSEN	CHRISTIAN	GUNNAR WOLDEMAR
HANSEN	MARK	CHRISTOPHER
HAO	XIAOHUI	
HARADA	HITOSHI	
HAREL-DESGROSEILLERS	VINCENT	
HARGREAVES	DAVID	GEOFFREY
HARKER III	HARRY	
HARLOW	LINDA	IRENE
HARRIS	ALAN	ROGER
HARRIS	NELSON	DAVID
HARSTAD	JOEL	DANIEL
HASHIM	MOHAMMED	KHALID
HASTENRATH	FLORIAN	COLLIN
HATCHER	KELSEY	ANN
HAUGEN	KNUT	
HAVARD	TAYLOR	MICHELLE
HAYEK	ELIAS	JOSEPH
HE	YANLING	
HEALEY	ETHAN	GEORGE
HEALY	ANNE-MARGARET	
HEALY	COLE	PAUL
HEIMAN	DAVID	WILLIAM
HELLESUND	SILJE	MARIE
HELM	JEFFREY	ROY
HELMS	DOROTHEA	JANE

Last name	First name	Middle name or initials
HELMS	RICHARD	MORGAN
HEMMINGS	REBECCA	JEAN
HENNESSY	KATRINA	
HENRY	MAIREAD	CECILIA
HEO	MI	JEONG
HEPWORTH	FRIEDA	MARIE
HERRMANN	SUSANNE	KATHLEEN
HERSHFIELD	JEFFREY	ALLAN
HERTSHTEN	RON	
HESKETH	THOMAS	EVAN
HEUBERGER	FLORENTIN	SIMON
HILL	KATHERINE	MARY
HILL	PENELOPE	ANN
HINAHON	EDGAR	BARRERA
HINAHON	ELSEMARIE	POBLETE
HINAHON	MARY	ANN POBLETE
HINTON	PAIGE	CATHERINE
HIROTANI	TAKASHI	
HISKENS	JUDITH	ELISE
HO	SIEW	LENG
HOGAN	TYYNE	MARY
HOLDSTOCK	JOHN	ROGER
HOLT	CHRISTINE	TRACY
HOLZ	CORINNA	SARAH
HONG	HWEE	P
HONG	HYOUNG	HEE
HONG	MOON	JUNG
HONG	SANGKI	
HOOKER	ALFRED	FRANKLIN
HOPKINS	JENNIFER	FAY
HORECKA	MARIA	
HORIUCHI	TAE	
HORLACHER	FRANZ	CHRISTIAN
HORLACHER	SABINE	RACHEL
HORNAKOVA	MARTINA	
HOUSTON	MAYU	
HOWARD	WILLIAM	ROBERT
HOWE	JANETTE	KIRSTIN
HOWER	ALICE	ROMANELLI
HOWER	LARRY	HAYWARD
HOWLEY	KRISTIN	FORD
HSU	CHIA	JUI
HSU	IGNATIUS	VI SHUM
HSU	KELLY	JO
HUANG	YUEH	O
HUBERT	CHRISTIN	NOEL
HUDSON	KEITH	
HUDSON	PETER	JAMES
HUGHES	SIMON	RONALD
HULMES	CHRISTOPHER	EDWARD
HUMPHREYS	AYLIN	RANDA
HUNENBERGER	ACHILLE	MARTIN
HUNTER	ERIK	CHRIS
HUNTER	TIMEA	
HUNTER-WALSH	JULIET	SUSAN
HUNTER-WALSH	LUCAS	IVAN
HUPFAUER-BECKH	JENNIFER	CATHERINE
HUXTABLE	AMANDA	CATHERINE
HWANG	BOKSIM	
IANNETTA	ISABELLA	CHRISTINA
IHARA	JUNKO	
IMAI	SADAMI	
INDRIATI	ETTY	
ISHAYA	JNANAMA	
ISTED	KIMBERLEE	ANNE
IWANOCZKO	KARL	GLEN
IZU	YUMIKO	
JACKMAN	LINDA	CAROLYN
JACKSON	CARY	KATHLEEN
JACOBS	SHOSHANNA	ROBERT
JANG	INGYOO	
JEFFARES	MONTANA	PATRICIA
JEFFRIES	WILLIAM	JOHN
JELMINI CELLERINI	ELENA	

Last name	First name	Middle name or initials
JENSMA	HIELKE	JOB
JEON	HYUN	SUK
JEON	JEONG	HO
JIANG	JIANHUA	
JIN	XIAOCHUN	
JINNAI	BUTSURIN	
JINNAI	YUKA	
JOEHL	HEIKE	URSULA
JOHNSON	MALCOLM	MARTIN-THURGOOD
JOHNSON	MICHAEL	BERNARD
JOINER	JACQUELINE	ANNE
JONES	ALICE	CHRISTINE
JONES	RICHARD	THOMAS
JOPP	FRED	
JOWELL	JOANNA	TANDY SUSAN
KAGAYA	TETSUO	
KAIEDA	SHOTA	CHRISTINE
KAIN	LEAH	MAE
KALCHIK	TERESA	MARY
KAM	JIN	CHIEH
KANAAN	WILLIAM	WAEI
KANE	MOLLY	
KASBERGEN	DEBBY	
KASKASOLI	ALEXANDRE	RIDA
KATO	HISAO	
KATO	TAKAKO	
KATZENBERG	MARY	ANNE
KAUNG	JANIE	LAI CHUN
KAYAGIL	ALEV	NAZAN
KEELE	ZORAN	JAMES
KELLER	JANINA	
KELLEY	LAURIE	ANN
KELLY	DAWN	
KENDALL	SHAUNA	GAIL
KERR	KELLEY	LYNN
KHIEV	SOPAGNA	
KIDD	RACHEL	LOUISE
KIDO	MISAKO	
KIDO	TAKAO	
KIENAST	LADINA	SIMONE
KIKUCHI	YOKO	
KILLENBERGER	MARKUS	TEEMU
KIM	JAI	HYUN
KIM	JINSOOK	
KIM	OJIN	
KIM	SEOK	
KIM	YONG	MI
KIM	YOO	JIN
KIMEL	ILAY	SHMUEL
KIMEL	LIAM	B
KING	BYRON	VAUGHAN
KING	DAVID	PATRICK
KINGMAN	MICHELE	
KINGSBURY	JOANNE	MAREE
KIRBY	DONNA	MICHELLE
KIVELL	RICK	NORMAN
KLAFAAK	LINDA	
KLEIN	REVA	JOY
KLEINHANS	BELINDA	
KLEISATH	EVAN	JAMES
KLINGERT	LEONHARD	
KNAGENHJELM	JANE	CAPPELEN SMITH
KNIGHT	CHRISTOPHER	MARK
KNIGHT	MELISSA	
KNUDSEN	KATRINE	SONDERBY MYSAGER
KOCH	KAREN	ANN
KODAMA	MASAKO	
KOMARNICKI	KEVIN	JOHN
KONAN	MARGERY	ANN
KONO	TERUO	
KORCOK	THOMAS	JAMES
KORNHAUSER	LARRY	HYAM
KOZLOWSKI	TOMASZ	
KREBSER	RACHEL	ELISABETH

Last name	First name	Middle name or initials
KRUPS	FREDERIK	
KUBASOVA	LUCIE	
KUBINSKI	CHRISTOPHER	JAN
KUKLINSKI	MARTIN	CHRISTINE
KULAK	JENNIFER	CONSTANTIN
KULYK	HALIA	
KUNZ	INGRID	JUDITH
KUO	SHOU	FU
KUROSAWA	KEIKO	M
KUROSAWA	KIYOSHI	
KVAREKVAL	RUNE	
KVAREKVAL	TORHILD	E
LABERGE	ANANDA	LEIGH
LACELLE	LISE	
LAFLECHE	JERILYN	ANITA
LAI	EMIL	NAI HONG
LAING	MICHAEL	JOHN
LAMB	TYLER	JAY
LAMERE	ROWEN	JAMES
LAMEYSE	MONIQUE	MELISSA
LANDESMAN	JAY	COSMO
LANG	DENISE	MARIE
LANGER	BERNADETT	MARIA
LAPORTE	NORMAND	
LARBI	SARAH	BRIGID
LATOTZKE	CECILIA	ISHTAR DURGA
LAU	SHIAO	LI
LAUGERUD	ERIKA	AMALIE ARNESEN
LAWRENCE	JUSTIN	DANIEL
LE GRELLE	JOSEPH	WILLIAM FRANCIS
LE LIVEC	RONAN	GERARD
LEACH	FIONA	ELIZABETH
LEBLANC	CATHY	
LEBLANC	ROBERT	LUC
LEE	DANNY	
LEE	JOO	YEON
LEE	KA	YEE
LEE	MINKYOUNG	
LEE	MYUNG	JIN
LEE	SANG	HWA
LEE	SANG	JIN
LEE-LOVOY	JODI	MICHELLE
LEER	LIVE	
LEES	KIMBERLEY	JANE
LEES	SCOTT	HARVARD
LEHMAN	CHRISTINA	RAE
LEHMANN	DANIEL	CHRISTOPH
LEITCH	HEATHER	ALICE
LENZ	JULIAN	LUDWIG
LESWICKC	ELIZABETH	ANN
LETTS	BARBARA	DAWN
LEVENSELLER-SMITH	ANGELA	MARIE
LEWIEN	PATRICK	DANIEL
LEWIN	JENNIFER	MICHELLE
LEWIN	OLIVIA	ANN
LEWIS	JENNIFER	JOAN PATRICIA
LEY	MARIA	THERESA
LHAMBY	FABIO	COLLEN
LI	JEFFERY	TAK CHUN
LI	XU	
LI	YUN	
LIANG	JING	
LIEB	SUSANNE	
LILLEY	MARGARET	RATA
LIM	GREGORY	TRAN
LIN	BENDAN	
LIN	QINGHUI	
LIN	ROBERT	TATE
LIND	GARETH	BRENT
LIND	ISABEL	ANN
LIND	NANCY	DIANE
LINEHAN	ASTRID	JOHANNE FRISVOLD
LINES	SHIRLEY	FRANCES
LIPP	MARKUS	

Last name	First name	Middle name or initials
LIPPS	NOZOMI	SUMIYA
LISAK	MAXIMILIAN	ADAM
LISSAMAN	CLIVE	ALLAN
LIU	BANG	KANG
LIU	CAROLINE	JOAN
LODEN	SUSAN	HOLLOWAY
LODETTI	KELLY	
LOHMANN	LYNN	MARIE
LOMAX	WILLIAM	R
LONGO	MARION	
LORENZ	STEPHANIE	CORNELIA MARIE
LOUDON	ELIZABETH	SOWERBY
LOUGHLIN	MICHAEL	GRAHAM
LOVOLD	MARKUS	WANG
LOVOY	TERJE	
LOVSLAND	VICKIE	IRENE
LOW	MELISSA	CANDICE
LOWERY	TANIA	NUR
LOYER	MARGOT	RENEE
LU	BEN	
LU	HONGPING	
LU	PEIYUAN	
LU	ZHENGYU	
LUBELL	DERRYL	SUE
LUBRICH	NAOMI	
LUN	ZHAO	
LUNDEVALL	EINAR	KATHRYN
LUNDIN	ERIK	ROLAND
LUSSER	ANDREA	HILDEGARD
LUSTI	DONNA	MARIE
LYLES	JOHN	HENRY
LYNCH	COURTNEY	ERIN
MA	PEI-CHUN	ELIZABETH
MAAS	JOHANNES	CHRISTOPH
MACHALE	SEAN	
MACHORRO	JORGE	FRANCISCO
MACLEAN	CATHERINE	MAY
MACCOURT	SALLY	ANNE
MADDEN	DARYL	PAUL
MADHA	MELINA	LOUISE
MAGNIN BODAGHEE	ISABELLE	
MAH	CHARLOTTE	SHAO ZHEN
MAINVIL	LOUISE	ANNETTE
MALLING	WILLIAM	PEMA NORBU HOLMES
MALLOCK	CALVIN	ROYCE
MALTMAN	CRAIG	J
MANLEY	ALEXANDER	WARRINGTON
MANLEY	JACK	WARRINGTON
MARCHAL	ANITA	
MARIANI-FORD	ALDA	DAISY
MARINO	NICOLYN	DIANE
MARITZ	NOELLE	
MARKUS	LIRON	
MARKUS	OFRI	
MARKUS	TAMARA	
MARRIOTT	ALEXANDRA	KENNETH
MARSHALL	JOHN	CHARLES
MARSHALL	RYAN	THOMAS
MARSHALL	SHARON	
MARTINELLI	LUKAS	ALEXANDER
MARTZ	CLIFFORD	ANDREW
MARUSICH	NATALYA	ANDREYEVNA
MARUYAMA	AIMI	
MARUYAMA	KOJI	
MASON	AMY	HELEN
MASON	MARY	HAYS
MASSON	ANNEMARIE	FRANCE
MASTERS	DAVID	SCOTT
MASUYAMA	SATOSHI	
MATLOCK	LESLIE	JANIS
MATMON	GUY	
MATSUMOTO	YOSHIHIRO	
MATSUYA	NATSUMI	
MATTHEWS	GRAHAM	YAKOV

Last name	First name	Middle name or initials
MATTHEWS HARDY	JESSICA	SUSAN
MATTSTEDT	NOELANI	MARIE
MAURICE	SHIRLEY	LUISE
MAY	ROWEN	JOHN
MAYR	GUENTHER	
MCCULLOCH	SUSAN	ANNE
MCDANIEL	JENNIFER	PAIGE
MCDONALD	CYNTHIA	LOUISE
MCGLAUN	GREGOR	CONSTANTIN
MCGREGOR	ROBERT	BRIAN
MCGREGOR	SKAIDRITE	
MCKE	SCOTT	DAID
MCKINNON	JUDITH	ARLENE
MCLEAN	JENNY	LYNN
MCPHETRES	SEBASTIAN	JAKE
MCRAE	CHRISTINA	KATHLEEN
MCROBBIE	EWEN	REID
MEDYNSKI	BEVERLEY	LYNN
MEERWIJK	ESTHER	LYDIA
MEHTA	SANJAY	NATWARLAL
MEIER	STEPHANIE	VICTORIA
MEIJERING	GEESJE	JOHANNA
MEKDACH	WAELE	
MELODY	JILL	
MENASHY	FRANCINE	SARA
MENDOZA	MITSUOKO	
METAXAS	ATHENA	SOPHIA
METZLER	VIKTOR	
MEYER	HEATHER	
MEYER	MARTIN	
MICHALKE	SIMON	MIHPIYA
MICKELSON	STEVEN	
MIDDLETON	BRENDA	RUTH
MILLS	CHRISTINA	KATE
MIMOSO	PHILIP	R
MIMURA	MEGUMI	
MINGHETTI	ROBERT	
MIRHADY	VERA	GRACE
MITSUI	DAISUKE	
MOESLI	NICOLAI	PIERRE
MONAGHAN	STACEY	LYN
MONROE	MELISSA	MEI-LING
MONTANERA	KATHERINE	ROSALIA
MONTI	ALESSANDRO	
MOREAU	MANON	ROSELYNE
MORGAN	SHARON	LEE
MORISOD	ELLIOT	FREDERIC
MORITA	FOUNGCHAT	UDOMLAPSAKUL
MORRISON	ROBERT	NEIL
MORSE	DRAKE	ALEXANDER
MORSE	NATALIE	SARAH ELIZABETH
MOSS	RICHARD	HOWARD
MOTOC	ANA	MIRONA
MOUAT	MICHAEL	COLIN
MOUJIB	HAJAR	
MUEHLHAEUSSER	REINHARDT	GUENTHER
MUENCH	GABRIELE	PHERESIA
MULDER	NORMAN	ROBERT
MULVENEY	WILLIAM	HAROLD
MUNEYASU	YUKO	FRAZIER
MURAI	KEIKO	
MURAI	YOSHIRO	
MURCH	PENELOPE	ADAIR
MUSZYNSKI	LISA	HIRTE
MYER	KATHLEEN	CONNIE
MYERS	THEA	BETHANY
MYKLEBURG	RITA	WANDA
MYRICK	THOMAS	GREGORY
NAIM RODRIGUEZ	NADIM	
NAKAMURA	YASUO	
NAKASHIMA	YOMIKO	
NAQUIN	MINAKO	I
NASH	WENDY	ANN
NEGISHI	EIKO	

Last name	First name	Middle name or initials
NEGISHI	KAZUKI	
NELSON	WENDY	JO
NENNIGER	REGINA	DIANNE
NEPTON	JENNIFER	MICHELE
NEUMEISTER	TATIANA	
NEWBATT	SIMEON	MICHAEL
NEWMAN	HEATHCLIFFE	WESTON
NEWTON	LORNA	JUNE
NG	NANCY	
NGUYEN	TRANG	THI THUY
NICHOLS	RYAN	GARY
NIEHAUS	ISABELLE	EMMA
NIETSCHE	JOHANNES	CHRISTIAAN
NIJSEN	STEFAN	JOHANNES ELISABETH
NISHI	MASATOMO	
NITSCHKE	DANIEL	ALEX
NOBLE	HILARY	IRENE LEITER
NORMAN	SARAH	ANNE
NORMAN ELLIOTT	ROSALINDE	HONORA
NORTH	SARAH	LOUISA MARGARET
OAKES	AUDRINA	PAISLEY
OCHIAi	MASAKO	
ODED	DAN	
ODED	HADAS	
O'DOHERTY	ANTHONY	JOHN
O'DONNELL	KELLY	ANNE
OGATA	JUNKO	
OGATA	TAKAHIRO	
OGURA	MAYA	
OJST	KEVIN	RICHRD
OKADA	KAZUYO	
OKADA	SHUZO	
OKIHARA	AKIKO	
OKUMURA	SHIZUKA	
O'MAHONY	BRIAN	NOEL
O'NEAL	ANNA	LOUISE
ONNENBERG	JAN	CHRISTOPH
ORANA	ILIR	
O'REILLY	EILEEN	MARY
OREJAS	JUAN	
ORLANDINI	MARIA	HELEN MATHILDE
ORSINI	MARCO	ANTONIO
ORTEGA	KYOKO	
ORTIZ	CARLA	ISABEL
OSBORNE	ROGER	SCOTT
O'SULLIVAN	JACK	EOIN
OTTERMANN-EAKIN	ERIC	MARTIN
OUCHI	KUGAO	
OUCHI	MIYUKI	
OULMI	WASSILA	
OWEN	NICHOLAS	WYNNE
PAGE	YUMI	
PALESTRO	CLARA	JULIA
PALKA	SUSAN	JANE
PALTOO	DAVENDRA	
PAO	NORMAN	CHI WEN
PAPATSAS	NIKOLAOS	
PARIS	LOUISE	REGINE
PARK	JOHN	MICHAEL
PARK	SOOANN	
PARKER	COLETTE	SANDRA
PARKER	LIAM	SEAN
PARKER	MARGARET	BARBARA
PARKER	SHELLEY	DIANNE
PAROLIN	ADRINAO	TOMASO
PASICZYNK	ULIANA	MARIA
PATRIARCHE	JOHN	CHARLES
PATTEN	LESLEY	ANN
PATTINSON	CHARLES	NORMAN
PAULSON	CARY	CHARLES
PEDDE	CATHERINE	ANN
PENALVER	AMADEO	
PEREZ	CAMILLE	DORETTE
PERREAULT	DANUTA	

Last name	First name	Middle name or initials
PERREAULT	JOSEE	
PERRY	OLIVIA	ALEXANDRA NICOLA
PETERSON	ANNIKA	LING
PETTY	TREY	LAWRENCE OTIS
PHILLIPS	MARY	
PIAMONTI	MASSIMO	
PIDGLEY	JESSICA	SARAH
PIEL	DAVID	CHRISTIAN
PIERRAT	JOSYANNE	
PIETROGRANDE	EUGENIA	
PINKOWSKY	WIEBKE	CLARA GERTUD
PISANO	MARIA	VITTORIA MARGHERITA
PLATH	KERSTIN	
PLUM	TERRA	JAYNE
POLON	BEVERLY	ANNE
POMPEI	JOHNNY	LUCIO
PONTE	ROBERTO	
POTH	LISA	BETTINA
POWER	CONNER	POWER
POYSTI	KEITH	NIKOLAI
PRINGLE	KENNEDY	S
PRIVILEGE	RACHAEL	MARIA
PROBST	JONAS	EMANUEL
PRZYGIENDA	ZOE	
PULIN	KEIKO	IWASHITA
QUE	CELINE	TIFFANY
QUINN	MARY	KATHLEEN
RADLOFF	MONIQUE	
RAMCHAND	JAI	KRISHNA
RANKIN	LAURENCE	JOHN
RAPOPORT	ALEXANDER	
RASMUSSEN	JAKOB	
RASMUSSEN	NANCY	YUSAN
RATZMANN	KATJA	ANNE DANIELA
RAUSCHER	MATHIAS	
REBEL	VIVIENNE	I
REBSTOCK	JAMES	EDWARD
REED	ALASTAIR	MARK
REED	BRIDGET	MARTINA
REES-JONES	CHRISTOPHER	GEORGE
REGENSBURGER	SEBASTIAN	LUCIEN
REGEV	ELLIOT	
REGEV	JONATHAN	
REIBER	ANDREA	CATHERINE
REICHE	PAMELA	SUE
REISER	SANDRA	
REMBOLD	VICTORIA	THERESA
RENDLE	NAHO	
REY	EMMANUEL	SIMON
REYNOLDS	MARTIN	ERIC
RICHARDSON	LAURA	ELAINE
RICHINS	HAROLD	JOSEPH
RICHINS	KATHLEEN	O'KEEFE
RIVERS	LINCOLN	PETER LEET
ROBERTSON	FREDRIC	EARL
ROBERTSON	LINDA	FRANCES
ROBICHAUD	CHARLES	JOSEPH
ROBINSON	KATHRYN	ELIZABETH
ROCHFORD	LISA	MARY
RODA	AMRIN	SINGH
RODA	GUNJAN	KAUR
RODA	HARSHARN	SINGH
RODA	LILLY	
RODE	STEVEN	MONTGOMERY
ROE	JENNIFER	JANE
ROGERS	ANN	MARIE
ROGERS	EIKO	
ROGERS	FORREST	
ROGERS	TRISTAN	PATRICK
ROLING	ALLISON	BETH
ROLSTON	HEATHER	ANN
ROSE	BRIAN	BENEDICT
ROSENBAUM	RONALD	SCOTT
ROSS	CLAIRE	ROSE

Last name	First name	Middle name or initials
ROSS	DAVID	BENJAMIN
ROTHE	ALEXANDRA	CATHERINE
RUBIN	JOHN	MARCUS
RUBINSTEIN	JAY	HANAN
RUCHTI	VINCENT	AMANDO
RULLGARD	HANS	ROBERT
RUMBOLD	FRANCES	ANN HAWKES
RUMMONDS	CHRISTIANE	MICHELLE
RUPP	TERESA	
SADINSKY	NICOLE	GERMAINE
SAFCIUC	ADRIAN	ION
SAGAR	COURTNEY	KAIULANI
SAHNI	PRERNA	
SAINT-CYR	CEDRIC	WILHELM BLANK
SAITO	YOSHITOMO	
SAITO	YUKIKO	
SAKAMOTO	KAYOKO	
SALMAN	OLIVER	CHRISTOS
SANDERSON	SHANNON	LEIGH
SANDFORD	DREW	BRETT
SANDFORD	ROBERT	ELDON
SARTORIUS	FERNANDO	JOSE
SASAKI	HIDETO	
SASAKI	MASAYO	
SASAKI	MIHO	
SATO	FUMITOSHI	
SAUCKE-LACELLE	AMY	JAMES
SAUER	ANGELIKA	ELIZABETH
SAUL	CHRISTINA	CATHARINA
SCHERRER	MICHEL	DEAN
SCHERZER	PETER	
SCHILDE	ANDREA	
SCHINDLE	VICTORIA	
SCHMIDT	REBECCA	KRISTINE
SCHMIDT-SPORKEL	HEIDI	ANGELIKA
SCHOOP	URS	D
SCHROER	LARA	
SCHUIL	MELANIE	MARY
SCHUSTER	STEFAN	
SEABORN	SANDRA	LAURE
SEARLS	ELIZABETH	DAVIS
SEARS	JAMES	ZOLLA
SEBASTIAN	MARTIN	JEREMY
SECRIST	WADE	MICHAEL
SEEBACH	NORA	MADLAINA
SEGAL	BROOKE	ELIZABETH
SEGAL	KATHRYN	RACHEL
SEGGERMAN	MAJA	TIMPSON
SEIDLER	JEAN	ELIZABETH
SELLERS	JAMES	DAVID AIKENS
SERRANO-LUGINBUEHL	SANDRA	ANNE
SEVEAU	MATTHIEU	
SEYDOUX	ARLENE	ELIZABETH
SEYDOUX	JUSTIN	ALBERT
SEYDOUX	RAPHAEL	PHILIPPE
SHANAA	BIANCA	CLAIRE
SHARMA	SANGITA	
SHARPE-HAMMANN	EMILY	BETH
SHAW	JULIA	VALETTE
SHEINY	SHIRIN	MOHSEN
SHEN	TREVOR	ANDREW
SHEN	XUEMEI	
SHEN	YUN	MEI
SHIER	EMILY	ANNE
SHIM	EUN	KI
SHIM	KYONG	UN
SHORT	NICOLA	CATHERINE
SHOUNG	NICHOLAS	
SHUPTRINE	BRIAN	RICHARD
SIBAKOV	HENNA	MARIA
SIBAKOV	SANTERI	M
SIEBER	SUSAN	MITYLENE
SIEDERSBERGER	LOUISA	PILAR
SIEWIORA	HALINA	MIROSLAWA

Last name	First name	Middle name or initials
SIKES	RICHARD	CHARLES
SIKES	RIHO	KARELSOHN KALDA
SIMMONS	SUSANNA	
SIMPSON	AUDREY	MARGUERITE
SINCLAIR	HEATHER	ANNE
SINGHAL	KUNAL	
SISON	ALEXANDRA	CHANEL CHIONGBAN
SIY	SHERILYN	TAN
SKANTZE	DONALD	ERIC
SKOWRON	MAIA	A
SKUTNIK-DOROCKA	KRYSTYNA	TAMMY
SMITH	ANDREW	RUSSELL
SMITH	BENJAMIN	BRITTEN
SMITH	JASON	MICHAEL
SMITH	KRISTEN	MICHELLE
SNISARENKO	JOHN	IWAN
SOAMES	FIONA	JANET
SOBIESKI	CHRISTOPHER	DAVID
SOLOMITA	MARIA	VITTORIA
SONNINO	ROBERTO	
SOPCAK	PAUL	ANDREAS
SOUTHERLAND	DAVID	GARLAND
SOUTHWORTH	JESSICA	ANNE
SOVEREL	NICHOLAS	OSBORNE
SPECK	CHRISTINE	DONNA
SPECK	MICHAEL	JONATHON
SPRATTE	SONJA	MICHAELA
ST SAUVEUR	ELAINE	LOUISE
STACK	JENNIFER	ANNE
STAINFORTH	LAURA	JUNE
STAMATOULAKIS	ANNA	
STEAD	GEOFFREY	R
STEEN	ROBERT	HOAGLAND
STEINBACH	WENDY	JOAN
STEINMETZ-WOOD	AIDAN	MATTHEW
STEPHENS	LORRAINE	RUTH
STERN	RUTH	
STEVENSON	ANDREW	ROBYN
STEVENSON	MELANIE	ROBYN
STEWART	MADISON	FRANCIS
STITOVIC	NINA	
STORKOVA	HANA	
STOYANOVA	ZORNITSA	STOYANOVA
STRAUB	DEBORAH	ANNETTE
STRAUSS	HELGA	ROSINA
ST-SAUVEUR	DIANE	
STUERKE	STEFAN	
STUERKE LEINWEBER	SILKE	LUISA
STYRCHAK	SHEILA	MARIA
SU	XU	
SUGITA	MAMORI	
SUN	YANFU	
SUZUKI	KAZUYO	
SVATOS	SARAH	MERI BARRIENTOS
SWAN	JAMIE	LEE
SWANSON	SCOTT	ROTHWELL
SYLVESTER	NICHOLAS	SCOTT
SZMURLO	ERIC	ROSS
SZTO	GEORGIA	MARIE
TABET	HAYLEY	HUIEUN KIM
TACHIBANA	REIKO	T
TAI	LIYING	
TAIT	KIMBERLEE	JAY
TAKAHASHI	IKUYO	
TAMURA	TAKUYA	
TAN	SHAUN	JANWAY
TAN	WILBUR	ASHLEY NGO
TANAKA	ATSUKO	
TANAKA	KODO	
TANDONNET	SOPHIE	HOKULANI VERONIQUE JESSICA
TANG	KWONG	TSUN
TANG	MENGHUA	
TANG	PAULA	JEAN
TANIGUCHI	MAI	

Last name	First name	Middle name or initials
TANIGUCHI	MICHIYO	
TANIGUCHI	TADANORI	
TARNAWSKY	MAXIM	DAVID
TAYLOR	JASON	NICHOLAS
TAYLOR	KEATON	
TAYLOR	SAMUEL	JACK
TEH	HUI	CHING YVONNE
TEO	MONICA	SHIH CHING
TERADA-WALSH	YUKO	
TERRY	SAMUEL	SCOTT
TERZARIOL	ISABELLA	
TESCHNER	REGINA	
TEUBER	JULIA	
TEUTSCH	JUSTIN	DAVID
THIEL	HILDA	MAGDALENA
THIERRY	DIEDERIK	ADRIANUS
THOMAS	BRENT	ALLISON
THOMAS	SHERILEE	ANN SHANNON
THOMPSON	JAMES	EDWARD
THOMPSON	JENNIFER	LUC
THOMPSON	WARREN	LEE
THOMSEN	JESS	MC CANN
THOMSON	KEVO	X
TIBREWALA	PRIYANKA	
TIDBECK	ELIN	ELISABETH
TINGLEY	VANESSA	ALEXANDRA
TITUS	MATTEO	GIORGIO FRANCESCO MARIA
TOATES	NIGEL	DAVID
TODD	ANTHONY	DESMOND
TOEWS	JENNETTE	HELEN
TOHMATSU	AKIKO	JUDITH
TOMA	AI	
TONACK	JONATHAN	CARL
TORIGOE	AKIKO	
TORIUMI	HIROSHI	
TORIUMI	TOSHIE	
TORKELSSON GLADER	ELLA	MARIA
TORRES ROSSEL	MACARENA	LUCIA
TRACEY	JESSICA	FRANCES SPENCER
TREBBI	ALESSANDRO	LAWRENCE
TRICHTER	DAN	
TRUSSARDI-BEER	ALEXANDRA	MELISSA
TSAO	JONATHAN	ROBIN
TURNER	AURORA	SHONA BERIN
TYLER	SARA	MAY
UEGAKI	HIROKO	
ULMER	JONATHAN	HOWARD
UNDERLAND	JADA	ISIS
UNGER	HERBERT	
UNGER	ROSEMARIE	
URE	COLIN	ALEXANDER MACEWEN
UTZIG	CAELAN	PATRICK
VALAR	KALINKA	REGINA
VALLADARES	MIGUEL	JOSE
VALLANCE	IRINA	
VALLDAL	TROND	
VAN DEN BERG	GEORGE	SEBASTIAAN
VAN DER LINDEN	GWENDOLYN	WILLEMIJN
VAN DER LOOS	KIAH	ILEANA
VAN OOYEN	PETER	CLAUDE
VAN WESENBEECK	MARIAM	
VANDEBOSSCHE	MARC	FLORENT
VASQUEZ	FELIPE	ISMAEL
VAUX	ANNA	KATHERINE
VERKERK	MARCEL	WILLEM
VIENS	DANIELLE	CLAUDIA
VILEN	SUSANNA	JOHANNA
VILLIGER	RAHEL	ANDREA
VOGEL	ALLISON	NORA
VOGEL	STEPHAN	HEINZ KONRAD
VOGEL FEITKNECHT	KATHARINA	GERTRUD
VOLI-MORGAN	CONSTANCE	A
VOLLAND	STEFANIE	
WADA	TOYOTARO	

Last name	First name	Middle name or initials
WADA	YOSHIKO	
WALL	BRANDON	MICHAEL
WALLS	CHRISTINA	SARAH
WALPOLE	IMOGEN	ROSE
WANG	CHUN	
WANG	HUE	CHIN
WANG	KAREN	SUE
WARCHAL	DANIEL	FRANK
WARMING	BELLE	CAROLINE
WARNER	ELEANOR	JANE
WARNER	EVE	MOLLY FRANCES
WARNER	GRACE	ALICE MARY
WARNER	MADELINE	ANNE ROSE
WARNER	SIMON	ANTHONY JAMES
WARNOCK	PETER	OLIVER
WATKINS	MALCOLM	FRANCIS
WATSON	ANNA	CELESTE
WEAVER	MATILDA	MARY
WEBER	LINDA	
WEBER	LUCAS	GEORG
WEEKS	MICHAEL	JEFFREY
WEINFELD	MARY	JANE
WEINROTH	MICHELLE	SUE
WEIR	ANASTASIA	
WEISER	CHARLES	ROBERT
WEISS	SEBASTIAN	
WEISSER	MICHAEL	KARL-HEINZ
WELDON	STEVEN	ANDREW
WELLARD	DAVID	JOHN
WELLARD	MOLLY	LYNNE
WELTER	WARREN	JOHN
WENIG	SANDRA	LOUISE
WENZEL	STEPHANIE	ELIZABETH
WEST-BROWN	MOIRA	JOSEPHINE
WESTHAVER	TRACY	THOMAS
WHEELER	SHARANNE	JUNE
WHITE	DIANNE	LYNN
WHITE	EMILY	ROSE
WHITE	HARRY	KINROSS
WHITE	THERESA	CATHERINE
WIDMAIER	PETER	CHRISTIAN FRIEDRICH
WIELAND	GINA	LAUREEN
WIELAND	THOMAS	KARLHEINZ
WIJAYA	SUHAN	
WIJSMAN	SUZANNE	IRENE
WILCOX	ANGELA	GERALDINE
WILCOX	HARRISON	MACLAINE
WILCOX	MICHAEL	PAGE
WILDER	SUE	ELLEN
WILLIAMS	DAVID	RICHARD
WILLIAMS	PETER	ANDREW
WILSON	EMMA	KATE
WILSON	JAMES	HAROLD
WILTSHIRE	BRANDON	MACKENZIE
WINGARDH	INGRID	KARIN BEATA
WINTER	REMKO	TSJIBBE
WIZENBERG	GAELE	SANDRA
WOITOWICZ	ANTOINETTE	MARIE
WOITOWICZ	JENICA	MARIE
WOITOWICZ	JUEL	KRISTINE
WOLF	AIDA	ELINA
WOLFE	LIMOR	
WOLFE	MAYTAL	
WONG	DANIEL	SHIU-LUNG
WONG	ELIZABETH	H
WONG	KAREN	
WU	ALLAN	CHENG YEU
WYCKHAM	CHRISTOPHER	MARK
WYMAN-CLARKE	ANDRIA	KAYE
WYNANS	DREW	MARIE
WYNN	LISA	LORRAINE
XU	JING	
YAMADA	MISUZU	
YAMAMOTO	KENTARO	ALBERT

Last name	First name	Middle name or initials
YANG	BAOYUAN	
YANG	LANFANG	
YAP	LIANG	
YAQUB	LILLIAN	MICHELLE
YAROSHEVICH	MAYA	ALEXANDRA
YEO	MARK	BOON GUAN
YINGER	KENNETH	RICHARD
YIP	ADRIEN	
YOKOYAMA	CHIHARU	
YOON	HYUNGN	YUN
YORDAN DOTAN	DORIT	PNINA
YOSHIDA	SEI	
YOUMANS	HANNI	LORRAINE
YOUNG	MICHAEL	CONOR
YOUNG III	GEORGE	CHRISTIAN
YU	HUA	
YU	MISUN	
YU	SHUI	
YUAN	FEI	
ZAHRNDT	MONICA	M
ZANTOW	JULIKA	ELISABETH
ZAPATA	MARIA	ELIZABETH
ZARB	THERESE	ALEXANDRA
ZARETSKY	ALEXEY	
ZEILLINGER	MARIAN	MARGUERITE
ZENGOS	HELEN	
ZENKOVICH	BARBARA	JOAN
ZHANG	CHUTIAN	
ZHANG	JIXI	
ZHANG	VALERIE	
ZIEMER	DANIELA	
ZIMBERG	PAUL	DARRYL
ZIMMERER	MAXIMILIAN	JOSEF

Dated: October 27, 2026.

Kevin T. Hall,

*Senior Revenue Agent Team 1942, CSDC—
Compliance Support, Development &
Communications, LB&I-WEIIC:IC:T4.*

[FR Doc. 2026-22229 Filed 10-29-26; 8:45 am]

BILLING CODE 4831-GV-P

DEPARTMENT OF THE TREASURY

United States Mint

Notification of Citizens Coinage Advisory Committee Public Meeting

ACTION: Notice of meeting.

Pursuant to United States Code, Title 31, section 5135(b)(8)(C), the United States Mint announces a Citizens Coinage Advisory Committee (CCAC) public meeting.

Date: November 17, 2026.

Time: 9:00 a.m. to 3:30 p.m. (ET).

Location: United States Mint,
Philadelphia, Pennsylvania.

Subject: Approval of the Fiscal Year 2026 CCAC Annual Report, and review and discussion of the reverse design portfolios for the 2028 American Youth Sports quarters and Paralympic half dollar.

Due to the secure nature of the meeting location, members of the public

will not be admitted. Interested members of the public may watch the meeting via live stream on the United States Mint's YouTube Channel at <https://www.youtube.com/user/usmint>. To watch the meeting live, members of the public should select the link for the day's CCAC meeting under the "Live" tab.

The public should call the CCAC HOTLINE at (202) 354-7502 for the latest updates on meeting time and access information.

For members of the public interested in watching online, this is a reminder that the remote access is for observation purposes only. Members of the public may submit matters for the CCAC's consideration by email to info@ccac.gov.

The CCAC advises the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals; advises the Secretary of the Treasury with regard to the events, persons, or places to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made; and makes recommendations

with respect to the mintage level for any commemorative coin recommended.

For Accommodation Request: If you require an accommodation to watch the CCAC meeting, please contact the Office of Equal Employment Opportunity by November 10, 2026. You may submit an email request to Reasonable.Accommodations@usmint.treas.gov or call 202-354-7260 or 1-888-646-8369 (TTY).

FOR FURTHER INFORMATION CONTACT:

Megan Sullivan, United States Mint Liaison to the CCAC; 801 9th Street NW, Washington, DC 20220; email megan.sullivan@usmint.treas.gov or call 202-354-7517.

(Authority: 31 U.S.C. 5135(b)(8)(C))

Eric Anderson,

Executive Secretary, United States Mint.

[FR Doc. 2026-22243 Filed 10-29-26; 8:45 am]

BILLING CODE 4810-37-P

DEPARTMENT OF VETERANS AFFAIRS**[Docket No. VA–2026–VACO–0001]****Privacy Act of 1974; System of Records****AGENCY:** Department of Veterans Affairs (VA), Office of Information and Technology**ACTION:** Notice of a Modified System of Records.

SUMMARY: Pursuant to the Privacy Act of 1974, notice is hereby given that the VA is modifying the system of records entitled, “Individuals Submitting Invoices—Vouchers for Payment and Accounting Transactional Data—VA” (13VA047). This system is used for payment processing, general accounting, benefit payment authorization for the benefit of veterans and their families, and government and commercial service providers for contract and/or reimbursement expenses.

DATES: Comments must be received by November 30, 2026. This modified system of records is effective as of November 30, 2026 unless modified by a subsequent notice incorporating any comments received.

ADDRESSES: Comments may be submitted through www.regulations.gov or mailed to VA Privacy Service, 810 Vermont Avenue NW, (005X6F), Washington, DC 20420. Comments should indicate that they are submitted in response to “Individuals Submitting Invoices—Vouchers for Payment and Accounting Transactional Data—VA” (13VA047). Comments received will be available at www.regulations.gov for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Morla Roberts, Privacy Officer Section Chief, Financial Services Center (FSC) VAFSCPRIVACYOFFICER@va.gov.

SUPPLEMENTARY INFORMATION: VA is modifying the system of records by revising the System Name, System Location, System Managers, Purposes of the System, Categories of Individuals Covered by the System, Categories of Records in the System, Policies and Practices for Storage of Records, Policies and Practices for Retrieval of Records, and Routine Uses. VA is republishing the system notice in its entirety.

The System Name and Purposes of the System are being modified to provide a better representation of the systems it covers as a Consolidated Enterprise Resource Planning System.

The System Location and System Managers are being updated to reflect changes in location and the new Point

of Contact, the new system owner, and privacy officer.

The Categories of Individuals Covered by the System and the Categories of Records in the System are being updated to reflect current records and eliminate duplicates.

The Policies and Practices for Storage of Records and Policies and Practices for Retrieval of Records are being updated to represent the adoption of new technologies, such as virtual servers and cloud computing, replacing paper copies and outdated technologies.

The Routine Uses are being amended to comply with Executive Order 14249 titled “Protecting America’s Bank Account Against Fraud, Waste, and Abuse” and cover existing and new information-sharing requirements.

The Report of Intent to Amend a System of Records Notice and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of the Office of Management and Budget (OMB) as required by 5 U.S.C. 552a(r) (Privacy Act) and guidelines issued by OMB (65 FR 77677), December 12, 2000.

Signing Authority

The Senior Agency Official for Privacy, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Dr. Paul Lawrence, Assistant Secretary for Information and Technology and Chief Information Officer, Department of Veterans Affairs approved this document on March 30, 2026 for publication.

Dated: October 28, 2026.

Stephanie Hotchkiss,

Government Information Specialist, VA Privacy Service, Office of Information and Technology, Department of Veterans Affairs.

SYSTEM NAME:

“Consolidated Enterprise Resource Planning Systems including Financial Reporting and Warehousing—VA” (13VA047)

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are stored in the Corporate Data Warehouse, Austin Information Technology Center in Austin, TX.

SYSTEM MANAGER(S):

Lee M. Brown, Lee.Brown3@va.gov, FSC Information System Owner; Morla D. Roberts, Morla.Roberts@va.gov, FSC

Privacy Officer; and Edward Neidzielski, Edward.Niedzielski@va.gov, FSC Data/Business Owner.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S.C. 3512; Federal Information Security Modernization Act of 2014; 38 CFR 17.120 through 17.132.

PURPOSE(S) OF THE SYSTEM:

This system is the Enterprise Resource Planning toolset for VA. The set of related systems provides transactions related to accounts receivable including cash receipts; accounts payable including automated disbursements; acquisitions including asset receipts, obligations, and contract awards; budget execution; fixed asset tracking; ledger management; project cost accounting; travel accounting; payment of benefits; medical claims payments and payroll purposes. Information is collected from recipients, vendors, VA administrations, medical centers, and other Federal entities for rendering payment and screening for improper payments to protect against waste, fraud, and abuse.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Veterans, veteran dependents, veteran caregivers, federal employees, vendors (individual and/or companies), volunteers, intra and inter-agency service providers, and members of the public who have a relationship with the agency.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include Full name, Address, Phone Number, Social Security Number, Medical Records, Claim/Statement Number, Date of Service, Beneficiary Information, Email Address, Date of Birth, Driver License (Number and State), License Plate, Place of Birth (City, State and Country), Banking Information (Routing/Bank Account Number, and Bank Name), Charge Card Number, Emergency Contact Information, DUNS numbers, IP addresses, retirement information, life insurance information, voluntary separation information, various pay incentives and awards, student loan repayment and Commercial Vendor identification listings, invoiced payment records, and Unique Entity Identifier.

RECORD SOURCE CATEGORIES:

Commercial vendors; individual or legal representative as part of an application for a benefit, contract or reimbursement request; VA administration, medical facility and/or medical center; Department of Treasury; Internal Revenue Service; and other Federal entities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

1. *Congress*: To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

2. *Data Breach Response and Remediation, for VA*: To appropriate agencies, entities, and persons when (a) VA suspects or has confirmed that there has been a breach of the system of records, (b) VA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, VA (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with VA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

3. *Data Breach Response and Remediation, for Another Federal Agency*: To another Federal agency or Federal entity, when VA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

4. *Law Enforcement Authorities, for Reporting Violations of Law*: To a Federal, State, local, territorial, Tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility of investigating or prosecuting a violation or potential violation of law, whether civil, criminal, or regulatory in nature, or charged with enforcing or implementing such law, provided that the disclosure is limited to information that, either alone or in conjunction with other information, indicates such a violation or potential violation. A disclosure of information about veterans or their dependents from VA claims files under this routine use must also comply with the requirements of 38 U.S.C. 5701(f).

5. *Department of Justice, Litigation, Administrative Proceeding*: To the Department of Justice (DoJ), or in a proceeding before a court, adjudicative body, or other administrative body before which VA is authorized to appear, when any of the following is a

party to such proceedings or has an interest in such proceedings, and VA determines that use of such records is relevant and necessary to the proceedings:

- (a) VA or any component thereof;
- (b) A VA employee in their official capacity;
- (c) A VA employee in their individual capacity where DoJ has agreed to represent the employee; or
- (d) The United States, where VA determines that litigation is likely to affect the agency or any of its components.

6. *Contractors*: To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for VA, when reasonably necessary to accomplish an agency function related to the records.

7. *Equal Employment Opportunity Commission*: To the Equal Employment Opportunity Commission in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law.

8. *Federal Labor Relations Authority*: To the Federal Labor Relations Authority in connection with the investigation and resolution of allegations of unfair labor practices, the resolution of exceptions to arbitration awards when a question of material fact is raised, matters before the Federal Service Impasses Panel, and the investigation of representation petitions and the conduct or supervision of representation elections.

9. *Merit Systems Protection Board*: To the Merit Systems Protection Board in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as authorized by law.

10. *National Archives and Records Administration*: To the National Archives and Records Administration (NARA) in records management inspections conducted under 44 U.S.C. 2904 and 2906, or other functions authorized by laws and policies governing NARA operations and VA records management responsibilities.

11. *Federal Agencies, for Computer Matching Agreements*: To other Federal agencies for the purpose of conducting computer matches, such as Department of Treasury/Department of Veteran Affairs Financial Services Center

(Treasury/VA FSC) Do Not Pay (86 FR 38561), to obtain information to determine or verify the eligibility of veterans receiving VA benefits or medical care under title 38.

12. *Federal Agencies, Courts, Litigants, for Litigation or Administrative Proceedings*: To another Federal agency, court, or party in litigation before a court or in an administrative proceeding conducted by a Federal agency, when the government is a party to the judicial or administrative proceeding.

13. *Health Care Providers, for Referral by VA*: To: (1) a Federal agency or health care provider when VA refers a patient for medical and other health services, or authorizes a patient to obtain such services and the information is needed by the federal agency or health care provider to perform the services; or (2) a Federal agency or to health care provider under the provisions of 38 U.S.C. 513, 7409, 8111, or 8153, when treatment is rendered by VA under the terms of such contract or agreement or the issuance of an authorization, and the information is needed for purposes of medical treatment or follow-up, determination of eligibility for benefits, or recovery by VA of the costs of the treatment.

14. *Health Care Providers, for Referral to VA*: To a non-VA health care provider when that health care provider has referred the individual to VA for medical or other health services.

15. *Federal Agencies, for Recovery of Medical Care Costs*: To Federal agencies and government-wide third-party insurers responsible for payment of the cost of medical care for the identified patients, to seek recovery of the medical care costs. These records may also be disclosed as part of a computer matching program to accomplish this purpose.

16. *Treasury, for Withholding*: To the Department of the Treasury for the collection of title 38 benefit overpayments, overdue indebtedness, or costs of services provided to an individual not entitled to such services, by the withholding of all or a portion of the person's Federal income tax refund, provided that the disclosure is limited to information concerning an individual's indebtedness by virtue of a person's participation in a benefits program administered by VA.

17. *Treasury, to Report Waived Debt as Income*: To the Department of the Treasury as a report of income under 26 U.S.C. 61(a)(12), provided that the disclosure is limited to information concerning an individual's indebtedness that is waived under 38 U.S.C. 3102, compromised under 4 CFR part 103,

otherwise forgiven, or for which the applicable statute of limitations for enforcing collection has expired.

18. Treasury, for Payment or Reimbursement: To the Department of the Treasury to facilitate payments to physicians, clinics, and pharmacies for reimbursement of services rendered or to veterans for reimbursement of authorized expenses, as well as to collect, by set off or otherwise, debts owed the United States.

19. Treasury, for the Do Not Pay Working System: To the Department of the Treasury when disclosure of the information is relevant to review payment and award eligibility through the Do Not Pay Working System for the purposes of identifying, preventing, or recouping improper payments to an applicant for, or recipient of, Federal funds, including funds disbursed by a State (meaning a State of the United States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian Tribe) in a State-administered, federally funded program.

20. Treasury, to Report Earnings as Income: To the Department of the Treasury to report calendar year earnings of \$600 or more for income tax reporting purposes.

21. Guardians ad Litem, for Representation: To a fiduciary or guardian ad litem in relation to his or her representation of a claimant in any legal proceeding as relevant and necessary to fulfill the duties of the fiduciary or guardian ad litem.

22. Guardians, Courts, for Incompetent Veterans: To a court, magistrate, or administrative tribunal in matters of guardianship, inquests, and commitments; to private attorneys representing veterans rated incompetent in conjunction with issuance of Certificates of Incompetency; or to probation and parole officers in connection with court-required duties.

23. Claims Representatives, for Title 38 Benefits: To accredited service organizations, VA-approved claim agents, and attorneys acting under a declaration of representation, so that these individuals can aid claimants in the preparation, presentation, and prosecution of claims under the laws administered by VA upon the request of the claimant and provided that the disclosure is limited to information relevant to a claim, such as the name, address, the basis and nature of a claim, amount of benefit payment information, medical information, and military service and active duty separation information.

24. Third Party, for Benefit or Discharge: To a third party upon the

written request of the patient's next-of-kin in order for a non-judicially declared incompetent patient or, consistent with the best interest of the patient, a member of the patient's family to receive a benefit to which the patient or family member is entitled or to arrange for the patient's discharge from a VA medical facility. Sufficient data to make an informed determination will be made available to such next-of-kin. If the patient's next-of-kin is not reasonably accessible, the Chief of Staff, Director, or designee of the custodial VA medical facility may disclose the information for these purposes.

26. Governmental Agencies, Health Organizations, for Claimants' Benefits: To Federal, State, and local government agencies and National Health Organizations (National Institute of Health, American Medical Association and American Cancer Society) as reasonably necessary to assist in the development of programs that will be beneficial to claimants, to protect their rights under law, and ensure that they are receiving all benefits to which they are entitled.

27. Consumer Reporting Agencies: To a consumer reporting agency for the purpose of locating the individual, obtaining a consumer report to determine the ability of the individual to repay an indebtedness to the United States, or assisting in the collection of such indebtedness, provided that the provisions of 38 U.S.C. 5701(g)(2) and (4) have been met, provided that the disclosure is limited to information that is reasonably necessary to identify such individual or concerning that individual's indebtedness to the United States by virtue of the person's participation in a benefits program administered by the Department.

28. Attorneys, Insurers, Employers, for Preparation, Presentation, Prosecution of Claims: To attorneys, insurance companies, employers, third parties liable or potentially liable under health plan contracts, and courts, boards, or commissions as relevant and necessary to aid VA in the preparation, presentation, and prosecution of claims authorized by law.

29. Nonprofits, for Release of Names and Addresses: To a nonprofit organization if the release is directly connected with the conduct of programs and the utilization of benefits under title 38, provided that the disclosure is limited the names and addresses of present or former members of the armed services or their beneficiaries, the records will not be used for any purpose other than that stated in the request, and the organization is aware of the penalty provision of 38 U.S.C. 5701(f).

30. Outreach, for Title 38 Benefits: To any State, local, territorial, Tribal, or other governmental agency upon request for the purpose of outreach concerning a benefit under title 38 U.S.C.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored electronically on a VA server, in paper folders, magnetic discs, magnetic tape, and in a momentum cloud application. Paper documents may be scanned/digitized and stored for viewing electronically.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name and identification number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records in this system are retained and disposed of in accordance with the schedule approved by the Archivist of the United States, General Records Schedule 1.1: Financial Management and Reporting Records, Item #010.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

VA will store records produced within this system of records in an area that is physically and technologically secure from access by unauthorized individuals. Only authorized personnel will transport records within this system of records. VA will process records produced within this system of records under the immediate supervision and control of authorized personnel in a manner that will protect the confidentiality of the records, ensuring that unauthorized persons cannot retrieve any records by computer, remote terminal, or other means. VA will store records using FIPS 140-2 compliant encryption. Systems personnel must enter personal identification numbers when accessing records on the agency's systems. VA will strictly limit authorization to those electronic records areas necessary for the authorized analyst to perform his or her official duties.

RECORD ACCESS PROCEDURES:

Individuals seeking information on the existence and content of records in this system pertaining to them should contact the system manager in writing as indicated above or may write or visit the VA facility location where they normally receive their care. A request for access to records must contain the requester's full name, address, telephone number, be signed by the requester, and describe the records sought in sufficient detail to enable VA

personnel to locate them with a reasonable amount of effort.

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend records in this system pertaining to them should contact the system manager in writing as indicated above or may write or visit the VA facility location where they normally receive their care. A request to contest or amend

records must state clearly and concisely what record is being contested, the reasons for contesting it, and the proposed amendment to the record.

NOTIFICATION PROCEDURES:

Individuals who wish to be notified if a record in this system of records pertains to them should submit the request following the procedures

described in “Record Access Procedure,” above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

85 FR 22788 (April 23, 2020); 88 FR 60269 (August 31, 2023).

[FR Doc. 2026-22254 Filed 10-29-26; 8:45 am]

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FEDERAL REGISTER

Vol. 91

Friday,

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October 30, 2026

Part II

Department of Education

34 CFR Parts 600, 602, and 668

Accreditation, Innovation, and Modernization: The Secretary's Recognition of Accrediting Agencies; Institutional Eligibility Under the Higher Education Act of 1965, as Amended; Student Assistance General Provisions; Final Rule

DEPARTMENT OF EDUCATION**34 CFR Parts 600, 602, and 668****[Docket ID ED–2026–OPE–1042]****RIN 1840–AD82****Accreditation, Innovation, and Modernization: The Secretary's Recognition of Accrediting Agencies; Institutional Eligibility Under the Higher Education Act of 1965, as Amended; Student Assistance General Provisions****AGENCY:** Office of Postsecondary Education, Department of Education.**ACTION:** Final rule.

SUMMARY: The Department revises the existing accrediting agency recognition regulations to implement the directives set forth in Executive Order 14279, Reforming Accreditation to Strengthen Higher Education, and other Administration priorities, align the regulations more closely with statute, and reduce regulatory burden.

DATES: This final rule is effective July 1, 2027.

Implementation dates: For the implementation dates of the regulatory provisions, see the *Implementation Date of These Regulations* of this document.

FOR FURTHER INFORMATION CONTACT: For further information related to recognition of accrediting agencies, Elizabeth Daggett, Director, Accreditation Group, Office of Postsecondary Education, Telephone: (202) 453–7615. Email: elizabeth.daggett@ed.gov. For all other information related to this document, Aaron Washington, Office of Postsecondary Education, Telephone: (202) 987–0911. Email: aaron.washington@ed.gov.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

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I. Executive Summary

The Secretary of Education recognizes accrediting agencies under existing regulations at 34 CFR part 602 to ensure that agencies are reliable authorities regarding the quality of education or training offered by the institutions or programs they accredit for the purposes of the Higher Education Act of 1965, as amended (HEA), or for other Federal purposes. Recognized institutional accrediting agencies serve as key gatekeepers in determining which institutions may participate in the Federal student aid programs, which currently provide more than \$100 billion in Pell Grants and Federal student loans annually. To ensure that the Department only recognizes those accrediting agencies focused on high-quality, valuable education for students, we are realigning the regulations for recognition of accrediting agencies to have a greater focus on student achievement and ensure programs provide a high-quality, high-value education.

The final rule removes unnecessary requirements on agencies and the institutions or programs they accredit. These regulations eliminate requirements not required by statute, including the “two-year rule” for initial recognition of agencies, prescriptive site visit mandates, unnecessary documentation requirements, and rigid, overly long processing and procedural timelines.

These commonsense regulations also address the barriers that limit institutions from adopting practices that advance credential and degree completion and spur new models of education. They also remove existing regulatory barriers impeding institutions’ ability to change accrediting agencies or work with more than one accrediting agency, while agencies will have more flexibility to apply certain standards that meet the needs of their accredited institutions and programs.

The final rule also introduces a new review framework for better oversight of key institutional accrediting agencies that serve as the primary gatekeepers for the Federal student aid programs, and whose potential failures pose the greatest risk to taxpayers.

Additionally, to reduce administrative costs that are negatively impacting college affordability, the final rule requires recognized accrediting agencies to apply their standards in ways that minimize institutional administrative burden, avoid duplicative reporting, and support the implementation of lower-cost, higher-value educational models. These changes also will shift the focus of institutions toward more cost-effective practices for staffing, facilities, student services, and program design.

The final rule promotes greater integrity in decision making by recognized accrediting agencies and eliminates previous regulatory exceptions that pose potential conflicts of interest. The final rule also eliminates geographic-scope distinctions for institutional accrediting agencies and makes other anticompetitive behavior a negative factor in consideration of agency recognition.

The final rule reinforces the existing legal, constitutional, civil rights, and consumer protection obligations already required of recognized accrediting agencies and the institutions and programs that they accredit. For example, under the final rule, accrediting agencies recognized by the Secretary must ensure that the institutions and programs they accredit have and apply policies consistent with all Federal and State laws and respond appropriately to findings of noncompliance by competent authorities. The final rule also prevents recognized accrediting agencies from applying standards that direct accredited institutions and programs to violate such laws. New student outcome and program-level performance expectations for the applications of agency standards will focus both accrediting agencies and institutions on important objective measures of student and institution performance such as course completion, licensure pass rates, and economic returns.

Further, the final rule addresses the persistent and costly issues with transfer of credit policies that have burdened students. These regulations reduce the likelihood that students will be required to undertake duplicative coursework and incur additional tuition charges that are not necessary. Although institutions will continue to have latitude to deny transfer of credit based on the credit failing to meet the receiving institutions’ standards, institutions will have to explain those standards and provide written reasoning to the student for such denial. These regulations also require greater transparency before a student decides to transfer to another institution, so he or

she can have a full understanding of the scope and cost of transferring to that institution.

Taken together, this student-oriented final rule realigns the Secretary's recognition of accrediting agencies with a high-quality, high-value education that is free from unlawful discrimination and other violations of Federal law.

1. Summary of Major Provisions

These final regulations:

- Amend § 600.11 to make it less burdensome for institutions that are changing accrediting agencies or wish to utilize more than one accrediting agency.

- Amend § 602.2 to require the Department to provide public notice on its accreditation website if the Secretary denies continued recognition to a previously recognized agency, or if the Secretary limits, suspends, or terminates the agency's recognition before the end of its recognition period.

- Amend § 602.3 to define and use the term "institution" in these regulations instead of "institution of higher education" which is defined in the HEA, and elsewhere in the Department's regulations, referring to a narrower subset of institutions, and to add a definition for "related, associated, or affiliated trade association."

- Amend § 602.10 to clarify that the Secretary's recognition extends only to those accrediting agencies whose institutions or programs actively participate in a Federal program.

- Amend § 602.11 to require accrediting agencies to clearly describe the scope of their accrediting activities and remove geographic restrictions that restrict institutions and programs from choosing an accrediting agency.

- Amend § 602.12 to remove references to geographic areas and geographic constraints and require review of contractions of scope. Additionally, amend the regulations to clarify the policies and capacity an accrediting agency must have to seek initial recognition, and eliminates the "two-year rule" for initial recognition.

- Unreserve and amend § 602.13 to specify that an accrediting agency's recognition by the Department does not provide any immunity from antitrust laws.

- Amend § 602.14 to strengthen the fiscal and administrative criteria an accrediting agency must meet to prove it is fully separate and independent from any related, associated, or affiliated trade or membership organization.

- Amend § 602.15 to require accrediting agencies to administer their

standards, policies, and procedures in a manner that minimizes unnecessary compliance costs and administrative burdens on accredited institutions, as well as require agencies to maintain appropriate conflict of interest controls and policies.

- Amend § 602.16 to codify that an agency may establish additional lawful accreditation standards that are consistent with ensuring institutional or programmatic quality and integrity as it deems appropriate.

- Amend § 602.17 to clarify expectations for reviewing student achievement and faculty related policies, including academic freedom and intellectual diversity. Additionally, add new requirements regarding institutional cost-benefit analyses, institutional flexibility and mission, program length review, and safeguards against misrepresentation.

- Amend § 602.18 to require that accrediting agency decisions be neutral with respect to viewpoint and ideology, except for agencies with a religious mission.

- Amend § 602.20 to provide guidance to accrediting agencies on how to structure their arbitration procedures and remove overly prescriptive requirements.

- Amend § 602.21 to remove overly prescriptive review requirements.

- Amend § 602.22 to refine the list of changes requiring agency approval, add prison education programs as a defined substantive change, and remove outdated and overly prescriptive requirements.

- Amend § 602.23 to require accrediting agencies to ensure institutions comply with all applicable Federal and State laws and remove overly prescriptive requirements.

- Amend § 602.24 to strengthen accrediting agencies' oversight of institutional changes, expand requirements for teach-out planning, including transcript access, and increase transparency and support for students when institutions face disruptions.

- Amend § 602.24 to establish clearer, fairer rules for credit transfer by defining consistent criteria, prohibiting discriminatory denials, requiring acceptance of comparable credits, and providing students with an appeals process.

- Amend § 602.25 to remove overly prescriptive requirements for demonstrating due process.

- Amend § 602.26 to update and modernize the required content of agency notices and better align these requirements with contemporary methods of disclosure and allow temporary continuation of eligibility for

title IV, HEA funds for institutions to exhaust all due process options.

- Amend § 602.27 to require agencies to update the Department's website on a regular, timely basis to display the current accreditation status of all institutions and programs.

- Amend § 602.28 to broaden the circumstances under which an accrediting agency must re-evaluate an institution or program following negative actions by other authorities.

- Amend § 602.30 to modernize how accrediting agencies submit applications and reports to the Department.

- Amend § 602.32 and split into two sections: § 602.31 and § 602.32.

- Amend § 602.31 to modernize and streamline the procedures accrediting agencies must follow when submitting applications for initial or renewed recognition.

- Amend § 602.32 to modernize and clarify the processes used to review an accrediting agency's expansion or contraction of scope, compliance report, and increase in headcount enrollment.

- Amend § 602.33 to modernize and streamline the procedures for review of agencies during the period of recognition, including the review of monitoring reports.

- Amend § 602.34 to require the National Advisory Committee on Institutional Quality and Integrity (NACIQI or Advisory Committee) to review applications for contractions of scope, and for accrediting agencies to post public notice of upcoming NACIQI reviews.

- Amend §§ 602.35, 602.36, and 602.37 to update cross references.

- Amend § 668.43 to require transfer of credit disclosures and direct applicable written notices to students.

2. Summary of Costs and Benefits

As further detailed in the Regulatory Impact Analysis (RIA), the final rule includes numerous provisions that may impact students, institutions, accrediting agencies, and the Federal government. Specifically, the final rule includes provisions related to transfer of credit policies, which may benefit students by making it easier for students to transfer credits to continue their postsecondary enrollment at a new institution. Students will likely benefit from these changes by spending less time and money retaking courses that failed to transfer, whereas institutions may experience costs due to the suspected foregone tuition revenue from transfer students.

The final rule also encourages accrediting agencies to include new criteria that evaluate program and institutional outcomes. This may

impose new costs on accrediting agencies, which may need to develop such criteria, and on institutions, which may need to implement changes to meet such criteria. Furthermore, the final rule will remove several barriers for new accrediting agencies to emerge and obtain Department recognition, which may ultimately benefit accrediting agencies through the reduction in administrative burden to gain initial recognition and maintain recognition. Additionally, the final rule would also require accrediting agencies to adopt several new policies and procedures that aim to increase college affordability and innovation, while also putting downward pressure on credential inflation. Students may benefit from these provisions if the changes result in more affordable and flexible educational opportunities.

As noted in the RIA, the Department does not estimate a significant net budget impact on the title IV, HEA Federal student aid programs from the final rule. In prior regulations¹ the Department estimated the accreditation reform would result in an increased number of applications for recognition due to easier recognition of new accrediting agencies. Increased petitions are also expected given an expanded scope to new credential levels, and the option for alternative standards to allow for faster introduction of innovative programs. In 2019, we did not estimate a significant change in repayment performance as institutions with less favorable program outcomes could find more lenient accrediting agencies. Institutions with strong programs can take advantage of the flexibility allowed by the substantive change policy revisions to expand their program offerings. At the time we noted the uncertainty of the extent to which increasing accreditation options and encouraging program innovation would shift Federal loan and grant volumes among more options for students versus generating new volume, and that uncertainty remains. Additionally, greater acceptance of transfer credits may increase Federal grant and loan volumes by encouraging some students to complete degrees but also may reduce volumes by credits being recognized by the institutions receiving transfers. In retrospect, we know the number of institutions that changed agencies was

fairly low and it is difficult to attribute particular changes in volume to accreditation reforms given other economic, demographic, and programmatic developments during the same period.

II. Purpose of This Regulatory Action

In accordance with Executive Order (E.O.) 14279, this regulatory action realigns the Secretary's criteria for recognition of accrediting agencies to promote high-quality, high value, and affordable education for students that—

- Promotes such academic programs and activities at higher education institutions that are focused on student outcomes and are free from unlawful discrimination and other violations of Federal law;
- Reduces barriers that limit competition, innovation, and new education models that advance credential and degree completion;
- Holds institutions accountable for discrimination and other unlawful acts; and
- Advances academic freedom, intellectual inquiry, and student learning by ensuring that accreditation requires that institutions support and prioritize intellectual diversity among faculty.

III. Background

Section 496 of the Higher Education Act of 1965, as amended (HEA), requires the Secretary of Education (Secretary) to establish criteria for determining whether an accrediting agency is a reliable authority, for purposes of participation in programs authorized under the HEA and other Federal programs, on the quality of education or training offered by the institutions and programs that they accredit. Such criteria are required to include appropriate measures of student achievement.

Consistent with the statute, the Secretary has established regulations for recognition of accrediting agencies at 34 CFR part 602 and has revised these regulations periodically.

E.O. 14279, titled "Reforming Accreditation to Strengthen Higher Education," issued on April 23, 2025, by President Trump, directs the Secretary to take several actions related to the recognition of accrediting agencies or associations by the Department. Some of these actions require changes to existing regulations.

These regulatory changes realign the Secretary's criteria for recognition of accrediting agencies to promote high-quality, high value, and affordable education for students that—

- Promotes such academic programs and activities at higher education institutions that are focused on student outcomes and are free from unlawful discrimination and other violations of Federal law;

- Reduces barriers that limit competition, innovation, and new education models that advance credential and degree completion;
- Holds institutions accountable for discrimination and other unlawful acts; and
- Advances academic freedom, intellectual inquiry, and student learning by ensuring that accrediting agencies review institutional policies in these areas.

Specifically, the Executive Order directs the Secretary to—

- Resume recognition of new accrediting agencies to foster competition and expand institutional options; and
- Mandate that accrediting agencies require member institutions to use data on program-level student outcomes to improve such outcomes, without reference to race, ethnicity, or sex.

The Department undertook this rulemaking in part to address the goals contained within the Executive Order, but also to propose substantive changes that would reform the static and outdated higher education accountability system. The final rule is intended to increase competition among accrediting agencies by reducing barriers to entry, facilitating institutional mobility among recognized agencies, and reducing regulatory requirements that may unnecessarily discourage the formation of innovative accrediting organizations and other related practices. Increased competition is expected to improve institutional responsiveness, reduce accreditation costs over time, and encourage greater innovation in the market for quality assurance validation.

Increasing competition among recognized accrediting agencies is likely to improve the quality, responsiveness, and effectiveness of accreditation. Accreditation has historically seen very little competition because it evolved from voluntary membership peer review groups to set uniform academic standards within those groups. Institutional accrediting agencies rarely engage in head-to-head competition; institutions face difficulty in changing accrediting agencies due to high switching costs and potential risks in maintaining eligibility for Federal student aid for their students; and there are regulatory barriers to the recognition of new agencies. During negotiated rulemaking, the Department explained

¹ Student Assistance General Provisions, The Secretary's Recognition of Accrediting Agencies, The Secretary's Recognition Procedures for State Agencies—84 CFR 58834—<https://www.federalregister.gov/documents/2019/11/01/2019-23129/student-assistance-general-provisions-the-secretarys-recognition-of-accrediting-agencies-the>.

that competition among accrediting agencies is expected to generally improve quality and expand choices for institutions.

Competition creates incentives for agencies to innovate, respond to workforce changes, expand choices for institutions among agencies engaged in various types of innovative activities, and to develop new measures for assessing student success by institutions.

As explained by a Department economist during negotiated rulemaking, there is a high concentration of institutions that are accredited by a handful of institutional accrediting agencies. The Department recognizes that empirical evidence measuring the causal effect of institutions changing accrediting agencies is limited. Because institutions have historically rarely switched agencies, and those that do may differ systematically from those that do not, it is difficult to isolate the independent effect of changing agencies on institutional outcomes. Moreover, previous regulatory barriers have resulted in too few agency switches to permit rigorous statistical analysis. The absence of such evidence, however, does not undermine the broader economic evidence concerning the benefits of competition in quality assurance markets.

Economic research has consistently found that competition encourages innovation and improved performance. Joseph Schumpeter argued that competition produces “creative destruction” that drives innovation by creating new markets that render older ones obsolete, and more recent empirical work has found that introducing competition into concentrated markets substantially increases innovation. The Department believes these findings are relevant because higher education accreditation has historically exhibited many characteristics of an uncompetitive market.

Competition is also expected to improve the informational value of accreditation. During negotiated rulemaking, the Department explained that institutions seek credible signals of educational quality, and that in a competitive accreditation market, agencies would compete to provide those signals. Rather than offering only a binary “approved/not approved” determination, competing accrediting agencies may distinguish themselves by offering scaled ratings for institutional quality. On April 14, 2026, during opening remarks for negotiated

rulemaking, the Assistant Secretary for Postsecondary Education stated:

“Competition will include competition for relevance and universities will signal their quality level through accreditation . . . Current accrediting agencies give universities and colleges pass-fail grades which provide very little useful information.”²

This concern was further underscored in a recent decision letter from the Senior Department Official (SDO) to an accrediting agency, which cautioned that accreditation can devolve into a bureaucratic, “check-the-box” exercise in which meaningful, substantive feedback is replaced by a binary determination of compliance.³ The official emphasized that accreditation should serve as a process that not only assesses compliance with minimum standards but also identifies opportunities for institutions and programs to strengthen their operations and improve educational quality.

This reasoning is consistent with the economic literature on certification intermediaries. In “Information Revelation and Certification Intermediaries”, Alessandro Lizzeri⁴ demonstrates that monopolistic certifiers have incentives to reveal only limited information, whereas competition among certifiers results in more informative quality signals. Similarly, in “The Effect of Information on Product Quality: Evidence from Restaurant Hygiene Grade Cards” Giner Zhe Jin and Phillip Leslie^[4] found that more detailed quality information improves quality outcomes.

A recent paper provides additional support for the Department’s efforts to promote competition among accrediting agencies. Hatfield and Lowery⁵ develop a theoretical model of certification markets, with particular attention to higher education accreditation. They find that monopoly accrediting agencies have incentives to establish inefficiently low-quality standards and impose

institutional requirements unrelated to educational quality. Competition can raise quality standards and reduce such requirements. The authors further demonstrate that entry by an accrediting agency with preferences different from those of incumbent agencies can produce substantially greater improvements in quality and reductions in bias than entry by an otherwise similar agency.

These findings support the Department’s efforts to reduce barriers to entry, facilitate institutions’ ability to change accrediting agencies, and encourage competition among agencies with different approaches to evaluating educational quality. Although the study is theoretical, it provides an economic basis for concluding that greater competition can improve accreditation’s effectiveness in protecting students and taxpayers while preserving institutional autonomy and encouraging innovation.⁶

Competition can also strengthen, rather than weaken, quality of institutions and programs. During negotiated rulemaking, the Department explained that in instances where only one recognized accrediting agency effectively serves a sector, the withdrawal of recognition may significantly disrupt institutions and students, making it more difficult to impose such a penalty. By contrast, when multiple recognized agencies are available, institutions have viable alternatives, reducing barriers to enforcement. As the Department stated during negotiated rulemaking:

“With regional and programmatic monopolies, withdrawal of recognition can throw industries into chaos . . .” If the accreditation market is competitive, institutions can more easily switch accrediting agencies, which reduces incentives to continue the recognition of an agency out of fear of potential adverse fallout in the market.” While some hesitation to withdraw recognition may always be present, the Department believes that the more alternative accrediting agencies are available, the less hesitant the Department will be to derecognize agencies out of worry over market disruption.⁷ The Department believes competition will increase accountability both for institutions and for accrediting agencies themselves.

Finally, competition will encourage innovation in accreditation. Accrediting agencies that face meaningful competition will have stronger

² Opening Remarks—David Barker—Assistant Secretary for the Office of Postsecondary Education—<https://www.ed.gov/media/document/2026-negotiated-rulemaking-aim-transcripts-day-2-am-113991.pdf>

³ Senior Department Official/Secretary’s Decision Letter to the Commission on Massage Therapy Accreditation date October 21, 2026—<https://surveys.ope.ed.gov/erecognition/#/public-documents>

⁴ Alessandro Lizzeri, *Information Revelation and Certification Intermediaries*, The RAND Journal of Economics. Vol. 30, No. 2 (Summer, 1999), pp. 214–231.

⁵ John William Hatfield and Richard Lowery, *Quis Custodiet Ipsos Custodes? Competition, Quality, and Bias in Certification Markets*, Working paper, University of Texas at Austin, October 2, 2026. Available at SSRN: <https://ssrn.com/abstract=7527099>

⁶ *Ibid.*

⁷ Accreditation, Innovation, and Modernization (AIM) Committee—4/14/26 (page 10)—<https://www.ed.gov/media/document/2026-negotiated-rulemaking-aim-transcripts-day-2-am-113991.pdf>.

incentives to develop new approaches to quality assurance, reduce unnecessary costs, respond to institutional diversity, and improve services to institutions and students. As explained in the Department's written responses during negotiated rulemaking, barriers to switching generally reduce competition and increase market power through a lock-in effect. Eliminating or reducing those barriers promotes innovation and responsiveness.

For these reasons, the Department finds that reducing unnecessary barriers to competition among qualified accrediting agencies is likely to improve accreditation over time while preserving the Department's responsibility to establish minimum standards for Federal recognition. The Department does not believe competition will cause a "race to the bottom" but rather, the opposite will likely occur. Recognized accrediting agencies must continue to satisfy all statutory and regulatory recognition requirements, while competing to provide higher quality services, with more informative and innovative quality assurance services. As the Assistant Secretary stated during negotiated rulemaking, "We shouldn't fear healthy competition. It is the basis of a free market economy, and we need more of it in the coddled, protected business of higher education."⁸

IV. Implementation Date of These Regulations

Generally, the regulations included in this document are effective on July 1, 2027. Section 482(c) of the HEA requires that the Department publish final regulations affecting programs under title IV of the HEA in final form by November 1 to be effective for the next award year (July 1 of the calendar year following November 1).

However, the process for recognition of accrediting agencies is multi-year and the implementation of the changes to these regulations in the recognition process will require planning and coordination between Department staff and agencies who are seeking initial recognition or renewal of existing recognition prior to the July 1, 2027, effective date.

The Department is providing the following additional clarification of the implementation timeline:

For recognized agencies that submitted their applications for renewal of recognition prior to July 1, 2026, Department staff have been reviewing

the applications under the regulations that were in place prior to the promulgation of these regulations. The agencies will have an opportunity to respond to the draft staff report when completed. After receiving a response from the agency on the draft staff report, the Department will present its final staff report on each application to the Advisory Committee at the 2027 meetings and proposed first meeting of 2028, which will be based on compliance with the regulations that were in effect prior to the promulgation of these regulations.

For agencies seeking initial recognition that submitted their application for recognition after July 1, 2026, those agencies must submit applications for review based on adherence to the requirements in these revised regulations.

Additionally, Section 482(c)(2) permits the Secretary to designate any regulatory provision as one that an entity subject to the regulations may choose to implement earlier and the conditions for early implementation. To facilitate the implementation of these final regulations, the Secretary is designating all sections of this regulation for early implementation beginning on January 1, 2027, provided that accrediting agencies that decide to adopt any new provisions prior to July 1, 2027, do not impose new requirements on institutions or programs resulting from that early implementation that would take effect prior to July 1, 2027.

Because compliance with these regulations may require accrediting agencies to make substantive revisions to their policies and procedures, which may necessitate stakeholder notice and comment periods and formal adoption by an authorized decision-making body, as well as training for agency staff and peer reviewers responsible for implementing the new requirements, accrediting agencies are strongly encouraged to initiate the necessary revisions and training promptly to ensure compliance with the new requirements by the applicable effective dates set forth herein.

V. Authority for the Regulatory Action

The authority for this rulemaking is Section 496 of the HEA. Section 496(a) of the HEA provides criteria that an accrediting agency must meet for the Secretary to recognize it as a reliable authority as to the quality of education or training offered. The same section states that the Secretary shall, after notice and opportunity for a hearing, establish criteria for such determinations.

Section 496(o) of the HEA directs the Secretary to establish, through regulation, procedures governing the recognition of accrediting agencies and the appeal of recognition decisions. At the same time, Congress provided that the Secretary shall not promulgate regulations with respect to the standards of an accrediting agency described in Section 496(a)(5). The Department interprets these provisions together to mean that the Secretary may establish recognition criteria governing whether an accrediting agency functions as a reliable authority under Section 496, while leaving accrediting agencies the responsibility for developing and applying their own substantive accreditation standards. Accordingly, these regulations establish the criteria the Secretary will use in determining whether an accrediting agency qualifies for Federal recognition. Except where expressly required by statute, the regulations do not prescribe the substantive content of accreditation standards, but instead establish minimum expectations regarding the processes, consistency, transparency, and lawful administration of those standards.

The Department has also reviewed existing regulations considering Section 496(o). Where current regulations prescribe requirements that extend beyond recognition procedures and instead direct the content or administration of accrediting standards without a clear statutory basis, the Department removes or simplifies those requirements to better align the regulations with Congressional direction and remove administrative burden.

Severability

"It is axiomatic" that a regulation may be invalid in part but not in whole or as applied to one set of facts but not another. *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 329 (2006). If a court finds one part of a regulation is unlawful, the "normal rule" is to enjoin only that part. *Id.* (quoting *Brockett v. Spokane Arcades, Inc.*, 472 U.S. 491, 504 (1985)).

It is the Department's intent that if any provision of this subpart or its application to any person, act, or practice is held invalid, the remainder of the subpart or the application of its provisions to any person, act, or practice shall not be affected thereby.

Statutes and regulations are severable if the separate provisions are "wholly independent of each other" and can operate independently. *Brockett v. Spokane Arcades, Inc.*, 472 U.S. 491, 502 (1985). That is the case here. No part herein will be affected if another

⁸ Accreditation, Innovation, and Modernization (AIM Committee)—4/14/26 (page 10)—<https://www.ed.gov/media/document/2026-negotiated-rulemaking-aim-transcripts-day-2-am-113991.pdf>.

part is found to be unlawful. Nor does the Department believe courts or regulated parties would be unable to apply the rule if one part is held invalid. *Cf. Dep't of Educ. v. Louisiana*, 603 U.S. 866, 868 (2024) (per curiam) (denying the government's request to stay a preliminary injunction against an entire rule where only parts were found to be invalid because "schools would face in determining how to apply the rule for a temporary period with some provisions in effect and some enjoined").

VI. Analysis of Public Comments and Changes

On August 20, 2026, the Secretary published a Notice of Proposed Rulemaking (NPRM) for these regulations in the **Federal Register** (91 FR 53940). The Department received 7,051 comments on the proposed regulations. The Department has grouped the comments by functional topics and by similar themes. We discuss substantive issues under the sections of the regulations to which they pertain. In instances where individual submissions appeared to be duplicates or near-duplicates of comments prepared as part of a write-in campaign, the Department posted one representative sample comment along with the total comment count for that campaign to www.Regulations.gov, which continues to be our standard practice. We considered these comments along with all the other comments received. In instances where individual submissions were bundled together (submitted as a single document or packaged together), the Department posted all the substantive comments included in the submissions along with the total comment count for that document or package to www.Regulations.gov. Generally, we do not address minor, non-substantive changes (such as renumbering paragraphs, adding a word, or typographical errors) within this final rule. Additionally, we generally do not address changes or comments recommended by commenters that the statute does not authorize the Secretary to make (such as forgiving all student loans), or comments pertaining to operational processes. Analysis of the comments and of any changes in the regulations since publication of the NPRM (91 FR 53940) follows.

Process for Out-of-Scope Comments

The Department does not typically address comments that are out-of-scope. For purposes of this final rule, out-of-scope comments are those that are not addressed in the NPRM (91 FR 53940) altogether. Generally, comments that are

outside of the scope of the NPRM (91 FR 53940) are comments that do not discuss the content or impact of the proposed regulations or the Department's evidence or reasons for the proposed regulations.

Technical Corrections

The Department made no substantive changes to the final rule, retaining the text agreed upon by the negotiated rulemaking committee and proposed in the NPRM. The Department made the following minor, non-substantive technical edits to improve clarity of the regulation.

602.2(b)—How do I know which agencies the Secretary recognizes?

Discussion: The Department is correcting a reference for clarity and to conform with regulatory drafting standards. The reference previously read "published in the **Federal Register** pursuant to subsection (a) of this section," and we are changing it to refer to "paragraph (a) of this section."

Changes: The Department updated paragraph (b) of this section to read as follows after the words "**Federal Register**": ". . . pursuant to paragraph (a) of this section."

§ 602.3—Definition of "Designated Federal Official"

Discussion: The Department is correcting a reference that appears in the definition of *Designated Federal Official*. That definition previously referenced section 10(f) of the Federal Advisory Committee Act, which was repealed by Section 7 of Public Law 117–286. This section, among several others, was moved to a different section of 5 U.S.C. Chapter 10. The correct reference should be 5 U.S.C. 1009(e).

Changes: The Department updated the definition of *Designated Federal Official* to read: "*Designated Federal Official* means the Federal officer designated under 5 U.S.C. 1009(e)."

§ 602.3—Definition of "Related, Associated, or Affiliated Trade Association"

Discussion: The Department must update the capitalization of the word that begins each new paragraph under in the definition of *Related, associated, or affiliated trade association* with a capital letter to conform with regulatory drafting standards.

Changes: We updated the definition to read as follows: "*Related, associated, or affiliated trade association* means an organization that:

(i) Is generally a membership organization;

(ii) Is organized to promote a line of commerce, business, industry, or profession;

(iii) Does not engage in a regular business of a kind ordinarily carried on for profit, and no part of the net earnings of which inures to the benefit of any member; and

(iv) Is related to a particular accrediting agency in that the agency accredits institutions or programs that prepare students to enter the workforce of the same or substantially the same line of commerce, business, industry, or profession that organization promotes."

§ 602.3—Definition of "Representative of the Public"

Discussion: The Department must update the Arabic numerals to Roman numerals in the definition of *Representative of the public* to conform with regulatory drafting standards.

Changes: We have renumbered the definition to read as follows:

"*Representative of the public* means a person who is not—

"(i) An employee, member of the governing board, owner, or shareholder of, or consultant to, an institution or program that either is accredited or preaccredited by the agency or has applied for accreditation or preaccreditation;

(ii) A member of any trade association or membership organization related to, associated with, or affiliated with the agency; or

(iii) A spouse, parent, child, or sibling of an individual identified in paragraph (i) or (ii) of this definition."

§ 602.15(d)—Administrative and Fiscal Responsibilities

Discussion: The Department clarifies that the requirements of the paragraph are only in reference to "recognized" agencies.

Changes: The Department updated § 602.15(d) to read: "The agency will cooperate with other recognized agencies and the Department in the development of common templates and forms for institutions or programs to submit when seeking to change accrediting agencies."

§ 602.17(a)(1)(vii)(C), (a)(3) and (a)(3)(i)—Application of Standards in Reaching Accreditation Decisions

Discussion: The Department must update incorrect cross references under § 602.17(a)(1)(vii)(C).

Changes: The Department updated § 602.17(a)(1)(vii)(C) to read: "(C) In the case of a private institution, policies that if established guarantee the same or similar protections as those described in subsections (A) and (B) above."

Discussion: The Department must update the cross reference in § 602.17(a)(3) from (vi) to (v) because we intended to cross reference fiscal and administrative capacity instead of student support services. We also updated § 602.17(a)(3)(i) to add a verb with the stem and clarify who must complete the cost/benefit analysis.

Changes: The Department updated the provisions under § 602.17(a)(3) and (a)(3)(i) to read:

“(3) When applying its standards according to § 602.16(a)(1)(iv) and (v), conducts:

(i) A review of any cost/benefit analysis performed by an institution. Cost/benefit analysis means a review by the agency of the institution’s budget, resource utilization and allocation, and, if existing, its business/strategic plan, continuous improvement strategic plan, and review of whether the institution considers whether the expected benefits of the institution’s activities justify the associated financial, administrative, and opportunity costs and the impact of capital expenditures on future operating expenses;”

§ 602.21 *Review of Standards*

Discussion: The Department must remove the word “is” before “relevant” because the word “is” was inadvertently published in the NPRM.

Changes: The Department updated § 602.21 to read:

“The agency must maintain a comprehensive systematic program of review that occurs at regular intervals, involves all relevant constituencies (including students), and that demonstrates that its standards are adequate to evaluate the quality of the education or training provided by the institutions and programs it accredits and relevant to the educational or training needs of students.”

§ 602.22(a)(1)(ii)(H)—*Substantive Changes and Other Reporting Requirements*

Discussion: The Department must italicize the Arabic numerals after paragraph § 602.22(a)(1)(ii)(H) to conform with regulatory drafting standards.

Changes: The text will now appear as: “(1) Academic control by the institution.

(2) The institution has adequate faculty, facilities, resources, and academic and student support systems in place.

(3) The institution is financially stable.

(4) The institution had appropriate planning for the addition.”

§ 602.23(l)—*Operating Procedures All Agencies Must Have*

Discussion: The Department must update § 602.23(l) (1) and (2) so that the word “or” appears after § 602.23(l)(2) because agencies have the option to choose one of the three structured mechanisms for individuals to communicate directly with an agency.

Changes: The Department updated the paragraph to read:

“(l) The agency must establish and maintain at least one structured mechanism through which currently enrolled students, employed staff, and employed faculty of accredited or preaccredited institutions or programs may communicate directly with the agency concerns related to the agency’s accreditation standards or the institution’s or program’s compliance therewith. Such mechanism(s) must be designed to ensure that information received is substantive and manageable in volume. Permissible mechanisms include, but are not limited to, any one or more of the following:

(1) A registration process through which students, staff, or faculty may sign up to participate in structured meetings with agency representatives during scheduled site visits or virtual visits, subject to reasonable limits on the number of participants and appointment availability;

(2) Randomized panels of students, staff, or faculty selected by the accrediting agency or its authorized representatives to participate in confidential interviews or focus groups during site visits, conducted in a manner that ensures a representative cross-section of the institutional community; or

(3) Student, faculty, and staff surveys independently administered by the agency as part of an initial or renewal of accreditation process which minimally address the standards areas required by § 602.16(a).”

§ 602.24(d)—*Additional Procedures Certain Institutional Agencies Must Have*

Discussion: The Department must update the Roman numerals to Arabic numerals to conform with regulatory drafting standards. We must also update § 602.24(d)(2) to ensure there are no institutions identified in any teach-out plan.

Changes: The Department updated (d) to read:

“(d) *Closed institution.* If an institution the agency accredits or preaccredits closes without a teach-out plan, the agency must work with the Department and the appropriate State

agency, to the extent feasible, to assist students in finding reasonable opportunities to complete their education without additional charges, including by—

(1) Working with institutions to secure teach-out agreements; or

(2) Where a teach-out agreement cannot be arranged, working with institutions to secure transfer options;

(3) Making teach-out or transfer options, the terms of such options, and information on obtaining transcripts, loan discharges, and reimbursement publicly available on the agency’s website; and

(4) Sharing such information with appropriate State agencies and, as applicable, with other recognized accrediting agencies.”

§ 602.27 *Other Information an Agency Must Provide Department*

Discussion: The Department must update the title of this section to correct a typographical error by adding “the” after the word “provide” in the amendatory language.

Changes: We updated the title of this section to:

“§ 602.27 Other information an agency must provide the Department.”

§ 602.30(a)(3)—*Agency Applications and Reports To Be Submitted to the Department*

Discussion: For consistency with § 602.16(d), we must add “direct assessment education” to § 602.30(a)(3).

Changes: The Department updated § 602.30(a)(3) to read:

“(3) Documentation of how an agency that includes or seeks to include distance education, correspondence courses, or direct assessment education in its scope of recognition applies its standards in evaluating programs and institutions it accredits that offer distance education, correspondence courses or direct assessment education.”

§ 602.31(a)(3) and (a)(7)—*Procedures for Submitting Applications for Recognition and Renewal of Recognition*

Discussion: We must add “. . . the Secretary determines that . . .” to § 602.31(a)(3) for consistency with the other provisions in that section. We also must add § 602.31(a)(7) to clearly state the type of application required for agencies seeking initial recognition.

Changes: We updated § 602.31(a)(3) to read:

“(3) If the Secretary determines that an agency or its officers or directors have been the subject of legal actions, complaints, or other compliance issues that individually or in the aggregate raise substantial concerns regarding the

agency's compliance with this part, the agency must submit a comprehensive application that addresses the agency's compliance with all criteria in subpart B of this part."

We updated § 602.31(a)(7) to read:

"(7) An agency submitting an application for initial recognition must submit a comprehensive application that addresses the agency's compliance with all criteria in subpart B of this part."

§ 602.31(b)(2)—Procedures for Submitting Applications for Recognition and Renewal of Recognition

Discussion: The proposed text included an unclear reference to "subparagraph (1)." We have revised the reference to be more specific and refer to paragraph (b)(1) of the same section.

Changes: We updated § 602.36(d) to read:

"(2) Within 10 business days after publication of the notice described in paragraph (b)(1) of this section, the agency must publish the request for information on the agency's website to include instructions on how the public can submit information in response to the request."

§ 602.36(d) Senior Department Official's Decision

Discussion: The Department must amend § 602.36(d) by replacing "of" in the current paragraph with ". . ." following the publication of transcripts of . . ." to match the change made to § 602.35(a).

Changes: The Department updated § 602.36(d) to read:

"(d) Except with respect to decisions made under paragraph (f) or (g) of this section and matters referred to the senior Department official under § 602.37(e) or (f), the senior Department official notifies the agency in writing of the senior Department official's decision regarding the agency's recognition within 90 days following the publication of transcripts of the Advisory Committee meeting or conclusion of the review under paragraph (b) of this section."

Directed Question

§ 602.15—Administrative and Fiscal Responsibilities

The Department sought feedback about the extent to which the "conflict of interest" requirements impact accrediting agencies in relation to 401K plans, health insurance, and other areas. We understood that there may be some agencies who utilize the same resources as their related, associated, or affiliated trade association in these certain areas, and that there may be some

consideration to the amount of time and resources it would take to unwind the sharing of resources in such instances.

Comments: Some commenters stated that for a programmatic accrediting agency, they believed that requiring independent human resources and benefits administration, IT infrastructure, legal and finance support, marketing, and standalone facilities within the one-year timeline would be challenging. Some of these agencies believed that these changes would result in costs that agencies would pass on to institutions through higher accreditation fees to programs. Commenters argued their belief that the proposed regulation directly undercuts the rule's own goal of reducing regulatory burden and cost under § 602.15(c). The two main suggestions for provisions under § 602.14 and § 602.15 on separate and independent requirements were: (1) rescind the amendments to the regulations or (2) provide more time to comply with the requirements. For a full list of recommendations, please see the discussions under § 602.14 and § 602.15.

Discussion: The Department disagrees with the recommendations. The Department's phase-in of the final rule for applications for initial and renewed recognition that were submitted during the transition period of the final rule will provide agencies approximately 20 months, through July 1, 2028, to make the necessary changes to comply with the regulations. If an agency is unable to comply by that date due to existing lease obligations, it may contact the Department to provide specific details regarding its circumstances. The Department may consider an agency's demonstrated, substantive progress toward achieving full compliance within a reasonable timeframe when determining whether to maintain its recognition status. Such progress must be supported by objective, verifiable evidence of concrete actions taken and measurable progress toward compliance, rather than statements of intent or unsupported assurances. The Department may require the agency to submit periodic reports and supporting documentation to assess its progress and determine whether the agency is on track to achieve full compliance within the applicable timeframe.

Changes: None.

Regulatory Impact Analysis—Data Constraints

The Department recognizes that there is limited data available to estimate the proposed regulation's potential impact on accrediting agencies, institutions,

programs, and students. Due to the scarcity of existing information, the Department invited public feedback on possible methods and data sources that could further strengthen the analysis presented in the RIA.

Comments: Several commenters urged the Department to withdraw the proposal because the commenters believed that the Directed Question in the NPRM conceded that the Department lacks empirical data on the effects of these changes.

Discussion: The Department disagrees with commenters' assertion that its solicitation of public feedback to strengthen the RIA demonstrates a lack of empirical data to support the proposed changes. This assertion misconstrues the purpose of the Department's request for feedback, which is intended to ensure that its analysis is informed by the best available information and evidence. Seeking public input is a means of strengthening the analytical basis for informed policymaking, not an indication that the analysis lacks an adequate evidentiary foundation. In response to some commenters' feedback, the Department has supplemented the RIA with additional information to further support the proposed changes. This includes additional estimates for changes in title IV student aid disbursements that result from credit transfer policies and an increase in innovative and flexible educational models.

Changes: None.

General Comments

Comments: Several commenters requested phased implementation to allow them time to develop systems to implement these changes.

Discussion: Except as otherwise noted, the regulations will not be effective until July 1, 2027. We believe that the eight months between November 2026 and July 2027 is sufficient time to update standards, policies, and procedures to achieve compliance by the established deadline. Further, the Department has noted implications for specific provisions of the regulations under the *Implementation Date of These Regulations* section.

Changes: None.

Comments: Some commenters requested that the Department publish subregulatory guidance quickly after the final rule is published. For example, one commenter requested a prioritized list of items the Department intends to finalize as guidance, a data-access roadmap that describes how program-level outcomes, licensure data,

assessment scores, and unemployment insurance (UI) wage records may be securely obtained and used, model templates for agency petitions, confidentiality markings, and remediation/transition plans to reduce burden and increase consistency, and an interagency/State liaison process for expedited sharing of restricted outcomes data and coordinated teach-out/closure responses.

Discussion: The Department recognizes that institutions, accrediting agencies, States, and other stakeholders may benefit from additional information regarding implementation of the final rule. The Department has a long-standing practice of providing technical assistance, guidance, and other informational resources, as appropriate, to facilitate compliance with regulatory requirements. However, the Department declines to commit to issuing specific guidance documents, model templates, roadmaps, timelines, or interagency coordination procedures within a prescribed timeframe.

Changes: None.

Comments: Several commenters stated that before finalizing these amendments, the Department should state, for each regulatory change, the specific problem it addresses, provide evidence of the problem, and then state the results it is expected to produce. One commenter also stated that the final rule should establish a transparent post-implementation review, using a pre-rule baseline and reporting results at defined intervals, including an initial review within 24 months and a fuller review within five years.

Discussion: The Department has explained the reasons for the regulatory changes in the NPRM and further elaborates on these here. We also decline to regulate the Secretary in a way that would require the Secretary to release reports not required under the law.

Changes: None.

Comments: Several commenters argued that the negotiated rulemaking committee did not reflect a good-faith effort to represent all significantly affected interests. Some commenters believed that the committee was overly partisan. Other commenters believe that the committee lacked faculty members and other negotiators with specialized expertise needed to fully understand and address the complexities of the proposal. A few commenters stated that the nine-day negotiated rulemaking and 30-day comment periods were too short to gather substantive feedback from stakeholders.

Discussion: The Department firmly disagrees with the assertion that the

negotiated rulemaking process lacked good-faith efforts or the expertise necessary to adequately consider the issues. Consistent with the requirements of Section 492 of the HEA, the Department convened a negotiated rulemaking committee comprising representatives from a broad range of stakeholder groups reflecting the diverse sectors and interests within higher education. The Department believes that the committee benefited from the varied perspectives and expertise of representatives of institutions of higher education, students, institutional and programmatic accrediting agencies, State officials, and other stakeholders with substantial experience in accreditation policies and practices and related matters. The process was conducted to facilitate meaningful deliberation among stakeholders with relevant experience and expertise, and the Department rejects any characterization that disregards those efforts or the substance of the committee's work. In addition to information provided during negotiated rulemaking sessions, the Department considered stakeholder input received throughout the months-long rulemaking process, including comments submitted in response to the proposed regulations.

Prior to (public hearings), during (negotiators), and after rulemaking (public comment period), the Department has heard from thousands of stakeholders on the proposals. We believe we have afforded the public a substantial opportunity for meaningful input.

Changes: None.

Comments: One commenter opined that accreditation of local law schools should be left to the States in which the schools reside, and their licensing boards of higher education.

Discussion: The Department agrees that this could be an acceptable alternative. One goal of the final rule is to encourage new, innovative accrediting agencies to seek recognition from the Department, which should increase competition and quality of agencies. However, the Department is unable to independently foster new competition, as it requires action from new and nascent accrediting agencies.

Changes: None.

Comments: One commenter stated that the final rule should ensure that nothing in Part 602 leads accrediting agencies to penalize institutions whose assessment models assume super intelligence (SI) availability and measure human contribution directly.⁹

Discussion: Regulating the use of SI, or any other forms of data analysis and automation, in educational assessment goes beyond the scope of this final rule. Agencies are required to establish standards based on § 602.16 and apply them based on § 602.17. Nothing in this rule explicitly or implicitly prohibits use of SI or other tools available to the agency in carrying out these requirements.

Changes: None.

Comments: One commenter recommended that the Department require accrediting agencies to evaluate whether institutions maintain and consistently apply:

- Clear, publicly available academic appeal procedures;
- Timely student access to the records and evidence relied upon before an appeal is decided;
- Written, evidence-based reasons for final decisions;
- Conflict-of-interest protections and recusal procedures for decision-makers;
- An escalation or independent-review mechanism when the accuracy, completeness, or reliability of the underlying student record is disputed; and
- Public reporting of aggregate appeal outcomes and corrective actions, while protecting student privacy.

Discussion: While accrediting agencies have significant discretion to establish requirements for the institutions and programs that they accredit, the Department believes that the changes proposed by the commenter are not authorized by the statute.

Changes: None.

Comments: One commenter recommended that the final rule or accompanying guidance expressly identify Registered Apprenticeship as a workforce model that programmatic accrediting agencies should be prepared to evaluate under the proposed rule.

Discussion: While the Department strongly supports Registered Apprenticeships and has taken steps to remove barriers and otherwise facilitate the integration of this and other “learn and earn” models with the Federal student aid programs and other Department programs, we recognize the considerable oversight and evaluation of Registered Apprenticeships that is already conducted by the Department of Labor and State apprenticeship agencies. Moreover, Registered Apprenticeships are just one of many models currently being used for workforce development and education programs, and the Department does not

⁹ Pursuant to Executive Order 14434, 91 FR 63129 (Oct. 2, 2026), this document uses the term “Super

Intelligence” or “SI” instead of “Artificial Intelligence” or “AI.”

believe it is necessary at this time to reference any particular model in these regulations.

Changes: None.

Comments: One commenter recommended that the final rule require ongoing evaluation of unintended consequences. The commenter suggested the establishment of mechanisms for monitoring whether the reforms produce ideological sorting, strategic behavior, conflicts of interest, reduced educational diversity, or other unintended effects are needed.

Discussion: The Department believes the final rule is well-targeted and likely to achieve their desired objectives. The Department is constantly monitoring its policies and regulations and the changing environment in which they are applied. The final rule is the direct result of evaluating current regulations that amend both long-standing regulations and more recent changes.

Changes: None.

Comments: One commenter asked the Department to ensure explicit reference to “Tribal law” and “Tribal governments” in regulations and to clarify the final rule to recognize the incorporation of Tribal languages and culture within Tribal colleges or universities.

Discussion: The major reforms in these regulations—improving educational quality, protecting students and taxpayers, and ensuring recognized accrediting agencies support innovation, accountability, and legal compliance—apply to all accrediting agencies and the institutions and programs they accredit, including Tribal colleges or universities. The regulations already address issues of institutional mission and legal compliance, but the Department reserves the ability to issue subregulatory guidance as necessary to address specific matters of legal compliance that may arise.

Changes: None.

Comments: Another commenter stressed that the Department should require recognized agencies to disclose meaningful information concerning governance, finances, decision making, institutional reviews, appeals, peer review practices, conflicts of interest, accreditation outcomes, and measures of the accrediting agency’s own effectiveness.

Discussion: The Department acknowledges the need for additional agency transparency and has taken a number of steps in this final rule to increase disclosure and transparency and address conflicts of interest. Additionally, these regulations establish a new framework for improved and more thorough oversight of the

recognized accrediting agencies that serve as the primary gatekeepers for the Federal student aid programs.

Changes: None.

Comments: One commenter recommended that the Department requires programmatic accrediting agencies in licensed professions where practitioners exercise direct professional judgment affecting public welfare—such as social work, nursing, and counseling—to collect and publicly report student outcome data, including licensure examination pass rates by program.

Discussion: The Department acknowledges the value of student outcome data, particularly licensure pass rates, but notes that such data is already available through the state licensure process, and many accrediting agencies have licensure pass rate data and disclose that data for the programs that they accredit.

Changes: None.

Comments: One commenter stressed that the Department should evaluate downstream impacts on licensure portability and public protection.

Discussion: The Department believes we have adequate regulations regarding licensure under § 602.16(a)(1), § 602.16(g)(3), § 602.17(a)(1), and § 602.20(i)(1).

Changes: None.

General Agreement With the Regulations

Comments: Some commenters offered general support for the proposed rule. These commenters stated that the rule will increase competition among accrediting agencies, which will eliminate violations of antitrust laws, credential inflation, and increased costs for taxpayers and students alike. Commenters championed the Department’s efforts to focus on student achievement and outcomes, improve credit transfer to increase educational mobility, and reduce unnecessary administrative burdens. Commenters’ testimonials included:

- “The Department’s August 20, 2026 proposed rule is a necessary and potentially transformative correction to an accreditation system that has too often rewarded institutional conformity instead of measurable educational value.”

- “Accrediting agencies have often played a role in credential inflation. Programmatic accrediting agencies may add mandates that make it more expensive to operate a particular program, the costs of which are passed on to students through higher tuition prices.”

- “Competition among accrediting agencies can preserve a common safety floor while allowing different educational methods to prove themselves.”

- “Accrediting agencies should focus on whether schools are providing students with a quality education and helping them succeed. They should not be requiring schools to follow certain beliefs or practices that may be discriminatory or unrelated to the quality of education students receive. I support the Department’s proposal to make sure accreditation decisions are fair, strengthen oversight, and focus more on student outcomes.”

- “Accreditation should provide meaningful assurance of educational quality without encouraging institutions to become more alike simply because uniformity is easier to measure. A regulatory framework that combines rigorous accountability with genuine institutional differentiation will better serve students, institutions, and the public.”

- “The Problem: The current system focuses on bureaucratic processes rather than actual student outcomes like learning, graduation rates, employment, and loan repayment. The Solution: The proposed rule holds institutions accountable by enforcing state and Federal laws, setting minimum student performance standards, and measuring real-world outcomes. This reform is critical to fixing a broken system and restoring accountability to American higher education.”

- “. . . despite their immense power over institutions of higher education, accreditation agencies fail to ensure academic quality, operate like a monopoly, lack transparency, and stifle new and innovative educational models.”

Discussion: The Department thanks commenters for their support. We agree that the final rule will reduce burden on agencies and their accredited institutions and programs by eliminating requirements not required by statute, focus on educational quality with increased accountability on agencies, and ensure that the standards and policies of agencies do not violate Federal or State law.

Changes: None.

General Opposition to the Regulations

Comments: Some commenters opposed the proposed rule and urged the Department to withdraw or substantially revise the proposed rule. Commenters were concerned that these regulations will shift academic and financial judgments from institutions and accrediting agencies to the Federal

government and argue that educational quality, affordability, and accountability will suffer as a result. Commenters argued that the final rule would allow the Department to indirectly withhold Federal student financial assistance, either by requiring accrediting agencies to end accreditation or by ending recognition for the institution's accrediting agency, when institutions are under investigation for a variety of issues such as interpretations of civil rights laws or political and ideological disputes.

Discussion: The Department disagrees with these perspectives and notes that the final rule does not replace institutional or agency discretion or judgment nor does it politicize the recognition process for accrediting agencies. Rather, in issuing this final rule, the Department is strengthening transparency of agencies and the institutions and programs they accredit and improving consistency and student protections across institutions and programs. The final rule preserves the core role of accrediting agencies in setting standards for and evaluating academic quality. Nothing in the final rule authorizes the Department to impose Federal viewpoints on agency or institutional decision-making. The final rule properly sets certain baseline expectations for recognition of agencies by the Department as reliable authorities on educational quality, such as protections for students during disruptions of educational services and consistent treatment of transfer credits when students change institutions or advance to higher levels, which are essential to safeguarding the integrity of the Federal student aid programs and ensuring accountability to taxpayers.

Changes: None.

Comments: A few commenters expressed concerns for programs serving students in prison education programs. The commenters stressed the proposed rules could lead to politically motivated State action against a prison education or post-incarceration reentry program and could trigger a fast-tracked accreditation review, giving State actors a new lever to pressure programs they find objectionable.

Discussion: The Department maintains that all students, including those who are incarcerated, deserve increased accrediting agency oversight and will benefit from reinforcement of the existing legal, constitutional, civil rights, and consumer protection obligations already required of recognized accrediting agencies and the institutions and programs that they accredit.

Changes: None

Legal Authority

Comments: Some commenters did not believe the Department has the statutory authority to regulate in several areas of this final rule, including the amendments under § 602.13 that add regulations on antitrust law; § 602.14 and § 602.15 that amend requirements on conflicts of interest; § 602.17 that amends the application of standards in reaching accreditation decisions, including student achievement standards and agency requirements on the application of civil rights law; § 602.23 that amends regulations on operating procedures all agencies must have; and § 602.24 that amends requirements for credit transfers.

Commenters often cited several statutory provisions to support their claims. Commenters stated Section 496(a)(5) of the HEA prescribes the specific standards for accreditation. Some commenters believe that the Department has added new standards that do not currently exist in statute. Commenters also cited Section 496(g) of the HEA as Congressional intent on the limitation of the Department's authority to establish additional standards: "Nothing in this Act shall be construed to permit the Secretary to establish criteria for accrediting agencies or associations that are not required by this section. Nothing in this Act shall be construed to prohibit or limit any accrediting agency or association from adopting additional standards not provided for in this section. Nothing in this section shall be construed to permit the Secretary to establish any criteria that specifies, defines, or prescribes the standards that accrediting agencies or associations shall use to assess any institution's success with respect to student achievement". Commenters cited Section 496(o) that states the Secretary "shall not promulgate any regulation with respect to the standards of an accrediting agency or association described in subsection (a)(5)".

Finally, commenters cited Section 103 of the Department of Education Organization Act as evidence of Congressional intent on the limits of the Department's authority: "No provision of a program administered by the Secretary or by any other officer of the Department shall be construed to authorize the Secretary or any such officer to exercise any direction, supervision, or control over the curriculum, program of instruction, administration, or personnel of any educational institution, school, or school system, over any accrediting agency or association, or over the selection or content of library resources,

textbooks, or other instructional materials by any educational institution or school system, except to the extent authorized by law".

Discussion: The Department disagrees with these commenters. The Secretary has express authority to "by regulation provide procedures for the recognition of accrediting agencies or associations and for the appeal of the Secretary's decisions," 20 U.S.C. 1099b(o), and to "establish criteria" through notice-and-comment rulemaking to determine whether an agency is a "reliable authority as to the quality of education or training," 20 U.S.C. 1099b(a). Thus, Congress expressly directed the Secretary to establish criteria for determining whether an agency is a reliable authority of the quality of education and training of the institutions and programs that it accredits. Congress narrowly limited the Secretary's authority in this area is prohibiting "promulgat[ing] any regulation with respect to the standards of an accreditation agency or association described in subsection (a)(5)." 20 U.S.C. 1099b(o).

The limitation in this section only means that the Department cannot add to the standards enumerated in subsection (a)(5). However, the Secretary is not prohibited from establishing the criteria used by the Department to determine whether an agency's standards, including those described in subsection (a)(5), comply with the statute and regulations.

The Department is not requiring any agency to adopt any requirements as standards. Instead, these regulations inform how the Department will assess whether the standards an agency has adopted are adequate to show that the agency is a reliable authority on institutional quality.

Changes: None.

Comments: Some commenters questioned the Department's authority to make many of the changes proposed to § 602.17. These commenters believe that the Department added new requirements to § 602.17 in contravention of express statutory prohibitions. Specifically, the commenters pointed to Section 496(g) of the HEA (20 U.S.C. 1099b(g)), 20 U.S.C. 1099b(o), and Section 103 of the Department of Education Organization Act. While many of the commenters were skeptical of the Department's authority to add any of the new requirements in § 602.17, many focused especially on the inclusion of student achievement, academic freedom, and cost-benefit analysis.

Discussion: The Department disagrees with these commenters. The Secretary

has express authority to “by regulation provide procedures for the recognition of accrediting agencies or associations and for the appeal of the Secretary’s decisions,”

20 U.S.C. 1099b(o), and to “establish criteria” through notice-and-comment rulemaking to determine whether an agency is a “reliable authority as to the quality of education or training,” 20 U.S.C. 1099b(a). Thereby, Congress has commanded the Secretary to establish criteria by which the Secretary will determine whether an agency is a reliable authority of institutional quality. Congress limited the Secretary’s authority in this area by prohibiting the Secretary from “promulgat[ing] any regulation with respect to the standards of an accreditation agency or association described in subsection (a)(5).” 20 U.S.C. 1099b(o).

The Department believes the best reading of this section is that the Department cannot add to the standards listed in subsection (a)(5). But, given the express command to establish criteria by which the Secretary will determine whether an agency is a reliable authority of institutional quality, the Secretary is not prohibited from explaining the criteria that the Secretary will use to determine whether an agency’s subsection (a)(5) standards are effectively applied and enforced.

This is what the Department has done in Section 602.17. Section 602.17 does not add to the standards an agency must consider when assessing an institution’s faculty, for example. Rather, these are the criteria the Department will use to determine whether an agency has effective subsection (a)(5) standards.

This interpretation is further supported by Section 496(a)(4)(A) of the HEA, which expressly requires accrediting agencies to consistently apply and enforce their standards, and section 496(n), which requires the Secretary to conduct a comprehensive and independent evaluation of accrediting agencies. These provisions authorize the Department to evaluate not only whether agencies have adopted standards, but also how those standards are applied and enforced. The requirements in § 602.17 implement these statutory responsibilities without prescribing the substantive content of accreditation standards. This distinction rests on the substance of the requirements, not merely their placement in the regulations.

To the extent the commenters believe that the Department is adding standards to Section 602.16, they are mistaken. While the Department’s initial discussion draft prior to negotiated rulemaking included proposed changes

to 602.16, the Department heard from several negotiators that the changes being sought were focused on the application of standards rather than changing the content of the standards themselves. Instead, these amendments inform how the Department will assess whether the standards an agency has adopted are adequate to show that the agency is a reliable authority on institutional quality. The negotiated rulemaking committee extensively discussed and ultimately reached consensus on changes to Section 602.17 to address how the Department determines whether agencies have effective mechanisms for evaluating compliance with its standards. The changes that were agreed upon by the negotiated rulemaking committee were proposed by the Department in the NPRM. These changes make only clarifying and technical changes to the requirements for standards in 602.16 and amend the evaluative criteria in 602.17 for the agency’s application of standards in reaching accreditation decisions, which are designed for the Department to determine whether an agency is a reliable authority of educational quality for purposes of the HEA and other Federal purposes.

Changes: None.

Comments: Other commenters stated that the Department lacks authority to promulgate Section 602.14. In particular, the commenters argued that the Department could not apply the separate and independent requirement to programmatic accrediting agencies who do not serve as title IV gatekeepers. One commenter stated that the HEA was amended more than 30 years ago (Public Law 103–208) to make clear that “separation was not required for accrediting bodies with no title IV purpose.” The commenter stated that contemporaneous legislative history reinforces this point, because a US Representative, in introducing the Higher Education Technical Amendments of 1993, stated that: “. . . membership organizations requested clarification of the requirement for accrediting bodies to be separate and independent from their accrediting associations. Statements made on the House floor during consideration of the Higher Education Amendments of 1992 clarified that this separation was not required for accrediting bodies with no title IV purpose. However, the Department of Education informed us that a technical amendment is necessary to achieve congressional intent. Without this clarification these organizations will be required to undergo costly restructuring to meet the separate and independent requirements.”

Discussion: The Department disagrees with the commenters. We first note that accrediting agencies will be required to demonstrate a Federal link in order to be recognized by the Department. Programmatic agencies who do not demonstrate such a link will not be considered for recognition and therefore need not comply with the separate and independent requirements. In any case, purely programmatic accrediting agencies recognized under 602.14(a)(3) are not required to comply with the separate and independent requirements in 602.14(b).

All accrediting agencies, including programmatic ones, are required to comply with 602.15, including by demonstrating clear and effective controls to avoid or resolve conflicts of interest. The commenters do not dispute the Department’s authority to regulate under this section. To the extent commenters argue that the Department is effectively imposing the separate and independent requirements through 602.15(e), they are mistaken. Section 602.14(b) requires structural separation, meaning an agency must be independent of any related, associated, or affiliated trade association in its governance, budget, and personnel. In contrast, Section 602.15(e) does not require that separation. It requires only that the agencies identify and disclose relationships with trade associations and maintain clear and effective controls to prevent those relationships from improperly influencing accreditation decisions. An agency may maintain such relationships and comply with 602.15(e), so long as appropriate safeguards are in place.

The Department discussed at length its concerns with the influence that related, associated, or affiliated trade associations exert over accrediting agencies, leading the agencies to adopt standards and practices that do not always advance students’ interests. The commenters fail to explain why the Department is incorrect to call this influence a conflict of interest or why the Department should not take steps to rein it in. The longstanding nature of the relationship between an accrediting agency and a related, associated, or affiliated trade association does not negate the existence of a conflict of interest, nor does it justify permitting such a conflict to persist.

Finally, the Department takes note of the legislative history cited in a comment but also notes that legislative history cannot change the plain language of the statute. *See State Farm Fire and Cas. Co. v. U.S. ex rel. Rigsby*, 580 U.S. 26, 36–37 (2016).

Here, the relevant statutes grant the Secretary authority to promulgate regulations and do not limit the Secretary's authority to specify what is considered a conflict of interest.

Changes: None.

§ 600.11 Special Rules Regarding Institutional Accreditation or Preaccreditation

Comments: Some commenters strongly supported the amendments to § 600.11. They believed that competition among accrediting agencies will strengthen accountability, provide quality assurance, encourage innovation, and make accrediting agencies more responsive. Other commenters stated that the proposed regulations would lower barriers to entry while retaining statutory quality controls for agency recognition. Commenters stated that agencies should have incentives to demonstrate their value through effective quality assurance, reasonable processes, responsive service, appropriate standards, and efficient oversight. These commenters believed that allowing institutions to more easily change accrediting agencies creates those incentives and reduces the risk that accreditation relationships become permanent regardless of an agency's performance.

Discussion: We agree and thank the commenters for their support. The final rule reduces regulatory burden on agencies in several areas but enhance accountability and direct focus on agencies' application of their standards and policies during the Department's recognition process.

Changes: None.

Comments: Some commenters stated that loosening requirements for institutions to change accrediting agencies will result in institutions seeking out agencies with the lowest standards. Common themes in the comments opposing the amendments were (1) the regulations would weaken accreditation and result in a "race to the bottom" in terms of academic quality, (2) relaxed requirements for changing agencies and fewer barriers to Federal recognition would result in institutions shopping for the agencies with the weakest standards, (3) institutions would be able to easily evade accountability, (4) the rule ignores the negative consequences of policies that create competition for competition's sake, and (5) this change, combined with changes under § 602.11 and § 602.12, will drastically lower the requirements of accrediting agencies to be more easily recognized by the Department, with the probability of

predatory institutions gaining accreditation increasing.

Discussion: The Department has not reduced statutorily required oversight of accrediting agencies nor encouraged them to have lower standards. The commenters will note that all the statutorily required standards under Section 496(a)(5) remain unchanged. The Department has also added additional safeguards in the form of application of the required standards under § 602.17 to ensure agencies are accounting in their policies for things like post-completion and graduation outcomes, the educational and economic returns of programs, academic freedom protections, cost-benefit analysis of institutional activities, and optimization of students' time to credential to reduce the amount of borrowing for students.

The regulations will not result in a race to the bottom. In fact, the Department has raised the bar for outcomes of students receiving title IV, HEA assistance at eligible institutions. An agency will still apply to the Department for recognition and be evaluated by both Department staff and NACIQI, receive approval from the senior Department official, and continue to be re-recognized by the Secretary through Departmental periodic review of the agency's compliance with the rigorous standards contained in the regulations.

Changes: None.

Comments: A few commenters provided specific recommendations that they believe would strengthen protections in the rule. One commenter stated that the Department should require an institution to submit its complete accreditation and compliance record, including all adverse and interim actions, unresolved findings, complaints, financial risk indicators, program review materials, teach-out obligations, corrective action plans, and relevant State or Federal actions. The receiving agency should be required to review that record and provide the Secretary with a written certification that it has considered the institution's prior history and determined that the change is not intended to evade oversight or obtain a less rigorous review. The commenter made additional requests regarding public disclosure of the change in agency and clear timelines to be published about the process for changing agencies. The Department should also require an institution to publicly disclose its reason for changing accrediting agency and any pending or recent adverse actions.

A different commenter stated that agencies should submit the most recent

accreditation determination letter; visiting-team reports and other agency feedback from the prior three years; information on pending consumer complaints and investigations by State and local licensing and law-enforcement agencies; and a status confirmation from the institution's current accrediting agency stating whether it has opened inquiries, engaged in substantive dialogue about compliance, or taken any action.

Another commenter stated that the NPRM assurance that institutions "subject to an adverse action cannot switch" is not reflected in the regulatory text itself, which requires a Secretarial finding of evasive intent. The commenter recommended restoring the current 24-month look-back, and providing that an institution under probation, show cause, suspension, or adverse action may not designate a new accrediting agency as its gatekeeper for the Federal student aid programs until the action is resolved or the receiving agency has independently reviewed and adopted findings on each deficiency identified by the prior agency.

Discussion: The Department declines the commenters' suggestions because they are not based in statute. We believe the new regulations under § 600.11(a)(1)(ii) are sufficiently rigorous to ensure that the Department is able to ascertain that an institution is trying to evade, avoid, misrepresent, or undermine the integrity of any title IV, HEA programs, which includes if an institution was subject to an adverse action by an agency.

Changes: None.

Comments: One commenter requested that the Department consider language that would protect institutions from penalizing actions by a current accrediting agency when exercising their right to choose another agency under § 600.11.

Discussion: If an institution believes that its current accrediting agency has taken adverse or punitive action against it in response to its efforts to change accrediting agencies, the institution may document those concerns in the materials it submits to the Department pursuant to § 600.11(a)(1). The institution may also submit a complaint directly to Department staff for review.

Changes: None.

Comments: One commenter stated that the Secretary should not be the sole arbiter of whether an institution's cause for switching accrediting agencies is "reasonable." The commenter stated that the determination would rest entirely with one political appointee, with no independent review, no defined evidentiary standard, and no public

rationale requirement. The commenter recommended that the Department vest this determination in NACIQI or a comparable independent body.

Discussion: The discretion to approve or deny a change in accrediting agencies even prior to this proposal rested with the Secretary. The Department maintains the proper protocols, ethical practices, and staff to ensure consistency, transparency, and fairness in all decision-making.

Changes: None.

Comments: One commenter stated that the final rule and accompanying guidance should specify how eligibility for title IV, HEA program funds is affected when an institution holds more than one institutional accreditation, how the institution designates a primary agency and changes that designation, and what disclosure to students is required.

Discussion: The current process for reviewing multiple accreditations addresses these issues, and the Department does not expect the process related to those issues to change. Under the regulations, Department evaluates whether an institution has demonstrated reasonable cause for adding an additional accrediting agency based on information provided by the institution and other information available to the Department. As a reminder, under 34 CFR 668.43(a)(6), institutions are responsible for providing information that is readily available to enrolled and prospective students about the names of associations, agencies, or governmental bodies that accredit, approve, or license the institution and its programs and the procedures by which documents describing that activity may be reviewed under 34 CFR 668.43(b). If a new agency begins to accredit an institution, the Department expects the institution to disclose the appropriate information to enrolled and prospective students as soon as possible.

Changes: None.

Comments: A few commenters stated that institutions should be able to protect their students by avoiding a gap in title IV aid between the previous accreditation and the new accreditation, especially in the health care and veterinary professions. The commenter also stated that although the rule states that new agencies should avoid unnecessary costs to institutions in the accreditation process, institutions that change agencies may have to account for increased accreditation costs, and those costs may be passed along to taxpayers or students.

Discussion: While there may be an outlier, the Department does not envision a circumstance in which an

institution voluntarily chooses to switch accrediting agencies and causes a gap in title IV funds access. The institution would retain title IV eligibility under its original agency until the change in accrediting agency was complete.

With respect to concerns about increased costs associated with changing accrediting agencies, the Department notes that these regulations do not require an institution or program to change accrediting agencies. Rather, the regulations are intended to facilitate such changes when an institution or program determines that doing so is appropriate. Accordingly, an institution or program anticipating increased costs that could necessitate ongoing increases in students' cost of attendance should carefully evaluate whether changing accrediting agencies is in the best interests of its students. The Department recognizes, however, that the potential benefits of changing accrediting agencies may outweigh the associated costs, depending on the institution's or program's circumstances and the interests of its students.

Changes: None.

Comments: Several commenters supported the amendments to the provision on an institution having accreditation from multiple entities under § 600.11(b). One commenter stated that the regulations correctly read HEA Sections 496(h) and (i) as requiring disclosure and reasonable cause, not as granting the Department a general veto over an institution's choice of quality assurance partner. The enumerated grounds for finding cause unreasonable are the right guardrails and are narrowly drawn. Another commenter stated that allowing an institution to have accreditation from multiple agencies will encourage more agencies to apply to the Department for recognition, thus leading to increased oversight of agencies and better quality assurance of institutions and programs.

Discussion: We agree and thank the commenters for their support.

Changes: None.

Comments: Several commenters opposed the changes under § 600.11(b) because they believe institutions will be incentivized to seek dual accreditation, likely from a new accrediting agency with less rigorous standards, as a safety net if they fail to meet the standards of one of the more established accrediting agencies.

Discussion: We believe a guardrail exists in the regulation for this situation. One of the provisions under § 600.11(b) is that an agency cannot carry accreditation from multiple agencies to "avoid or delay enforcement or oversight by the Department or an

accrediting agency." Accordingly, the Department has adequately addressed the commenters' concerns.

Changes: None.

Comments: One commenter was concerned that the wording of § 600.11(b)(2) could be interpreted in a way that would prevent the Secretary from acting against poorly performing institutions. The commenter recommended that, since revoking accreditation is often a yearslong process, the Department revise § 600.11(b)(2) to read "The Secretary will not solely determine the cause of having multiple accrediting agencies to be unreasonable due to a probation or equivalent, show cause order, or suspension order."

Discussion: If the Secretary determines that an accrediting agency is not compliant with statute or regulations, there are many mechanisms to review, sanction, or revoke recognition of the agency. This provision alone does not prohibit the Secretary from taking action in response to violations of statute or regulations.

Changes: None.

Comments: One commenter requested that the Department identify, as examples of "reasonable cause," an institution's decision to add an agency whose scope covers workforce, certificate, apprenticeship-aligned, or eligible workforce programs.

Discussion: We decline to create a list of reasons why an institution can have accreditation by multiple agencies. If the Department develops a list, we must have a rationale for why one reason is included and another is not. We have provided in the regulation that as long as none of the criteria are violated under § 600.11(b)(1)(ii), then the institution can have accreditation from multiple agencies.

Changes: None.

Comments: One commenter recommended that future accreditation-reform initiatives expressly support technology and shared infrastructure designed to reduce the administrative burden associated with seeking, maintaining, and changing accreditation.

Discussion: The Department supports the use of technology and shared infrastructure (so long as it does not violate § 602.13) to reduce the burden of an institution seeking, maintaining, and changing agencies.

Changes: None.

Comments: One commenter stated that the Secretary should consider when a change of agency follows an unresolved compliance concern raised by the current agency, regardless of whether the institution's stated reason is

compliance with State law, and require the institution to disclose any outstanding findings.

Discussion: We believe the commenter's suggestion is accounted for under § 600.11(a)(1)(ii).

Changes: None.

§ 602.2 How do I know which agencies the Secretary recognizes?

Comments: One commenter agreed with the changes under § 602.2 stating that the amendments increase transparency and more timely access to information regarding accreditation actions.

Discussion: We thank the commenter for their support.

Changes: None.

Comments: One commenter recommended that the Department include the history of accreditation actions rather than only the current status and flag any institution operating under a continuation of eligibility granted under § 602.26, so a student can see that a college is drawing Federal aid despite an adverse accreditation action.

Discussion: We decline the commenter's recommendation. We believe this would be redundant to requirements under 602.26(f) that require an agency to maintain on its website a clear record of all actions taken for each institution or program it accredits or preaccredits for a period of at least five years.

Changes: None.

§ 602.3 What definitions apply to this part?

Accrediting Agency or Agency

Comments: A few commenters supported the amended definition. One commenter stated that the revisions are an important shift from process-based compliance toward substantive quality assurance. The commenter stated that peer review should remain available, but the Federal government should not dictate unnecessary details for those processes. The commenter believed that reducing Federal micromanagement can allow accrediting agencies to devote more attention to student achievement, institutional performance, educational quality, and meaningful improvement while simultaneously reducing unnecessary administrative costs for institutions. Another commenter who supported the rule stated that accrediting agencies may wish to include professionals and experts on site visit teams who do not directly fit within the strictest meanings implied by "peer" or "peer reviewers."

Discussion: We agree and thank the commenters for their support.

Changes: None.

Comments: Some commenters opposed the Department's definition of accrediting agency or agency. Commenters opposed the removal of the requirement that an agency conduct activities through peer review. Commenters urged the Department to maintain the requirement for peer review for the following reasons:

- Peer review is central to credibility independence and essential to the evaluation process, and peers are the most competent individuals capable of assessing quality of instruction.

- Experts such as engineers, doctors, writers, physicists, and veterinarians know their subjects but have no understanding of education, teaching, or students.

- The peer review process avoids the injection of political ideologies, political appointees, and overreach of outside Federal agencies into the accreditation process.

- With no guardrails, agencies may contract individual reviewers with little to no expertise in the areas they are reviewing.

- Current regulations already require agencies to include practitioners and employers as a part of their evaluation teams.

- The Department itself encourages peer review in the preamble explanation to changes to site visits under § 602.24(b).

Discussion: The regulatory requirement that an agency conduct activities through peer review is not prescribed in statute under the HEA. Where current regulations prescribe requirements that extend beyond recognition procedures and instead direct the content or administration of accrediting standards without a clear statutory basis, the Department removes or simplifies those requirements to better align the regulations with Congressional direction.

The regulations allow for an accrediting agency to continue utilizing the peer review model. There is no prohibition on peer review if that is the best option for the agency; however, the regulations do acknowledge that peer review is not the only appropriate model for the review of an institution or program. For example, an agency may determine that a practicing veterinarian or group of practicing veterinarians may be better suited for the review of a program than a professor(s) of veterinary sciences.

Under § 602.15(a)(2), any agency must have competent and knowledgeable individuals, qualified by education or experience as appropriate for their roles. This provision continues to include the

agency's decision-making body and site reviewers. With this final rule the Department declines to apply a "one size fits all" approach to how an agency reviews its accredited institutions and programs; however, we still maintain high standards under § 602.16 and application of those standards under § 602.17 for the reviews.

Note that the preamble language for § 602.24 states "peer" or "independent" review: "For example, having a peer or independent reviewer alongside accrediting agency staff would help the evaluation reflect professional expertise and perspectives that extend beyond accrediting agency staff alone. Peer reviewers bring field specific knowledge that allows them to assess academic standards, administrative capacity, and institutional practices with appropriate depth. Independent reviewers, likewise, help the accreditation process not be unduly influenced by an agency's internal perspectives or by longstanding relationships with institutions."

Changes: None.

Comments: One commenter asked, what is the Department's expectation for who conducts a review of a professional program?

Discussion: The Department will not mandate who conducts the review of any program, including professional programs. By removing the requirement for peer review, agencies have flexibility to innovate and create a unique review process for institutions and programs. Note that while the final rule provides for flexibility and innovation, the language under § 602.15(a)(2) still requires that an agency has competent and knowledgeable individuals, qualified by education or experience in their own right, as appropriate for their roles.

Changes: None.

Comments: One commenter asked the Department to clarify that regardless of whether reviewers are peers, agency staff, or other qualified experts, the review must apply rigorous standards through a competent, independent, and well-trained team.

Discussion: The commenter's statement is correct. Under § 602.15(a)(2), any agency must have competent and knowledgeable individuals, qualified by education or experience in their own right, as appropriate for their roles.

Changes: None.

Institution

Comments: A few commenters recommended that the Department use the term "postsecondary institution" rather than simply "institution" because it would preserve the Department's

objective of avoiding the narrower statutory term “institution of higher education” while more clearly identifying the category of institutions governed by the accreditation regulations. Another commenter was concerned that replacing language traditionally tied to educational entities as “Institutions of Higher Education” with the broader term “institution” may unintentionally expand eligibility too far beyond organizations whose primary mission is education and learning.

Discussion: The Department sought to simplify the term in an effort to not repeat the phrase throughout 34 CFR part 602. We believe the definition of “institution” is clear and simple. We specifically state that the term means an educational institution that meets the requirements of paragraph (1) of the definition of eligible institution found in 34 CFR 600.2; therefore, there is no possibility that the eligibility could expand beyond (1) an institution of higher education, as defined in § 600.4, (2) a proprietary institution of higher education, as defined in § 600.5; or (3) a postsecondary vocational institution, as defined in § 600.6.

Changes: None.

Related, Associated, or Affiliated Trade Association

Comments: One commenter stated that the definition is overly expansive and will capture trade associations that do not have a direct relationship with agencies and negatively impact the ability of those organizations to work effectively with accrediting agencies, especially if accrediting agencies are member organizations of such trade associations.

Discussion: The Department disagrees with the commenter because the definition does require a direct relationship. One of the components of this definition is that the organization “. . . is related to a particular accrediting agency in that the agency accredits institutions or programs that prepare students to enter the workforce of the same or substantially the same line of commerce, business, industry, or profession that organization promotes.”

Changes: None.

§ 602.10 Link to Federal Programs

Comments: One commenter supported the amendments to § 602.10. The commenter stated that Congress has assigned recognized accrediting agencies an important responsibility to serve as reliable authorities regarding educational quality. That responsibility should remain at the center of the recognition framework. Where Congress has expressly required agencies to

perform Federal functions, those requirements must be honored. But Federal recognition should not unnecessarily expand the agency’s role beyond those statutory responsibilities or encourage agencies to regulate matters disconnected from educational quality.

Discussion: We agree and thank the commenter for their support.

Changes: None.

Comments: Several commenters stated that the changes to 602.10 will result in programmatic accrediting agencies no longer seeking recognition from the Department. The commenters believe that agencies that accredit “professional programs” should be regulated by the Secretary to ensure quality. The commenter recommended that the Federal link should include a designated “professional program,” and those agencies should be required to seek Department recognition. Another commenter stated that agencies that oversee law, medical, dental, veterinary, pharmacy, and nursing schools should be required to be recognized by the Department due to their role in the U.S. social system.

Discussion: The Department disagrees with the recommendation. Section 496(a) requires a link to Federal programs in order for the Secretary to grant recognition. Institutional accrediting agencies primarily act as title IV gatekeepers for an institution to be eligible to participate in the title IV student financial aid programs. State licensure of professions does not establish a Federal link and law, medical, dental, veterinary, pharmacy, or nursing schools fall within an institutional accrediting agency’s grant of accreditation to the institution. For programmatic accrediting agencies, the Federal link is usually through a non-HEA Federal program, and the Department will continue to recognize or review for recognition any agency with a non-HEA Federal link actively utilized by its accredited programs as well.

The Department will not recognize any agency that does not have a direct Federal link with either the Department or another Federal agency. As noted earlier, the Federal link is a statutory requirement for the Department’s recognition and it is not intended to be a signal to State governments or licensure agencies to rely on those agencies for licensure or other State requirements.

Changes: None.

Comments: One commenter opposed permitting an agency to satisfy the Federal link requirement on the basis of institutions that have designated

another agency. The provision exists to enable stand-by accreditation. The commenter recommended that the Federal link be satisfied only by institutions that designate the agency.

Discussion: As stated in the final rule in 2019 when added, this provision is designed to decrease barriers to entry and enable new agencies to more easily enter the marketplace. Until a new agency is recognized, it is highly unlikely that an accredited institution would relinquish its current accreditation that enables it to meet title IV institutional eligibility requirements to attain accreditation from that new agency, even though the new agency may be better suited to the institution’s mission. Therefore, we decline the commenter’s suggestion to remove the provision.

Changes: None.

Comments: One commenter stated that the regulations do not address what happens to an agency that loses recognition if after two years there are no institutions or programs that rely on the agency’s accreditation to establish or continue eligibility to participate in Federal programs. The commenter stated that the Department should add provision for a notice period, teach-out, and title IV consequences.

Discussion: If an agency has no institutions that participate in the title IV programs, then there would be no reason for a teach-out or notice period because no entity associated with the agency would be disbursing title IV aid to students. In the case of non-HEA Federal programs, we cannot account for all nuances of each program but would again state that there would be limited impact to students if no Federal link is established. The two-year window is to ensure only accrediting agencies that have institutions and programs that utilize Federal programs are seeking recognition to avoid wasting Department and taxpayer resources.

Changes: None.

Comments: One commenter asked the Department to confirm that an agency’s Federal link under § 602.10 may be established through Workforce Pell participation alone, without requiring a longer-format credential.

Discussion: The Department confirms that an eligible institution is permitted to offer only eligible workforce programs qualifying for Pell Grants (colloquially referred to as “Workforce Pell”). And, to that extent as such an institution participating in the Pell Grant program would be eligible for at least one title IV, HEA program, accreditation of such an institution would satisfy the Department’s requirements for a Federal link even if

the institution did not offer eligible programs other than eligible workforce programs.

Changes: None.

Comments: One commenter asked the Department to state in implementing guidance that where a Federal agency conditions employment on programmatic accreditation, the qualifying condition should be accreditation by an agency recognized by the Secretary, rather than accreditation by a single named organization.

Discussion: The Department declines the commenter's request. Section 496 (m) of the HEA states that "the Secretary may only recognize accrediting agencies or associations which accredit institutions of higher education for the purpose of enabling such institutions to establish eligibility to participate in the programs under this Act or which accredit institutions of higher education or higher education programs for the purpose of enabling them to establish eligibility to participate in other programs administered by the Department of Education or other Federal agencies."

The Department does not have authority over another Federal agency's policies. A separate Federal agency may condition employment on a specific programmatic accrediting agency that is not recognized by the Department, but the statute is clear that the Federal link that agencies need to establish for Department recognition is related to a program administered by a Federal agency, not conditions of employment by a Federal agency.

Changes: None.

Comments: One commenter asked the Department to state in the preamble to the final rule that the test in § 602.10(a) governs reliance under § 602.10(c): an institution that is accredited by two accrediting agencies and participates in the title IV, HEA programs could designate either agency as its primary agency for title IV purposes and could therefore be used by either agency to demonstrate its Federal link. The commenter also suggests that the Department conforms the text by adding to § 602.10(c) a sentence to that effect so that the two paragraphs apply one test.

Discussion: We confirm that if an institution is dually accredited, even if the institution designates another institutional accrediting agency as its Federal link, that would satisfy the requirements for initial recognition under § 602.10(c). Additional conforming regulatory text is not necessary.

Changes: None.

Comments: One commenter stated that proposed § 602.10(c) would establish a two-year post-recognition condition under which a newly recognized agency loses recognition if no institution relies on its accreditation within that period. The commenter stated that the final rule should explain how the Department expects the provision to operate in professional sectors where institutional switching may occur slowly for reasons unrelated to accrediting agency quality.

Discussion: All accrediting agencies must demonstrate a Federal link for Federal recognition. If an agency that accredits an institution loses the Department's recognition after two years under § 602.10(c), then the institution it accredits never participated in an HEA or non-HEA Federal program; therefore, there would be no Federal consequence to the institution due to the loss of the agency's recognition.

Changes: None.

Comments: One commenter requested that the Department clarify the requirements for new agency recognition by (1) stating objective recognition criteria with defined review timelines; (2) providing a provisional or developmental recognition status through which a new agency can demonstrate performance on a defined cohort before full recognition; and (3) ensuring that experience requirements can be satisfied by demonstrated competence of an agency's standards, processes, and personnel, so that specialized quality-assurance bodies are not excluded by criteria only incumbents can meet.

Discussion: While we decline to regulate the Secretary in a way that would place arbitrary deadlines on the Department, we believe that several of the commenters' suggestions are already accounted for in the final rule at § 602.12 Accrediting Experience, § 602.16 Accreditation and preaccreditation standards, § 602.17 Application of standards in reaching accreditation decisions, § 602.30 Agency applications and reports to be submitted to the Department, and § 602.31 Procedures for submitting applications for recognition and renewal of recognition.

Changes: None.

§ 602.11 Extent of Accrediting Activities

Comments: Several commenters offered general support for the elimination of references to geographic scope under § 602.11. The commenters believe that differentiating between regional and national accrediting agencies implies that an institution

accredited by a regional accrediting agency may be superior or represent a different level of quality.

Discussion: We thank the commenters for their support. These final rules make clear that the Department recognizes institutional or programmatic accrediting agencies only. We hold all agencies to the same rigorous standards.

Changes: None.

Comments: One commenter questioned the need for further regulation on regional and national accreditation. The commenter stated that this amendment is not necessary as the Department published a final rule on November 1, 2019, noting that "the terms "regionally accredited" and "nationally accredited" will no longer be used or recognized by the Department. The commenter stated that the Department taking additional action after six years is unnecessary as recognized institutional accrediting agencies have been considered national agencies following this rule.

Discussion: We proposed to fully eradicate the terminology because regulations under § 602.11(b) still refer to a region. The Department seeks to continue to break down the notion that there is a difference between institutional accrediting agencies. We believe these amendments will encourage States and other Federal agencies to continue to remove policies that favor institutions—and therefore their students—accredited by former "regional" agencies over institutions accredited by "national" agencies.

Changes: None.

Comments: A few commenters disagreed with the Department's removal of geographic restrictions from recognized agencies. One commenter stated that accrediting agencies will be making decisions on programs with which they have little experience or knowledge. Another commenter stated that regional and national accrediting agencies held institutions to different standards and produced different outcomes. The commenter pointed to the Department's regulatory impact analysis, Figures 3.1 to 3.3, plots of graduation rates, completer earnings, and loan delinquency by accrediting agency. The commenter argued that the solution would be to organize agencies by tiers of demonstrated rigor defined at the outset, which the prior regional versus national approach approximated.

Discussion: Since 2019, the Department has viewed institutional accrediting agencies with no distinction for geographic regions, unless noted within their scope of recognition. We have been careful not to make any distinction as all agencies are required

to meet the same standardized requirements in the regulations. This is a floor not a ceiling; agencies have the flexibility and autonomy to create additional standards so long as they do not conflict with Federal or State law. The Department will discontinue the practice of stratification of agencies based on incomplete data or assumptions and instead hold all agencies to the same rigorous thresholds and standards.

Lastly, regarding the commenter's statement that an agency may not have the necessary experience to accredit institutions outside of a specific region, the commenter will note that the very next section of the regulations, § 602.12, contains extensive requirements regarding the required experience of an agency for recognition. For example, § 602.12(b) states that "An agency seeking initial recognition must undergo the Secretary's recognition process, defined in § 602.31, and an evaluation of the agency's compliance with the Secretary's recognition criteria, defined in 34 CFR part 602, for the purpose of determining if the agency is a reliable authority as to the quality of education or training provided by the institutions or programs it accredits before its application for recognition may be considered by the Advisory Committee."

Changes: None.

Comments: One commenter stated that the Department should clarify what constitutes an adequate description of the "extent" of accrediting activities and, more importantly, what evidence an agency must provide to demonstrate that it has the capacity, policies, and procedures necessary to operate within that extent. For example, if an agency expands from accrediting institutions in a limited number of States to truly operating nationally, should the Department evaluate staffing capacity, reviewer availability, institutional volume, travel and monitoring capacity, financial resources, governance infrastructure, or other operational factors?

Discussion: The factors noted by the commenter are evaluated during a renewal of recognition review.

Changes: None.

§ 602.12 Accrediting Experience

Comments: Several commenters supported removing the requirement under current § 602.12(a)(2) that an agency conduct accrediting activities, including deciding whether to grant or deny accreditation or preaccreditation, for at least two years prior to seeking recognition (two-year rule). Commenters stated that the two-year rule provided

no practical path to an agency's recognition due to expense and time it would take to obtain agency recognition from the Department. One commenter stated the two-year rule represented a categorical barrier rather than a quality check.

Another commenter stated that opening the system to qualified new agencies will permit accreditation to evolve alongside higher education and the American workforce. New educational delivery models, rapidly changing technologies, artificial intelligence, shorter-term credentials, competency-based education, and changing employer needs present challenges that the accreditation system must be capable of addressing. Emerging agencies may develop different methods of evaluating outcomes, using data and technology, measuring competencies, and assessing whether programs are preparing students for employment and further education. Competition does not guarantee innovation, but eliminating unnecessary barriers gives innovation an opportunity to occur.

Discussion: We agree and thank the commenters for their support.

Changes: None.

Comments: Some commenters opposed removing the two-year rule under current § 602.12(a)(2). They stated that accreditation exists to protect students and taxpayers by ensuring that a reliable, experienced authority is vouching for institutional and program quality, and a faster path to recognition should not come at the expense of that assurance. Several commenters stated that such a change would allow organizations with no record of responsible conduct to be created at will, which removes the value of accreditation entirely. Other commenters believed that the amendments of § 602.12 enable the creation of accrediting agencies with arbitrary standards and will increase accreditation of predatory institutions that saddle students with debt.

One commenter stated that the Department did not provide sufficient data to support the rescission of the two-year rule, and instead the Department merely speculates that its lower bar will entice new agencies to seek recognition and further speculates that developing the accrediting agency market will lead to competition and better educational outcomes. The commenter contended that the changes would fall short of enabling the Department to meet its statutory obligation to conduct a "comprehensive review and evaluation" prior to recognition, as required by 20 U.S.C. 1099b(n). In addition, the commenter

stated that the proposal is contrary to law as the Secretary can "only recognize" accrediting agencies which "accredit" (present tense) institutions or programs for the purpose of enabling participation in Federal funding, per 20 U.S.C. 1099b(m).

Discussion: As stated in the NPRM, a two-year requirement is not statutory and represents undue and unnecessary burden for accrediting agencies seeking recognition. Note that the new provisions create guardrails and high standards for agencies by requiring that the agency be legally established to operate in the relevant jurisdiction and that the agency has standards and operating procedures consistent with applicable regulations. Additionally, all agencies are reviewed for compliance with the Secretary's Criteria for Recognition and are subject to the recognition process, which ensures a comprehensive evaluation.

The Department disagrees with the commenter's argument that the Secretary can "only recognize" accreditors which "accredit" (present tense) institutions or programs. Section 496(m) describes the purpose of recognition, not a requirement that an agency already have accredited institutions or programs. This interpretation is consistent with Section 496(a)(2)(A), which defines qualifying agencies by their principal purpose of accreditation. The Secretary must still conduct a comprehensive review and determine that an applicant satisfies all applicable statutory requirements, including demonstrated ability and experience, but the statute does not require two years of prior operations.

Changes: None.

Comments: One commenter stated that the rescission of the two-year rule creates a situation in which an unrecognized agency will conduct a full evaluation of an institution that already holds recognized accreditation, and the quality of that single decision will carry the petition. The commenter asks the Department to confirm that an institution in this position satisfies § 600.11(b) if it makes the submission and designation within a reasonable period after the agency's recognition and that its eligibility is not interrupted in the interval.

Discussion: The Department will address specific operational and implementation questions in subregulatory guidance. The Department agrees that an institution should not experience an interruption in title IV eligibility solely because it obtains accreditation from an agency that subsequently receives recognition. An institution that maintains

accreditation from an already recognized agency retains its eligibility on that basis, provided it continues to satisfy all applicable requirements.

Changes: None.

Comments: Several commenters suggested that before recognizing a new accrediting agency the Department should:

- Require credible evidence that the agency has experienced and properly trained peer reviewers; transparent and consistently applied standards; effective conflict-of-interest protections; a demonstrated ability to evaluate institutional quality and student outcomes; and adequate procedures for complaints, appeals, monitoring, teach-outs, and institutional closures.

- Establish a formal public-comment opportunity as part of the initial recognition process for newly established accrediting agencies, particularly where recognition may affect regulated professions.

- Ensure that State licensing authorities, educational institutions, professional organizations, students, employers, existing accrediting agencies, and other affected stakeholders have a meaningful opportunity to identify potential implications for educational quality, licensure eligibility and portability, workforce mobility, and public protection, especially if scope of practice and license portability could be impacted.

- Require that an agency's accrediting experience covers the range of degrees, certificates, institutions, and programs for which it seeks recognition. An agency that has reviewed a single certificate program should not be recognized to accredit doctoral institutions.

- Adopt a three-year initial recognition period with a required monitoring report, rather than five years, and confirm that first-time applicants receive the most rigorous review track rather than the lightest.

- Establish explicit risk-based triggers for enhanced monitoring of newly recognized agencies, including rapid growth in portfolio size, an elevated rate of adverse actions or closures among accredited institutions, and accreditation of institutions that recently changed agencies.

Discussion: The Department believes that many of the suggestions are accounted for in the regulations under § 602.3 (see that section for a discussion on reviewers), § 602.14, § 602.15, § 602.16, § 602.17, and § 602.24. The Department declines recommendations that are not expressly stated in the HEA.

Changes: None.

§ 602.13 Effect of Recognition

Comments: A few commenters offered general support for the provision stating that the Secretary's recognition of an agency confers no antitrust immunity. One commenter stated that some agencies have operated like anticompetitive gatekeepers. Another commenter stated that the regulations make clear that accreditation should not be used to impose unnecessary educational requirements that restrict entry into a profession.

Discussion: We thank these commenters for their support.

Changes: None.

Comments: One commenter stated that the regulations repeat requirements that already exist in Federal law and are enforced through the Department of Justice. The commenter stated that inclusion of § 602.13 in the regulations suggests that the Department seeks to enforce provisions within the purview of other Federal agencies. The commenter recommended eliminating § 602.13.

Discussion: The Department noted in the NPRM—and repeats here—that it is not the enforcer of antitrust law, but accrediting agencies are expected to comply with Federal law, including avoiding anti-competitive practices. The purpose of this provision is to make it clear that agencies cannot affirmatively claim that they enjoy any antitrust immunity flowing from their recognition. “Repeals of the antitrust laws by implication from a regulatory statute are strongly disfavored.” *Norfolk & W. Ry. Co. v. Am. Train Dispatchers Ass’n*, 499 U.S. 117, 129 (1991) (quoting *United States v. Phila. Nat. Bank*, 374 U.S. 321, 350 (1963)). There is nothing in this regulation or the HEA that suggests that the antitrust laws are displaced explicitly or implicitly, and the amendments in § 602.13 make that explicitly clear.

Furthermore, the Department would not enforce the antitrust laws under § 602.32(3) either. When enforcing § 602.32(3), the Department would rely on, as evidence of an antitrust violation, a final judgment in state or Federal court, an admission by an accrediting agency, or a settlement where the agency admitted to have engaged in anticompetitive conduct. Only in these circumstances would the Department view the conduct as a negative factor when reviewing for compliance under § 602.32(3). Mere allegations of anticompetitive conduct would not be a sufficient basis for the Department to view that conduct as a negative factor when adjudicating an agency's recognition.

Changes: None.

Comments: One commenter stated that the final rule should make clear that § 602.13 neither creates antitrust immunity nor constitutes a finding concerning the legality of any particular agency's conduct.

Discussion: We believe the regulation is clear as it is currently written.

Nothing in the regulation suggests or should be taken to mean that the regulations under § 602.13 confer antitrust immunity, nor that the Department has made any findings concerning any particular agency.

Changes: None.

Comments: One commenter stated that the Department should clarify that legitimate quality assurance activities undertaken pursuant to Federal recognition are not themselves evidence of anticompetitive conduct and that new agencies do not undermine scope of practice and patient protections enacted by State licensure boards.

Discussion: The Department declines to prescribe specific activities by accrediting agencies that may or may not be evidence of anticompetitive conduct. Each recognized accrediting agency is responsible for ensuring that its activities comply with all applicable Federal and State laws, including antitrust laws, and may wish to consult with legal counsel regarding its compliance obligations.

Changes: None.

Comments: A commenter stated that there is no specific exemption for accrediting agencies in the antitrust laws, and case law has long supported the view that accrediting agencies are subject to such laws, but at the same time § 602.17(a)(1)(ii)(E) requires accrediting agencies, in setting and applying student achievement standards, to assess the reasonableness of institutional and programmatic earnings relative to cost of attendance.

The commenter also stated that the Department seeks to have accrediting agencies conduct a “cost-benefit” analysis under proposed § 602.17(a)(3) of an institution's “budget, resource utilization, and allocation.” The commenter believes that these provisions are fundamentally irreconcilable with the statement that accrediting agencies are subject to antitrust laws.

The commenter further expressed that by compelling accrediting agencies to engage in cost-based assessments while simultaneously denying them any antitrust protection for doing so, the proposed rule creates a trap: an agency that complies with the Department's mandate exposes itself to an antitrust claim or enforcement action, while an

agency that declines to comply in order to mitigate antitrust risk faces loss of recognition. The commenter stated that the Department cannot lawfully impose regulatory obligations that force accrediting agencies to violate antitrust laws while simultaneously stating that such agencies are not immune from those laws.

Discussion: The Department does not believe the regulations are irreconcilable with antitrust laws. Nothing in the regulation requires an agency to set tuition and fees, assess an institution's tuition and fees with respect to other institutions, otherwise pressure or compel institutions to set tuition and fees at a certain level, or act against an institution because of the institution's tuition and fees. The standard requires an agency to assess whether the institution has done a reasonable analysis to determine whether its own tuition and fees are reasonable in light of its own costs. Beyond that, agencies and institutions may wish to consult with counsel to effectively implement these regulations within Federal antitrust law. This does not, contrary to the commenter's suggestion, require any institution to engage in concerted action with other institutions. In particular, institutions can make their own decisions about how to conduct the cost-benefit analysis, which requires institutions to engage in reasoned decision making and to avoid arbitrary requirements, including those that may be unduly costly. The Department certainly does not want accrediting agencies to engage in any conduct that would violate the antitrust laws, which may include accrediting agencies developing uniform standards for making decisions in institutions' cost benefit analysis that could, directly or indirectly, fix prices. To the degree that an accrediting agency has a good faith belief that a specific action would violate the antitrust laws and abstains from taking that action on those grounds, the Department will credit those concerns when evaluating the compliance with the recognition criteria.

The commenter is also mistaken with regard to the regulation requiring agencies to perform cost/benefit analysis. Agencies are only required to review cost/benefit analysis performed by institutions.

Changes: None.

§ 602.14 Purpose and Organization

Comments: One commenter requested that the Department provide a clear statement in the preamble to the final rule that programmatic accrediting agencies, which do not act as

gatekeepers of Title IV funds and are recognized under § 602.14(a)(3), are not subject to § 602.14(b).

Discussion: The commenter is correct; accrediting agencies that are recognized under § 602.14(a)(3) are not subject to the "separate and independent" requirements under § 602.14(b).

Changes: None.

Comments: One commenter recommended that under § 602.14(b)(2) the Department should adopt a defined cooling-off period for public members and should bar owners and shareholders of accredited institutions from voting on accreditation decisions.

Discussion: We decline the commenter's recommendation. We believe that the regulations are sufficiently rigorous to ensure that recognized agencies are separate and independent without additional requirements.

Changes: None.

Comments: One commenter asked for clarification of the requirements under § 602.14(b)(6) regarding

"... any complaints received during the current recognition period that are material."

Discussion: The Department understands that stakeholders will have questions regarding implementation of the final rule. We cannot address every situation within the regulations because the regulations are meant to be the general framework. We believe that the commenter's request is subregulatory in nature, and we may offer subregulatory guidance as necessary to inform implementation.

Changes: None.

Comments: One commenter stated that the Department should revise § 602.14(b)(6) to read "The authorized representative of the agency submits a signed statement certifying that it has met the requirements to be 'separate and independent' within each petition for recognition submitted to the Department, and includes in that statement information regarding any complaints received during the current recognition period that are material to the agency's adherence to the 'separate and independent' requirements in this section." The commenter stated that as written, the requirement is not clearly linked to § 602.14(b)(6).

Discussion: As noted by the commenter, the provision appears in Section 602.14(b). We believe that it is clear the complaints referenced regard complaints related to "separate and independent."

Changes: None.

Comments: Some commenters supported the rescission of the joint use

provisions under § 602.14(c) for the following reasons:

- The rescission gets rid of conflicts of interest, and accreditation should be an independent check to make sure an institution or program is actually qualified, not a gatekeeping tool used by industry groups to protect their own interests.

- Accrediting agencies should not be utilized to support or prop up membership organizations. They should be independent of influence and focus completely on accrediting institutions and/or programs.

- Affiliated trade or membership organizations should have no role in the accreditation process, specifically the appointment of accreditation members, approval of standards or policies, setting of fees, approval or oversight of budgets, oversight of the accrediting body, management of staff leaders, and oversight of legal representation.

- The provision will block programmatic accrediting agencies from unduly raising costs for students or contributing to degree inflation.

- The provision, in combination with amendments under § 602.15, will prohibit agencies from being run as a division of a lobbying group.

Discussion: We agree and thank the commenters for their support.

Changes: None.

Comments: A few commenters supported the changes under § 602.14 and stated that they should be strengthened to include further delineation between setting standards and auditing compliance. One commenter stated that the Department should also make clear how often the relevant Department staff will be checking to ensure that accrediting agencies and associations are not sharing resources. Another commenter stated that separate and independent should also refer to the independence of the Board from the chief executive officer of the accrediting agency itself.

A different commenter stated that the Department should require a materially independent public/consumer presence and prohibit any single related professional or educational organization from appointing, nominating, ratifying, or effectively controlling a majority coalition. The same commenter also recommended to define separate and independent to require separate legal incorporation, employer identification number (EIN), bank accounts, financial statements, audited books, governing body, employees, HR function, IT environment, document repositories, physical offices, insurance, legal counsel, lobbying/public-policy function, communications staff, and

contracting authority. A related organization should be permitted to submit input to the accrediting agency only through the same publicly documented process available to unrelated stakeholders.

Discussion: We decline the recommendations as the Department believes that the regulations are sufficiently rigorous to ensure that recognized agencies are separate and independent.

The Department recognizes that separating standard-setting from compliance evaluation may offer advantages, including reducing potential conflicts of interest and promoting more consistent enforcement of standards. Such an approach could also introduce additional costs and operational complexities. We believe this proposal warrants further consideration, including examination of quality assurance practices in other industries. Accordingly, we are not adopting additional requirements in this area in the present rulemaking, but may consider this approach in future regulatory actions.

Changes: None.

Comments: Some commenters opposed the changes to § 602.14. They believed the revised § 602.14 will discourage programmatic accrediting agencies from seeking recognition from the Department and dramatically increase operating costs for programmatic agencies that continue to seek Department recognition. Commenters believe that the regulations do not explicitly recognize that programmatic accreditation in regulated professions serve a different purpose from institutional accreditation. Several commenters stated that the amendments will severely disrupt professional preparation by forcing specialized, programmatic agencies to sever formal organizational ties with related professional associations. The commenters claimed that for fields such as education, veterinary sciences, and speech-language-hearing, this separation degrades the connection between academic training and real-world professional standards. Other commenters stated that the Department's rulemaking did not demonstrate that complete organizational separation is necessary especially because HEA Section 496(a)(3)(C) allows for the Secretary to waive the separate and independent requirement.

Finally, one commenter stated that the additions to § 602.14 impose additional requirements on accrediting agencies not present in statute. By adding additional criteria to the

statutory definition of separate and independent, the commenters believe that the Department is violating the prohibition on establishing additional criteria for accrediting agencies in § 496(g) and is impermissibly changing Congress's definition of "separate and independent."

Discussion: The statute does not differentiate the purposes of recognized accrediting agencies—other than whether they are institutional or programmatic and whether their Federal link is an HEA or non-HEA program. Therefore, there is no statutory basis for treating specialized, programmatic agencies differently, as the commenters suggest. The Department has been clear that we seek to eliminate conflicts of interest between accrediting agencies and related, associated, or affiliated trade associations, and the separation required by the regulations achieves that necessary goal to protect students.

We have addressed our statutory authority under the *Legal Authority* section of this final rule.

Changes: None.

Comments: Some commenters requested an exemption to the rescission of paragraph § 602.14(c) (about the joint use of personnel, services, equipment, or facilities) including:

- Agencies with 501(c)(3) status. The commenter stated that legal arrangements and contracts could be completed to allow for some shared services with partnering agencies to keep costs within range.

- Agencies that accredit institutions that offer programs like specialized health, podiatric medicine, and veterinary services. The commenter stated that for a relatively small health profession, requiring duplication of personnel, office space, technology, administrative services, and other infrastructure could impose substantial new costs.

- Agencies that accredit institutions that offer counselor education.

- All recognized programmatic agencies.

- Agencies that distinguish between resource-sharing that creates that risk and administrative resource-sharing.

Discussion: From the onset of this rulemaking effort, the Department has made clear that we seek to ensure independence between accrediting agencies and related, associated, or affiliated trade associations. We believe that continuing to allow organizations to jointly use space increases the risk of inappropriate collaboration between entities that may result in credential inflation that burdens students with additional unnecessary costs, increases

the risk of explicit or tacit collusion, and encourages the outsized influence of related, associated, or affiliated trade association that results in the postsecondary institution itself having less control over the curriculum and coursework.

Changes: None.

Comments: Some commenters offered alternatives to the amendments, including:

- Allow specific services to be excepted from the rescission of § 602.14(c), including joint use of legal services, IT services, accounting firms, evaluator training, technical assistance, and professional development.

- Give the Secretary the authority to grant a waiver to the joint-use prohibition for good cause.

- Specify that employment by a professional organization serving the same field as an accrediting agency's programs does not, by itself, indicate a lack of independence.

- Adopt a functional independence standard.

- Strengthen safeguards as opposed to institute a categorical exclusion.

- Clarify the scope of communication restrictions.

- Allow States sufficient time to amend their statutes and regulations.

- Provide a multi-year transition period for recognized agencies.

Discussion: We decline the commenters' suggestions; for the rationale, please see the immediate previous discussion to this section. The Department understands that agencies will have questions regarding implementation of the final rule. We cannot address every situation within the regulations because the regulations are meant to be the general framework. We believe that the commenters' requests are subregulatory in nature, and we may offer subregulatory guidance as necessary to inform implementation.

Changes: None.

Comments: One commenter suggested edits to the waiver provisions under the § 602.14(d) waiver.

Discussion: We decline suggestions to the waiver provisions because the final rule removes the waiver provisions.

Changes: None.

§ 602.15 Administrative and Fiscal Responsibilities

Comments: Several commenters offered general support for the amendments to § 602.15.

Discussion: We thank the commenters for their support.

Changes: None.

Comments: A few commenters supported the repeal of the prescriptive

body-composition mandates at § 602.15(a)(3) and § 602.15(a)(4).

Discussion: We agree and thank the commenters for their support.

Changes: None.

Comments: A few commenters were concerned that § 602.15(a)(3) would allow individuals who have never worked in a specific field to participate in the educational evaluation processes. Additionally, another commenter was concerned that the removal of § 602.15(a)(4) would remove the requirement for programmatic accrediting agencies to include educators, practitioners, and/or employers on their evaluation, policy, and decision-making bodies. The commenter questioned whether evaluation bodies would be made up of individuals whose experience might not be relevant.

Discussion: The Department disagrees with the commenters' assertions. The regulations under § 602.15(a)(2) require that "Competent and knowledgeable individuals, qualified by education or experience in their own right, as appropriate for their roles".

Changes: None.

Comments: One commenter stated that § 602.15(a)(6) is not waivable, and the Department should say so expressly. The final rule should provide that where a majority of an agency's decision-making body consists of current or former senior leadership of, or fiduciaries to, institutions the agency accredits, case-by-case recusal does not satisfy § 602.15(a)(6).

Discussion: Provisions under current § 602.15(a)(6) have been removed in this final rule.

Changes: None.

Comments: Several commenters offered general support for the provisions under § 602.15(c) stating that it will help reduce costs to institutions as part of the Paperwork Reduction Act (PRA).

Discussion: We thank the commenters for their support and agree that these changes should help reduce costs overall for institutions once implemented.

Changes: None.

Comments: One commenter stated that the Department should clarify that accrediting agencies should minimize unnecessary compliance costs and avoid duplicative demands when the same evidence is already available through other sources.

Discussion: We believe there is already language under § 602.15(c) that speaks to the commenter's request and that states "The agency conducts its accreditation activities in a manner that seeks to avoid unnecessary financial,

compliance, and administrative burdens, including by avoiding duplicative reporting, excessive documentation requirements, and unwarranted prescriptive processes."

Changes: None.

Comments: A few commenters stated that the Department has not adequately explained how it would determine whether an accreditation activity or requirement creates an "unnecessary" burden or how this provision would be applied through the recognition process. Commenters recommended that the Department should clarify those items in § 602.15(c).

Discussion: The Department declines this recommendation because adding such factors to the regulations would result in requirements that are too prescriptive and narrow. The Department may provide additional subregulatory guidance on this issue in the future if we determine that there is sufficient lack of understanding among accrediting agencies.

Changes: None.

Comments: One commenter encouraged the Department to examine functional relationships among accrediting agencies, professional associations, testing organizations, certification bodies, and other organizations.

Discussion: We believe we have struck a fair and nuanced balance under the regulations in § 602.14 and § 602.15 to reduce conflicts of interest between recognized agencies and their stakeholders. The Department recognizes that professional associations, testing organizations, certification bodies, and other organizations can provide valuable expertise, information, and services that contribute to effective accreditation. Such cooperation can improve the development of accreditation standards, facilitate the evaluation of educational quality, and reduce unnecessary duplication of effort.

At the same time, these organizations may have interests that differ from those of students and the public. The Department's regulations are intended to prevent relationships that create conflicts of interest or give outside organizations inappropriate influence over accreditation standards or other decisions, without unnecessarily restricting legitimate collaboration or the exchange of expertise. The Department believes this approach preserves the benefits of cooperation while ensuring that accrediting agencies remain accountable for independently carrying out their responsibilities to protect educational quality and the public interest.

Changes: None.

Comments: Under § 602.15(d), the Department requires that an accrediting agency will cooperate with other accrediting agencies and the Department in the development of common templates and forms for institutions or programs to submit when seeking to change accrediting agencies. One commenter suggested that the Department add language clarifying that an agency is not required to modify its standards or process for seeking accreditation as a part of the collaboration. The same commenter suggests that language be added to § 602.15(d) to clarify what is meant by "will cooperate with other agencies and the Department in the development of common templates and forms for institutions or programs to submit when seeking to change accrediting agencies." Lastly, the commenter suggests that language should be added to the regulations indicating that participating in the collaboration required by § 602.15(d) does not violate antitrust laws.

Discussion: We decline to accept the commenter's suggestions. The Department does not dictate an agency's standards. Per § 602.16 and § 602.17, we only note which areas an agency must have standards for and how those standards are applied. Additionally, this provision does not require an agency to modify its accreditation process because of any cooperation with another recognized agency.

All forms that the Department requires an accrediting agency to use must complete a process called an information collection request (ICR). ICRs have public comment periods; therefore, all agencies will be able to weigh in on forms or templates related to institutions or programs seeking to change agencies. The Department would not publish a form that violated antitrust laws. In addition, we do not enforce the antitrust laws, so it would not be appropriate to create an exhaustive list of regulatory provisions that do not violate antitrust laws.

Changes: None.

Comments: One commenter recommended extending the cooperative-format principle to academic records by amending § 602.15(d) to read, "The agency will cooperate with other agencies and the Department in the development of common templates and forms, and common data formats for the exchange of academic records and transfer of credit information, for institutions or programs to submit when seeking to change accrediting agencies or when

evaluating credit earned at another institution.”

Discussion: We decline to accept the commenter’s suggestion. The Department does not seek to standardize the entire accreditation process. Institutions and programs still need the flexibility to develop forms and output documents that best meet the needs of their specific student populations.

Changes: None.

Comments: Some commenters suggested removing § 602.15(e)(2). Commenters believe that the new requirements dictate the governance structures of private entities. Commenters interpreted the provision as beyond the narrow items delineated in Section 496(b)(2) of the HEA regarding public members and stated that an agency must be free to determine how it organizes its governance.

Other commenters stated that the regulation would require that an accrediting agency’s decision-making body not have the authority to set standards or policy if its members are also representatives of impacted institutions or programs. Commenters believe that the provision effectively prohibits peer review. Due to changes under § 602.3 that eliminate the requirement for peer review, commenters questioned who the Department expects to be a part of an agency’s review process of an institution.

Discussion: The commenters concerns are unfounded because these regulations are fully within the Department’s authority and are simply common-sense steps to prevent conflicts of interest by individuals who set an agency’s standards. The regulations prevent such individuals from setting standards that directly benefit their institution or program(s). The provision continues to allow anyone the agency chooses to be a member of the standards-setting body, which may include members of the agency’s decision-making body. However, the members of the standards-setting body cannot vote to adopt or revise standards or policies if they are an officer, director, or employee of an accredited institution or program because of the conflict of interest that this poses.

There is nothing to restrict an agency from including in its decision-making body employers, students, practitioners, administrators, academics, and/or educators from institutions or programs not accredited by the agency. This provision also does not limit members regarding other responsibilities of the decision-making body, which can include fiduciary, accreditation decisions, procedures for implementing

standards and policies, and other administrative procedures.

Changes: None.

Comments: Some commenters opposed the requirements for operational separation from related, associated, or affiliated trade association or professional organization under § 602.15(e)(4). The commenters stated that the provisions will substantially increase the cost of accreditation while also limiting the clinical, surgical, and educational expertise available to inform standards that directly affect the preparation of future podiatric physicians and surgeons. Several commenters were concerned that the requirements would go significantly beyond ensuring independent accreditation decision-making by prohibiting the sharing of personnel, services, facilities, equipment, information technology infrastructure, and office space with an affiliated professional organization. One commenter requested that the Department allow specialized and professional accrediting agencies to demonstrate independence through effective, enforceable safeguards rather than requiring complete physical and operational separation in all circumstances.

Discussion: Similar to responses under § 602.10 and § 602.14, the Department strongly believes that the shared use of resources, personnel, services, equipment, facilities, information technology, and office space, has led to the outsized and direct influence of related, associated, or affiliated trade association over accreditation standards and decisions.

These arrangements can give trade associations influence over the selection, supervision, and compensation of personnel, control over budgets and access to essential services, and access to confidential accreditation information. Even in the absence of direct interference in individual accreditation decisions, an accrediting agency’s dependence on a trade association for essential operational resources can compromise its ability to establish standards, conduct evaluations, and make accreditation decisions independently, particularly when those decisions conflict with the interests of the trade association or its members.

Such influence can harm students and the public in several ways. A trade association may have an interest in protecting its members from adverse accreditation decisions, even when those decisions are necessary to protect students. It may also seek to weaken standards that impose costs on its

members or, conversely, support unnecessarily restrictive standards that protect established institutions from competition and innovation. These conflicts of interest can result in students receiving an inadequate education, incurring debt for credentials of limited value, or being denied access to lower-cost or innovative educational opportunities. They can also expose taxpayers to losses when institutions that fail to provide adequate educational quality continue to participate in the Federal student aid programs.

Changes: None.

Comments: One commenter recommended that the Department should expressly state that “services” include legal, compliance, insurance, indemnification, government-relations, lobbying, communications and risk-management services.

Discussion: The Department declines to define “services” further. We believe the term used here is intentional and is widely understood within the community at-large. The regulations prevent accrediting agencies from sharing resources with any related, associated, or affiliated trade association or professional organization, including, but not limited to, services. All of the items cited by the commenter would be included in the umbrella concept of “shared resources,” and this term should be interpreted broadly.

Changes: None.

Comments: A few commenters opposed § 602.15(e)(5) entirely. One commenter stated that professional affiliation within the broader field does not necessarily create a conflict. The commenter recommended that the rule focus on whether an individual’s relationship creates a conflict that could compromise the specific decision. The commenter also recommended that the Department consider clarifying that recusal applies to decisions affecting an institution or program with which an individual has an officer, director, or employee relationship. This approach could avoid extending recusal requirements to circumstances in which an individual’s professional expertise or employment within the broader field does not create a conflict with the specific matter under consideration.

Discussion: We believe that the provision is clear and does not require additional clarification. Again, the Department strongly believes that close relationships between accrediting agencies and related, associated, or affiliated trade associations has led to the outsized and direct influence of accreditation standards and decisions. This provision ensures that the conflict

of interest is removed from the agency and the aforementioned entities.

Changes: None.

Comments: One commenter supported § 602.15(e)(7), which would require an agency that acts to restrict access to a profession to show by clear and convincing evidence that, among other things, the restriction is necessary to protect the public interest and which allows such restriction to include raising the cost or level of required education or training. Placing the burden on the agency is the appropriate allocation where the agency is the only path into the profession.

Discussion: We thank the commenter for their support.

Changes: None.

Comments: Several commenters opposed § 602.15(e)(7). One commenter believed that the provision permits the Department to second guess substantive programmatic accreditation standards whenever those standards may increase credentialing expectations, educational cost, or the level of required education or training. The commenters stated that a “clear and convincing evidence” standard, applied without regard to the professional consensus underlying a standard, could place the Department in the position of second-guessing peer-developed, patient safety-driven professional judgments—such as minimum competency thresholds tied to a licensing examination—using an evidentiary standard that is difficult to satisfy for any qualitative professional judgment, however well-founded.

Discussion: The Department will not second-guess an agency’s standard as long as it can provide clear and convincing evidence that the rationale for the restriction meets the requirements of § 602.15(e)(7).

Changes: None.

Comments: One commenter requested that the Department confirm in the preamble that the public interest provision under § 602.15(e)(7) accommodates educational standards adopted to meet independent national certification and State licensure requirements and to protect patient safety in relevant fields.

Discussion: The Department agrees with the commenter in that § 602.15(e)(7)(i) requires an accrediting agency to provide clear and convincing evidence that the independent national certification requirements are necessary to protect the public interest, the expected public benefits outweigh the cost the public, and no less restrictive alternative would protect the public interest when restricting access to employment in a profession, occupation, or vocation. As noted in

§ 602.23(h) of the final rule, an agency must not have policies that require institutions or programs to violate any State law.

Changes: None.

Comments: Commenters made multiple suggestions for § 602.15(e)(7) including: (1) stating that faculty and practitioner shortages must be part of the credential inflation analysis under § 602.15(e)(7), (2) requiring a less-restrictive alternative analysis, not merely requiring quality rationale (3) requiring an occupational entry impact assessment before every material impact change, and (4) having a recognized programmatic accrediting agency require Department approval before creating a bridge, equivalency, prerequisite-approval, or academic-clearance mechanism that determines whether education completed outside the accredited program satisfies requirements for individual occupational eligibility.

Discussion: It appears the same commenter submitted multiple individual comments to § 602.15(e) with the most being to (e)(7). We decline the suggestions because we believe the commenter’s suggestions are outside of the scope of § 602.15(e)(7).

Changes: None.

Comments: One commenter recommended that the Department

- Add § 602.15(e)(7)(ii)(D): “obtaining or acting to maintain any provision of Federal or State law, regulation, or program requirement that conditions employment, appointment, licensure, certification, or reimbursement on accreditation by that agency specifically, or that excludes graduates of programs accredited by another agency.”

- Add § 602.15(e)(7)(iv): “An agency named in any Federal or State law, regulation, or program requirement described in paragraph (e)(7)(ii)(D) must disclose, in each petition for recognition, each such provision known to the agency and any communication by the agency or by any related, associated, or affiliated trade association or professional organization with the issuing authority concerning its adoption, retention, or amendment.”

Discussion: We decline the additions. As noted in § 602.23(h) of the final rule, an agency must not have policies that require institutions or programs to violate any Federal or State law. We believe the suggested amendments would be overly burdensome for agencies and produce no substantially more beneficial impact than the new final rule.

Changes: None.

Comments: One commenter recommended that the Department

- Add § 602.15(e)(8): “Publicly disclose each requirement in the agency’s own standards that obligates a student or trainee to purchase or obtain any product, service, insurance, credential, examination, or membership, together with the identity of any related, associated, or affiliated trade association or professional organization that provides, sponsors, or receives any payment or other consideration in connection with it.”

- Add § 602.15(e)(9): “Where the agency’s standards require a student or trainee to obtain any product, service, insurance, credential, or examination, the agency must require as a condition of accreditation that the institution or program . . .”

Discussion: We decline the additions. We believe they would be too prescriptive. However, accrediting agencies may voluntarily adopt the commenter’s suggestions, and the Department would encourage such transparency.

Change: None.

Comments: Some commenters suggested removing § 602.15(f) because the language is unnecessary as agencies do not and, under the law, cannot restrict an institution’s legal obligations, including regarding the First Amendment. The commenter stated that public institutions already follow Federal law to implement the First Amendment’s freedoms of religion, speech, press, assembly, and petition. Another commenter stated that agencies do not have the expertise to interpret complex constitutional law issues.

One commenter suggested alternative language: “The agency’s accreditation standards, policies must not restrict public institutions from fulfilling their obligations under the First Amendment to the Constitution of the United States. These standards similarly also must not restrict any private institutions that, through their institutional policies, guarantee the same or similar protections for students or faculty, unless the institution has a religious mission.” Finally, the commenter asked the Department to clarify “. . . unless the institution has a religious mission.”

Discussion: The Department declines the commenters’ suggestion to remove the provision. The Department seeks to remind agencies of the obligations under the Constitution as required under E.O. 14279 to ensure that “accreditors are not using their role under Federal law to encourage or force institutions to violate State laws, unless such State laws violate the Constitution or Federal law.” The Department will

maintain the reference to “enforcement practices” in the regulation to ensure that agencies understand that they cannot enforce any agency provision, standard, or policy on an institution or program that violates the First Amendment. E.O. 14279 provided examples that the administration believes were violations of the First Amendment.

Finally, regarding the phrase “unless the institution has a religious mission,” the final rule is consistent with existing law for a religious-mission institution because the institution would not be required to adopt viewpoint-range, intellectual-diversity policies, or academic-freedom protections that would conflict with that mission. The substitute duty is inquiry and student learning consistent with the mission. This is not a general exemption from 602.16 standards, eligibility for title IV, HEA funds, student-achievement standards, fiscal capacity, or the core curriculum requirement in 602.18(b)(3). Separately, the final rule also says nothing in the viewpoint-neutrality paragraph for agencies that require an accrediting agency that itself has a religious mission to be neutral with respect to viewpoints. This is an agency-level clause, not an institutional one.

Changes: None.

Comments: Several commenters sought guidance or clarifications about various provisions under this section.

Discussion: The Department may issue subregulatory guidance or clarifications regarding specific issues addressed in these regulations if, following publication of the final rule, the Department determines that further clarification is necessary to support the regulated community’s understanding and implementation of the rule.

Changes: None.

§ 602.16 Accreditation and Preaccreditation Standards

Comments: A few commenters supported the amendments to § 602.16. One commenter stated that the changes to § 602.16 would strengthen the requirements for agencies to evaluate student outcomes, which is an important improvement that would benefit students and taxpayers. Agencies would be required to set standards for student achievement at the institutional and program levels, and the proposal allows agencies to tailor those standards for each institution.

Discussion: We agree and thank the commenters for their support.

Changes: None.

Comments: Several commenters expressed concern with the amendments to § 602.16. One

commenter stated that the changes undermine longstanding professional accreditation standards and put students’ eligibility for licensure at risk. Another commenter stated that defining success solely in relation to an institution’s mission, and thereby allowing different standards for different programs, could endanger the public because veterinary licensure authorizes practice across the full scope of the profession.

Discussion: We disagree with commenters. Except for the cross reference to § 602.17(a)(1) under § 602.16(a)(1)(i), the changes to this section are technical in nature and do not reference licensure. The regulations under § 602.16(a)(1)(i) currently allow for “. . . different standards for different institutions or programs . . .”. This is not a new policy; the statute has expressly permitted different standards for different institutions and programs since 2008 and the Department’s implementing regulations since 2009.

Changes: None.

Comments: One commenter stated that the Department provided insufficient explanation for the change under § 602.16(a)(1)(i) that adds “. . . at the institutional and program level . . .”. The commenter believes that the Department cannot use the regulations to impose an additional accreditation requirement that Congress did not authorize or to dictate the level at which an accrediting agency must evaluate student achievement.

Discussion: The Department has not added additional requirements or standards to the regulations. The accrediting agency is responsible for reviewing and confirming academic quality at an institution, and that includes the programs that the institution offers. That an agency would have standards for student success at both institutional and programmatic levels is consistent with the best reading of the statute. The commenter should recognize that review at both the institutional and programmatic levels is necessary to account for variations in quality and outcomes across programs within the same institution.

Changes: None.

Comments: One commenter supported the addition of “at the institutional and program level” in § 602.16(a)(1)(i). Institution-level averages conceal program-level failure, and making the program level explicit is worthwhile even though the Department characterizes the accompanying change from “set forth clear expectations” to “establish requirements” as not altering the regulation’s effect. The commenter requested that the Department confirm

in the preamble that agencies retain discretion to apply program-level review proportionately—an institution offering more than 120 programs and one offering six programs should not face identical documentation volume requirements for the same regulatory purpose.

Discussion: We thank the commenter for their support. Yes, agencies retain discretion to apply program-level review proportionately. We thank the commenter for their support.

Changes: None.

Comments: One commenter recommended that the Department clarify that agencies in § 602.16(a)(1) should assess whether undergraduate students have access to some form of review that is structurally independent of the original decision-maker for academic and administrative grievances that do not involve discrimination.

Discussion: We decline the commenter’s recommendation because we believe the new process outlined under § 602.23(l) is sufficient.

Changes: None.

Comments: One commenter recommended that § 602.16(a)(1)(i) should include time-to-declaration and major-transition metrics for undeclared, pre-major or exploratory students.

Discussion: The Department declines to add the metrics proposed by the commenter. Such requirements would be too prescriptive, and we prefer to allow accrediting agencies to make their own decisions about exactly what to measure within the parameters of 602.16(a)(1)(i).

Changes: None.

Comments: One commenter recommended updating § 602.16(a)(1)(i) to read:

“(i) Success with respect to student achievement at the institutional and program level in relation to the institution’s mission, which may include different standards for different institutions or programs and may recognize multiple pathways to academic progress and achievement, as established by the institution, including, as appropriate, consideration of State licensing examinations, course completion, job placement rates, and credit for prior learning, as described in § 602.17(a)(1).”

Discussion: The Department declines the recommendation of the commenter as we believe that the suggestion is technical in nature. The regulation says “. . . including, as appropriate”, which gives agencies and institutions flexibility to recognize multiple pathways to academic progress and achievement.

Changes: None.

Comments: One commenter supported the proposed provision under § 602.16(f) that would permit agencies to adopt additional standards beyond Section 496 of the HEA only where those standards are lawful and consistent with ensuring institutional or programmatic quality and integrity. The commenter stated that standards that are neither required by statute nor connected to quality or integrity impose cost without producing educational value, and students pay for that cost in tuition.

Discussion: We agree and thank the commenter for their support.

Changes: None.

Comments: Several commenters opposed § 602.16(f) that states an agency may establish any additional lawful accreditation standards that are consistent with ensuring institutional or programmatic quality and integrity as it deems appropriate. One commenter stated that this provision is an open door for the current administration to use partisan influence to promote a conservative agenda. Several other commenters stated that the amendment exceeded the Department's authority and had concerns that the Department would have too much discretion to determine what "lawful" means.

Discussion: We believe the commenters misinterpreted the provision. The provision allows an accrediting agency to establish additional lawful standards, not the Department. The commenters should note that the Department has not added additional standards under § 602.16.

Changes: None.

Comments: One commenter stated that the NPRM repeatedly references that the Department will clarify the regulations in the Accreditation Handbook, including under part § 602.16. The commenter stated that because guidance is not legally binding like regulation, leaving core implementation details to future guidance creates legal and operational uncertainty for accrediting agencies and institutions.

Discussion: The Department routinely issues subregulatory guidance to clarify regulatory requirements and facilitate implementation. Consistent with this longstanding practice, the Department uses the Accreditation Handbook to provide policy and operational guidance to accrediting agencies regarding implementation of 34 CFR part 602. To the extent the commenter's requests concern matters appropriately addressed through subregulatory guidance, the Department may provide further clarification, including through

the Accreditation Handbook, as necessary to support implementation.

Changes: None.

Comments: One commenter expressed strong support for the regulations under § 602.16(g)(3) and (g)(4).

Discussion: We appreciate the commenter's support. Please note that there are no proposed changes to these provisions.

Changes: None.

Comments: One commenter requested that the Department add § 602.16(g): "The agency's requirements must be stated in its own published standards. The agency may not require institutions or programs to conform to, or evaluate them against, the standards, the code of ethics, code of conduct, guidelines, policies, or positions of any other organization, whether by incorporation by reference or otherwise, except as required by applicable Federal or State law."

Discussion: We decline to accept the commenter's recommendation. We believe that the suggestion is already covered under § 602.18(a)(3).

Changes: None.

Comments: One commenter stated that proposed § 602.16(f) permits an agency to establish "any additional lawful accreditation standards." The commenter requested that the Department confirm in the final rule that a standard requiring an institution, its faculty, or its students to affirm a contested viewpoint as a condition of accreditation is not a "lawful" standard within the meaning of § 602.16(f).

Discussion: If faculty or a student believes that an agency is inappropriately or illegally requiring them to affirm a contested viewpoint, they can file a formal complaint with the agency itself. If the resolution is not satisfactory to the faculty or student, they can submit formal complaints about an agency to the Department at aslrecordsmanager@ed.gov or call 202-453-7615. The commenter may also attend a NACIQI meeting and provide public comment regarding an accrediting agency. The Department encourages the commenter to consult the **Federal Register** and the NACIQI website for announcements and information regarding upcoming meetings and opportunities for public comment.

Changes: None.

Comments: One commenter made multiple individual recommendations for § 602.16, including:

- Require accreditation standards to distinguish objective competency requirements from global discretionary judgments.

- Require that if a program director signs or transmits a verification document, the recipient should know what exactly is being attested.

- Direct agencies to prefer licensure outcomes, completion, validated competency performance, employment outcomes.

- Prohibit program completion documents from becoming private occupational licenses.

- Be aware that accreditation should set outcomes, not create a national ladder from associate through graduate education.

- State that Federally recognized accrediting agencies may define minimum educational outcomes but may not prescribe subordinate curricular architecture, competency taxonomies, assessment methods or progression systems unless those prescriptions satisfy a documented necessity and least restrictive-alternative test.

Discussion: We thank the commenter for submitting multiple thoughtful recommendations to this section of the rule; however, we decline to accept them because they go beyond the statutory framework, and we believe that they are more aspirational requests than specific regulatory proposals.

Changes: None.

§ 602.17 Application of Standards in Reaching Accreditation Decisions

Comments: Several commenters offered support for the amendments under § 602.17(a)(1). One commenter stated that agencies have not always done a good job upholding high standards of student achievement. The commenter stated that agencies also rarely sanction their member institutions for poor student outcomes. The Department's language does not specify a single numerical cutoff where agencies need to set their minimum expectations, but they must have minimum expectations documented. The commenters stated that one of the most critical minimum standards for agencies to enforce is the minimum expectations for retention, completion, and graduation rates.

Discussion: We agree and thank the commenters for their support. We believe that these amendments provide reasonable parameters that accrediting agencies can use to ensure educational quality without imposing specific mechanisms that agencies must use in their evaluation of institutions or programs.

Changes: None.

Comments: The largest percentage of comments focused on the proposed changes in § 602.17. Commenters raised

concerns about: (1) the Department's focus on economic returns in the assessment of student achievement, which they believed did not properly take into account institutional type or mission; (2) the inclusion of cost/benefit analysis when agencies are evaluating compliance with standards for facilities, equipment, and supplies and student support services; (3) the lack of availability of reliable data to assess student success outcomes with respect to student achievement under § 602.17(a)(1)(ii); (4) infringement into institutional autonomy, governance, and management, especially in regards to faculty; (5) minimal guidance or explanation of the new provisions; (6) administrative burden and cost implications; (7) the Department's lack of authority to add standards; and (8) how the Department will enforce provisions containing the phrases "academic freedom" and "intellectual diversity."

Commenters offered language suggestions, revisions, clarifications, and many asked for complete rescission of the proposal. Several institutions requested that the agencies that accredit their institutions receive special considerations with the final rule based on the populations they serve, including but not limited to religious institutions/programs, minority-serving institutions, tribal colleges and universities, small institutions, liberal arts institutions, and specialized institutions. If no changes are made in the final rule, some commenters requested that the Department release extensive subregulatory guidance explaining each of the provisions.

Discussion: For more information regarding the Department's legal authority to establish these requirements, please see the *Legal Authority* section of this final rule.

The changes to this section do not prescribe thresholds. An agency retains the authority to establish a threshold for compliance with the standards. The Department believes these changes will strengthen educational quality by prioritizing positive student outcomes over procedural compliance requirements that lack a demonstrated connection to those outcomes. These changes will result in lower costs for taxpayers and an increase in benefits for students. The Department declines to offer exceptions or carve-outs to these provisions because we seek to standardize application of the standards.

Following publication of the final rule in the **Federal Register**, the Department may issue nonbinding subregulatory guidance if it determines that additional

clarification is necessary to facilitate implementation.

Changes: None.

Comments: Some commenters opposed the amendments under § 602.17(a)(1). Opposition included, but was not limited to, legality, cost to agencies and institutions, lack of necessary data, and too much focus on the return-on-investment metrics.

Commenters stated that the proposal exceeds the Department's authority and constitutes Federal overreach. 496(a)(5) of the HEA prescribes the specific standards for accreditation. Some commenters believe that the Department has added new standards that do not currently exist in statute. The commenters often cited Section 496(g) of the HEA as expressing Congressional intent on the limitation of the Department's authority to establish additional standards: "Nothing in this Act shall be construed to permit the Secretary to establish criteria for accrediting agencies or associations that are not required by this section. Nothing in this Act shall be construed to prohibit or limit any accrediting agency or association from adopting additional standards not provided for in this section. Nothing in this section shall be construed to permit the Secretary to establish any criteria that specifies, defines, or prescribes the standards that accrediting agencies or associations shall use to assess any institution's success with respect to student achievement." Commenters cited Section 496(o) that states the Secretary "shall not promulgate any regulation with respect to the standards of an accrediting agency or association described in subsection (a)(5)."

Commenters also cited Section 103 of the Department of Education Organization Act as evidence of Congressional intent on the limits of the Department's authority: "No provision of a program administered by the Secretary or by any other officer of the Department shall be construed to authorize the Secretary or any such officer to exercise any direction, supervision, or control over the curriculum, program of instruction, administration, or personnel of any educational institution, school, or school system, over any accrediting agency or association, or over the selection or content of library resources, textbooks, or other instructional materials by any educational institution or school system, except to the extent authorized by law."

Commenters stated that amendments are too rigid and by themselves do not reveal the quality or value of an institution. Commenters stated that

educational quality cannot be measured solely through completion rates, employment outcomes, licensure exam results, or other metrics related to programs' return on investment. Other comments stated that the regulations will increase compliance costs to agencies and institutions, which will shift focus for quality to compliance for agencies and institutions and ultimately increase costs for students.

Finally, commenters stated that the Department's original proposal listed these requirements under § 602.16, but they were moved to § 602.17 during a subsequent day of negotiated rulemaking. Commenters believed that this was a tacit acknowledgement by the Department that it was adding extra-statutory standards.

Commenters offered many suggestions to the proposed regulations, including, but not limited to, rescinding the proposal or making the amendments optional or providing exceptions or carve-outs for a wide range of institutions and programs.

Discussion: We disagree with the commenters' statements. Sections 496(g), (o), and (p) limit the Secretary's authority to prescribe the substantive content of accreditation standards, particularly student achievement standards. They do not prohibit the Secretary from regulating how recognized agencies apply and enforce their standards. Section 496(a)(4)(A) expressly requires the Secretary to determine that an agency "consistently applies and enforces standards," and Sections 496(a)(6) and (c) establish requirements governing accreditation review and general operating procedures, respectively.

The Department therefore interprets Section 496 as distinguishing between prescribing the substance of an accrediting standard and establishing recognition criteria governing the consistent and lawful application of an agency's own standards. The Department maintains that the substance of this section is related to the Department's evaluation of how an agency applies its standards, and does not prescribe the content of the standards themselves.

For further discussion please refer to the *Legal Authority* section of this final rule. The Department is not providing exceptions to requirements in the regulations because the statute does not support the positions advocated by the commenters. The regulations follow the statute in establishing clear, uniform criteria for recognition of agencies, with only minimal differentiation in requirements between institutional and programmatic accrediting agencies.

Changes: None.

Comments: Several commenters supported language related to academic freedom and intellectual diversity throughout § 602.17(a)(2). Commenters stated that academic freedom and intellectual diversity reflect the principles that characterize American higher education. Another commenter stated that expecting agencies to evaluate intellectual diversity and protect open inquiry is not political bullying; it is a long-overdue return to basic academic standards. Assessing whether an institution allows diverse viewpoints directly measures whether it is actually teaching critical thinking.

Discussion: We agree and thank the commenters for their support.

Changes: None.

Comments: Some commenters opposed language related to faculty, academic freedom, and intellectual diversity throughout § 602.17(a)(2). Commenters stated the following in opposition to the provisions:

- They believe the proposed changes are unconstitutional and infringe on free-speech protections. Some commenters believe that the Department will target agencies and institutions that do not align with the Administration's agenda or political ideology. As a result, agencies will limit faculty speech at accredited institutions for fear of losing recognition, and institutions will limit faculty speech for fear of losing accreditation.

- They believe that the changes are unlawful, and raise objections similar to those that they raised in opposition of § 602.17(a)(1).

- They believe that the preamble to the NPRM effectively encourages institutions to use the Department's definition of "academic freedom" and may functionally compel agencies to adopt standards prescribed by the Department.

- They believe that the evaluation criteria will influence faculty behavior and encourage self-censorship even without directly restricting speech, particularly when they affect hiring, promotion, tenure, research, instruction, shared governance, or continued employment.

- They believe that there are no clear definitions of concepts like: "academic freedom", "intellectual diversity", "sufficient number of appropriately qualified faculty", "regularly evaluated on the performance of their instructional, research, or service responsibilities". The concepts are vague and can be misused to justify any adverse action that the Department seeks to take against an accrediting agency or institution.

- They believe that accrediting agencies lack the legal expertise and authority claims of constitutional and other legal violations, faculty speech disputes, and whether institutions have achieved sufficient intellectual diversity.

Discussion: See prior discussion under Legal Authority and § 602.17(a)(1) of this final rule. Academic freedom and intellectual diversity are important considerations in evaluating the quality of higher education. The new regulations require accrediting agencies, when applying their standards, to consider institutional policies and practices relating to academic freedom and intellectual diversity. Contrary to the hyperbole exercised by several commenters, the new regulations also do not prescribe the content of policies relating to academic freedom and diversity, do not require institutions to adopt particular policies, and do not require accrediting agencies to establish separate substantive standards in these areas.

An institution's decision not to adopt a formal policy on academic freedom or intellectual diversity does not, by itself, constitute noncompliance. Rather, an accrediting agency must consider relevant institutional policies and practices in the context of its existing standards and the institution's mission. Where an agency has adopted standards addressing these matters, it must apply and enforce those standards consistently.

These provisions govern the process by which accrediting agencies evaluate institutions, rather than prescribing particular accreditation standards.

Changes: None.

Comments: Several commenters had concerns with the required cost/benefit analysis under § 602.17(a)(3). Commenters stated that they believe that the requirement infringes on institutional governance, will increase costs and burden to institutions, and that the regulation is vague and unclear. A few commenters asked for clarification on whether the agency or institution conducts the cost/benefit analysis.

Discussion: The Department disagrees with the commenters. The Department provides more than \$100 billion annually in Pell Grants and Federal student loans, a substantial portion of which supports institutional revenue through tuition, fees, and other charges. Many institutions depend on these Federal student aid programs to sustain their operations. Accordingly, the Department has a responsibility to ensure that institutions receiving Federal funds exercise sound fiscal

stewardship, including by conducting meaningful cost-benefit analyses and evaluating how institutional spending decisions affect costs borne by students.

Section 602.16(a)(1)(iv) currently requires that an "agency's accreditation standards must establish requirements for the institutions or programs it accredits" in the area of "Facilities, equipment, and supplies." Because cost/benefit analysis is an integral part of responsible capital investment planning, the Department is requiring agencies to review whether institutions have conducted cost/benefit analysis and for agencies to review them if they are performed by an institution.

We disagree that this provision infringes on institutional governance because it only requires agencies to review analysis that is performed; there is no requirement for any institution to do or enact anything.

Cost-benefit analysis decreases costs and increases educational quality for students by ensuring that capital expenditures are properly scrutinized and justified.

Changes: None.

Comments: Several commenters supported replacing a mandatory self-study format with a comprehensive process that may include a self-study under § 602.17(b). One commenter noted that the change preserves rigorous evaluation while allowing institutions and accrediting agencies to use better and more efficient methods to demonstrate quality and continuous improvement.

Discussion: We agree and thank the commenters for their support.

Changes: None.

Comments: Several commenters opposed replacing a mandatory self-study format with a comprehensive process that may include a self-study under § 602.17(b). One commenter stated that accreditation should be an opportunity for an academic community to reflect on its internal practices as it typically leads to new insights and practices like how to more effectively assess whether classes are meeting student learning outcomes. Another commenter stated the self-study is a fundamental component of the peer-review process, providing institutions and programs an opportunity to evaluate their own performance against an agency's standards and identify areas for improvement before and during peer review.

Discussion: We agree with commenters that an institution or program should reflect on its internal practices and gain new insights on how to improve student learning outcomes. Under this final rule, we added more of

a regulatory framework under § 602.17(a)(1)(i) to help guide agencies on how to apply accreditation standards that focus on the assessment of critical student outcomes. These outcomes include, as applicable, State licensing or certification examination results; post-completion or graduation outcomes, including employment and continued education; and educational and economic returns evaluated in relation to the program's credential level, length, occupational context, and total cost of attendance.

We do not share commenters' belief that a self-study is the only assessment approach in determining educational quality. The Department has not rescinded the requirement for institutional or programmatic review, given that under this final rule, an institution or program must be able to conduct a comprehensive review that will help in assessing the educational quality. Instead of maintaining a one-size-fits-all approach, the Department is providing agencies with the flexibility to innovate its comprehensive self-evaluation process.

Changes: None.

Comments: Some commenters opposed language under § 602.17(g) and (h) because they believe the provision could cause institutions to abandon lawful outreach, recruitment, support, research, or demographic data collection out of fear for their accreditation.

Discussion: The provision does not eliminate lawful outreach, recruitment, support, research, or demographic data collection. Instead, it prohibits an agency from having standards that require institutions to violate Federal or State law. For example, on June 29, 2023, in *Students for Fair Admissions, Inc. v. President and Fellow of Harvard College*, 600 U.S. 181 (2023),¹⁰ the U.S. Supreme Court held that an institution violates the Constitution's Equal Protection Clause and Title VI of the Civil Rights Act when it uses race-based admissions programs that provide substantive advantages to applicants based upon their race. This means that an agency cannot have standards that encourage, direct, or otherwise require institutions or programs to have admissions targets based on race.

Changes: None.

§ 602.18 Ensuring Consistency in Decision-Making

Comments: Several commenters supported the provision in paragraph

§ 602.18(b)(4) that requires that agency decisions are neutral with respect to viewpoint and ideology that are unrelated to its accrediting policies or standards, except in the case of an agency with a religious mission. Several commenters provided personal testimony of when they believed agencies that accredited their institutions were not viewpoint neutral.

One commenter stated that a neutrality standard holds that accrediting agencies may not condition accreditation on an institution's adoption of any contested philosophical or theoretical framework. The commenter suggested that the Department release implementation guidance stating the following: "In determining whether an agency is a reliable authority as to the quality of education or training offered, the Secretary shall consider whether the agency conditions accreditation on an institution's or program's adoption of specific philosophical, theoretical, or ideological frameworks that are contested within the relevant scholarly literature. An agency may require student engagement with bodies of scholarly knowledge relevant to professional practice."

Another commenter stated that accrediting agencies should apply legitimate quality standards without rewarding favored institutions or punishing disfavored ones because of viewpoint.

Discussion: We thank the commenters for their support. While we do not agree with implementing the commenter's suggested text, the Department may offer subregulatory guidance as necessary with the appropriate guidance for the field to inform implementation.

Regarding commenters that had concerns about an accrediting agency, commenters can submit formal complaints about an accrediting agency to the Department by emailing aslrecordsmanager@ed.gov or calling 202-453-7615. The commenters may also attend a NACIQI meeting and provide public comment regarding an accrediting agency. The Department encourages the commenters to consult the **Federal Register** and the NACIQI website for announcements and information regarding upcoming meetings and opportunities for public comment. Please refer to the Implementation Date of These Regulations section of this final rule when submitting complaints about an agency regarding regulations that may not yet be effective.

Changes: None.

Comments: Some commenters were opposed to § 602.18(b)(4), which

requires viewpoint and ideological neutrality. Many of these commenters expressed their belief that political officials at the Department could characterize legitimate academic-quality decisions as ideological discrimination. Commenters also believe the requirements to be too vague and undefined. Some commenters stated that this provision, in combination with provisions under § 602.17 related to academic freedom and intellectual diversity, will grant the Federal government authority to scrutinize academic governance, faculty hiring and evaluation, and academic freedom of institutions. Several commenters stated that this requirement seems to be diametrically opposed to the repeated rationalization by the Department for the proposed regulation change, which was to reduce the administrative and financial burden required of accreditation.

Discussion: The Department disagrees with the commenters' assertions. The Department is regulating in this area to ensure that no viewpoint is preferred. This regulation ensures that accrediting agencies remain neutral and prioritize diversity of thought on campuses. A commenter to this rule offered a relevant summary of the provision by writing that "The neutrality principle we endorse forecloses both outcomes equally. Accrediting agencies may require student engagement with bodies of scholarly knowledge relevant to professional practice; they may not require that students demonstrate adoption of, or alignment with, any particular interpretation of that knowledge. This principle derives its durability precisely from its symmetry: it binds future Departments as much as it binds current ones, and it binds in both ideological directions."

Changes: None.

Comments: A few commenters questioned why agencies and institutions with a religious mission were exempt from the requirement under § 602.18(b)(4). One commenter stated that there is no alternative accountability mechanism for agencies with a religious mission. Another commenter stated that the proposal prioritizes religious accrediting agencies despite the United States having a longstanding separation of State and religion. Increasing religious prioritization neglects positions of public trust, improperly shifts focus away from student achievement to compelling institutions to adopt illegal and discriminatory religious ideology and practices, and intrudes on State and local authority.

¹⁰ *Students for Fair Admissions, Inc. v. President and Fellow of Harvard College*—https://www.supremecourt.gov/opinions/22pdf/20-1199_hgdj.pdf.

Discussion: The Department must exempt agencies with a religious mission from this provision because the First Amendment guarantees the free exercise of religion. Regulations limiting the free exercise of religion are contrary to the U.S. Constitution.

Changes: None.

Comments: One commenter requested that under 602.18(b)(4) the Department narrow the scope of the provision to prohibit specific, identifiable coercion: an agency may not condition accreditation on requiring students or faculty to affirm a particular ideological position or penalize an institution solely for protected academic speech.

Discussion: The provision does not allow an agency to require students or faculty to affirm a particular ideology. The provision requires the agency itself to make decisions that are neutral with respect to viewpoint or ideology of the accredited institution or program. An agency cannot penalize an institution or program solely for protected academic speech; freedom of speech is a constitutionally protected right, which the Department affirms under § 602.15 and § 602.17.

Changes: None.

Comments: One commenter recommended that the Department amend § 602.18(b)(4) to read: “Has adopted and followed procedures to ensure that agency decisions are neutral with respect to viewpoint and ideology that are unrelated to its accrediting policies or standards, except that nothing in this paragraph requires an accrediting agency with a religious mission to be neutral with respect to viewpoints, and nothing in this paragraph shall be construed to limit paragraph (a) or paragraph (b)(3) of this section, or to require an agency to treat as a departure from viewpoint or ideological neutrality an institution’s or program’s religious mission-based policies, decisions, and practices evaluated under paragraph (b)(3) of this section or under § 602.17(a)(2).”

The commenter claims that the exception in § 602.18(b)(4) is written for the accrediting agency and the religious-mission provisions at § 602.18(b)(3) and § 602.17(a)(2), by contrast, are written for the institution.

Discussion: We decline to accept the suggested language. This provision specifically provides an exemption for agencies with a religious mission to ensure viewpoint neutrality. Provisions under § 602.17(a)(2) require all agencies to apply standards related to an institution’s faculty that are consistent with the institution’s religious mission. We believe that the regulatory text provides the necessary clarity.

Changes: None.

Comments: One commenter requested that the Department protect descriptive and empirical scholarship. The use of demographic categories or terminology in legitimate research should not, by itself, be treated as evidence that scholarship advances a particular political or ideological agenda.

Discussion: Generally, the use of demographic categories or terminology in legitimate research should not, by itself, be treated as evidence that scholarship advances a particular political or ideological agenda. However, the Department cannot opine on hypothetical situations. Once the final rule is effective, the Department will confront issues related to specific agencies, institutions, programs, or students as they arise.

Changes: None.

Comments: One commenter offered support for the amendments to § 602.18(c), which broaden the alternative standards provision to reach practices that advance credential and degree completion and promote new models of education. The commenter asked the Department to confirm in the preamble that § 602.18(c) is available as a pathway for approving direct assessment and competency-based programs pending any broader Departmental action on the credit hour.

Discussion: Nothing prevents an accrediting agency from applying the flexibility in § 602.18(c) to its review process for direct assessment programs. However, in this circumstance, the agency must ensure that its approval process for direct assessment programs meet the requirements under § 668.10 and all other requirements in this part.

Changes: None.

Comments: One commenter opposed the Department’s proposal to broaden § 602.18(c) beyond “special circumstances” and “undue hardship on students,” and the three-year renewable noncompliance window. The commenter asserted that, taken together, these provisions convert what is supposed to be a narrow safety valve into a general license for indefinite noncompliance. The commenter recommended restoring current § 602.18(c) and limiting any noncompliance period to the timeframe in § 602.20(a)(2) without a separate extension mechanism.

Discussion: We believe the commenter was referring to § 602.18(d). The Department’s regulations do not permit indefinite noncompliance. Regulations under § 602.20(a)(2) apply to the amendments under § 602.18(d). The amendments under § 602.18(d) are solely meant to provide a good cause

extension to demonstrate compliance for circumstances outside the institution’s or program’s control, such as a natural disaster.

As noted in the NPRM, current regulations under § 602.18(d) are moved to § 602.20(i) with modifications.

Changes: None.

§ 602.19 Monitoring and Reevaluation of Accredited Institutions and Programs

Comments: One commenter recommended that § 602.19(b) be amended to add a requirement that an agency’s monitoring and evaluation approaches include a mechanism to track whether a self-identified institutional concern has appeared in similar language across prior review cycles and apply a heightened monitoring or documented-improvement standard once such recurrence is identified, rather than resetting to a standard review each cycle.

Discussion: The Department appreciates the suggestion of the commenter around Section 602.19; however, this section was not discussed in the negotiated rulemaking process or included in the revised final rule and remains unchanged.

Changes: None.

§ 602.20 Enforcement of Standards

Comments: A few commenters offered general support for the amendments to this section, in combination with regulations under § 602.18 and § 602.25. One commenter stated that institutions should know the standards that apply, receive notice of deficiencies, have reasonable time to respond, and hold a meaningful process for review.

Discussion: We agree and thank the commenters for their support.

Changes: None.

Comments: One commenter stated that § 602.20(h) is unclear as proposed. Specifically, the commenter argues that the phrase requiring an agency to “have a policy for restoring accreditation” is not consistent with the language later in § 602.20(h) indicating that the agency has the authority to determine the circumstances for when such restoration of accreditation is “appropriate.” In turn, the commenter asserts that the notion that an agency may determine the circumstances for when restoring accreditation is appropriate does not align with the phrase “including if required by an applicable judicial decision.”

Discussion: We disagree with the commenter. We believe § 602.20(h) clearly requires a restoration of accreditation policy that must, at a minimum, include the process for

restoring accreditation when required to do so by an applicable judicial decision. An accrediting agency is not prevented from restoring accreditation in circumstances other than judicial orders, but can include any circumstances that it determines are appropriate for a restoration of accreditation.

Changes: None.

Comments: One commenter stated that provisions under § 602.18(d) and § 602.20(i) are duplicative and inconsistent. The commenter stated that the two substantially overlapping provisions permit an agency to allow an institution to remain out of compliance for a period not to exceed three years.

Discussion: We believe the commenter has misinterpreted the regulations. There is no § 602.18(d) in the new regulations. Items under § 602.18(d) have been moved and amended under § 602.20(i).

Changes: None.

Comments: A few commenters stated that the compliance timeline under § 602.20(a)(2) may be too long for some programs and too rigid for all. One commenter stated that an agency that continues to certify quality while an institution spends four years out of compliance with that agency's own standards is not acting as a reliable authority, and students continue to enroll and borrow throughout. The commenter recommended to make the cap a ceiling rather than a default. The commenter further requested that the Department require that any timeline beyond one year be accompanied by a public statement of the agency's reasons, intermediate checkpoints with defined consequences for missing them, and notice to enrolled students that the institution is operating under a compliance plan.

Discussion: These provisions are current regulations, and the Department has not proposed changing them in the proposed rule or the final rule. Agencies, institutions, and programs have been operating under these rules prior to the new regulations; therefore, the Department sees no reason to update them at this time.

Changes: None.

Comments: Referring to the preamble explanation for the amendments to § 602.20(a)(4), one commenter stated that the final rule should adopt the same functional approach to transparency. Whether an agency calls a status a warning, show cause, probation, special report, heightened monitoring, follow-up report, compliance report, or another term should not determine whether the institution receives a specific written explanation. The trigger should be the

substance of the action: when an agency has identified an institution-specific compliance concern and, as a result, imposes a special reporting requirement, corrective-action requirement, heightened status, or other out-of-cycle obligation, the institution should receive the material basis and requirements in writing.

Discussion: Because the commenter did not provide a specific provision(s) to amend, the Department cannot respond thoroughly to the request. We believe that these rules already require an agency to communicate non-compliance with any standard to accredited institutions or programs in writing, no matter the term or status used by the agency, in § 602.20(a).

Changes: None.

Comments: A few commenters stated that changes would undermine efforts to resolve disputes between institutions and accrediting agencies through arbitration. Such mechanisms and procedures can provide institutions and agencies with a more efficient and less costly means of resolving disputes while preserving appropriate legal and procedural protections. One commenter stated that Federal regulations should not inadvertently undermine those mechanisms in favor of protracted administrative proceedings or litigation. To the extent institutions and agencies have established lawful processes for resolving disputes efficiently and fairly, the Department should preserve, and even encourage, the use of those processes to reach a binding outcome.

Another commenter urged the Department to utilize binding arbitration as an available means of resolving accreditation disputes and to reconsider changes to the existing due process framework that are unnecessary to protect institutions and may ultimately make those protections less effective. Another commenter stated that an accurate reading of both the statute and the regulation in fact permits accrediting agencies to require binding arbitration prior to the initiation of any other legal action.

One commenter provided alternative language:

“(e) All adverse actions taken under this subpart are subject to the arbitration requirements in 20 U.S.C. 1099b(e). Nothing in this section prescribes whether arbitration must be binding or nonbinding, which is determined by the agreement of the parties or applicable law. Agency policies governing the arbitration of disputes must: (1) Apply to all final adverse actions, however, an agency may require the institution or program to first exhaust the agency's appeal process;”.

Discussion: The Department refers the commenters to the relevant discussion in the NPRM, which states Section 496(e) of the HEA states that “The Secretary may not recognize the accreditation of any institution of higher education unless the institution of higher education agrees to submit any dispute involving the final denial, withdrawal, or termination of accreditation to initial arbitration prior to any other legal action.” Based on the statute, arbitration cannot be binding, because the statute only refers to “initial” arbitration and provides that the institution may still instigate “any other legal action” after arbitration. A binding arbitration agreement would prevent the institution from pursuing any other legal action. However, nothing in the statute or these regulations prevents an institution and agency from mutually agreeing to binding arbitration to resolve a lingering dispute later in the process, after such a dispute has arisen. Indeed, nothing in the statute gives the Department the authority to impose requirements for arbitration agreements other than that which is entered into when the institution is first accredited. The Department also released guidance in November 2023 that clarified that arbitration must be initial and non-binding. If an accrediting agency and institution choose to enter into binding arbitration after a dispute arises, then that is permissible because both parties come to an agreement as opposed to an agency requiring binding arbitration as a requirement to seek or maintain accreditation.

Changes: None.

Comments: A few commenters requested clarification of the provision under § 602.20 (h). One commenter stated that there is distinct difference between retroactive accreditation and restoration or reinstatement of accreditation, which are not co-terminus actions. These terms are not defined in the regulations, but they may need to be defined in regulation, especially as different agencies and the Department have varied over the past several years in their explanation of these terms and the regulatory implications thereof.

Another commenter stated that the Department needs to clarify if an agency must have a policy for restoration of accreditation (including retroactively).

Discussion: The Department agrees that an agency must have a policy for restoration of accreditation, which could be retroactive. The term retroactive accreditation has appeared in 34 CFR part 602 since 2019 under § 602.18(a)(7) without confusion. The Department declines to prescribe a definition to the terms because we

believe they are widely understood and common terms. If the Department recognizes a need in the future to provide further guidance on the terms, we may offer subregulatory guidance as necessary to inform implementation.

Changes: None.

Comments: One commenter recommends that any restoration of accreditation following arbitration or litigation be prospective and that the agency's record of the adverse action and its resolution remain publicly available under Sec. 602.26(f). The commenter stated that retroactive restoration rewrites history: it treats the period during which an institution operated under a final adverse action as though the action never occurred, erasing information that students who enrolled during that period relied on in making enrollment and borrowing decisions. It also weakens the deterrent value of adverse action itself, since an institution that expects any sanction to be retroactively expunged through arbitration has less reason to remediate promptly and more reason to litigate. Prospective restoration fully protects an institution that prevails on the merits going forward, while preserving an accurate public record of what the accrediting agency found, when, and how the dispute was resolved.

Discussion: In response to this comment, the Department notes that an agency may have such a policy if it chooses unless the resolution of a judicial decision requires the agency to retroactively restore accreditation and expunge the record of an adverse action against the institution. The Department is not dictating the elements of the restoration policy; we are providing agencies with flexibility to establish their own requirements. With this in mind, the agency must have such a policy and apply it consistently to all accredited institutions and programs.

Changes: None.

§ 602.21 Review of Standards

Comments: A few commenters were concerned that deleting current § 602.21(b)–(d) would remove the more concrete safeguards that give the review requirements meaning such as meaningful opportunity for input, notice of proposed standards changes, opportunity to comment, and consideration of timely comments. One commenter had several recommendations: (1) include language that states “The agency must maintain a comprehensive systematic program of review that occurs at regular intervals, involves all relevant constituencies, including students, and affords each relevant constituency a meaningful

opportunity to provide input into the review”; and (2) clarify that “relevant constituencies” may include affected governmental and judicial entities.

Discussion: We disagree with the commenter's assertion. The Department is removing prescriptive language that does not appear in statute while maintaining a requirement under § 602.21(a) that the review involve “all relevant constituencies.” The Department declines to specify the relevant constituencies, with the exception of students, to afford agencies autonomy and the ability to innovate.

Changes: None.

Comments: Several commenters believed that the reference to “return on investment” in the NPRM preamble discussion about the amendments to § 602.21 would require agencies to conduct a formal “return on investment” analysis, longitudinal study, financial analysis, or develop expensive surveys to provide to stakeholders regarding its standards. The full excerpt states: “An ineffective and outdated accrediting agency is not a good use of taxpayer dollars via the institutions or programs it accredits and may leave students without a good return on investment and with insurmountable student loan debt that they may struggle to repay debt.”

Discussion: Preamble language is not enforceable; it solely explains the regulatory text in plain language. The regulations under § 602.21 are deregulatory in nature, not prescriptive of any process. We have removed § 602.21(b)–(d) to eliminate burdensome regulations that are not statutorily required.

Additionally, while agencies must review standards at regular intervals, nothing in the regulatory text requires a standardized “return on investment” analysis. Agencies will note the Department has not defined the only substantive addition to § 602.21, which is “that occurs at regular intervals,” because we allow agencies the flexibility to determine the interval for the review of their own standards.

Changes: None.

§ 602.22 Substantive Changes and Other Reporting Requirements

Comments: Several commenters expressed agreement with the Department's intent to encourage responsible innovation and narrow the substantive change reporting requirements when the changes do not present meaningful risks to educational quality. These commenters acknowledged the reduced administrative overhead and lead times required. Commenters stressed the need

for clear definitions, common data standards usage where possible, clear guidance, adequate technical assistance, and a reasonable transition period to implement the proposed changes.

Discussion: We thank and appreciate the commenters' support of this provision.

Changes: None.

Comments: One commenter argued for the inclusion of direct assessment programs in the exemption of applying for accrediting agency approval, opining that an institution that has successfully obtained approval for two direct assessment programs and demonstrated a sound competency-definition and mastery-assessment methodology has proven the capability the prior-approval requirement exists to test. The commenter emphasized requiring approval of subsequent direct assessment programs is redundant and unnecessary.

Discussion: We decline to accept the proposal in the commenter's request. Due to the requirements of § 668.10(b)(2)(vi), the agency's definition of substantive change must continue to include the addition of each direct assessment program. Specifically, § 668.10(b)(2)(vi) requires an agency to evaluate an institution's offering of direct assessment program(s), include the program(s) in the institution's grant of accreditation, and provide approval documentation indicating agreement with the institution's methodology for determining the direct assessment program's equivalence in terms of credit or clock hours to obtain the Department's approval for participation in the title IV, HEA programs.

Changes: None.

Comments: Another commenter offered general support for the proposed changes to § 602.22 but emphasized that notifications can still be burdensome and requested that the Department clarify what the process of notification means both from the institution to the accrediting agency and then the agency to the Department.

Discussion: We do not expect additional burden for notifications required by this section under the final rule. The institution should follow the process determined by the agency for notifying applicable substantive changes. The agency should provide any required notifications to the Department—as it does for any other notification of a required decision or action—via the Database of Accredited Postsecondary Institutions and Programs (DAPIP).

Changes: None.

Comments: A few commenters recommended the Department further

clarify the ability of agencies to define substantive changes beyond the specified list.

Discussion: The final rule does not limit an accrediting agency's ability to specify additional changes that it determines are substantive. The substantive changes noted by the Department are the minimum expectations for review.

Changes: None.

Comments: Another commenter expressed mixed support for § 602.22 but recommended requiring the accrediting agency to monitor an institution for a defined period following a change of control and track key aspects, and to report what it finds through the recognition process. The commenter further recommended that regarding additional locations, the Department add a growth-rate trigger, so the prior-approval shortcut option is unavailable to an institution whose headcount enrollment or number of locations has increased beyond a specified threshold over the preceding two years. The commenter also recommended that the Department clarify that this option removes prior approval only and would not displace site-visit or branch-campus obligations.

Discussion: We appreciate the commenters' support for several changes but disagree with the commenter's suggestions for changes. We do not believe it is necessary for an accrediting agency to monitor an institution for a specific period of time following every change in control, although an accrediting agency could choose to do this of its own volition. We also do not believe that a growth-rate trigger is appropriate in all cases and decline to limit an accrediting agency's discretion to determine when an institution's growth rate has become problematic.

Changes: None.

Comments: One commenter agreed with the removal of "high-impact, high-risk changes" in the agency's definition of substantive change.

Discussion: The Department intends to reduce burden on both institutions and agencies. The final rule provides a definition of substantive change that applies to a more precise set of situations, arrives at a better balance of needed oversight, and returns some degree of deference to the agencies to make the decisions on what the substantive changes are and how they are processed.

Changes: None.

Comments: Another commenter stressed that eliminating prescriptive requirements should not inadvertently eliminate appropriate oversight of

changes that may affect institutional capacity, educational quality, student support, or reduce oversight in areas that may increase the potential of financial risk.

Discussion: The Department agrees with this comment. However, we maintain that some requirements and processes are overly prescriptive and not based on statute. The final rule eliminates some burdensome and complex regulations yet retains the statutory requirement for appropriate oversight of changes.

Changes: None.

Comments: One commenter disagreed with these changes because the items being removed are most closely associated with program quality deterioration.

Discussion: The intent of the final rule is to be less prescriptive in defining when and what institutions and agencies must do in reporting and reviewing changes. Accrediting agencies maintain the discretion to identify cases when the quality of an institution's academic programs is deteriorating, and do not need the Department to specify the circumstances in which every agency applies additional scrutiny. We expect accrediting agencies to maintain reasonable procedures to identify situations in which the quality of an institution's academic programs is declining and take appropriate action.

Changes: None.

§ 602.23 Operating Procedures All Agencies Must Have

Comments: One commenter supported the amendments to paragraph § 602.23(c) requiring that an accrediting agency review complaints against itself in a timely, fair, equitable, and unbiased manner, take appropriate follow-up action, and document complaints and actions taken. The commenter recommended requiring every recognized accrediting agency maintain a clearly identifiable public procedure for complaints against the agency itself and a record showing the date received, issue raised, classification, reviewing body, conflict-of-interest safeguards, disposition, follow-up action, and date resolved.

Discussion: The Department does not believe edits are necessary to § 602.23(c) as the additional requirements are too prescriptive and would add unnecessarily to regulatory burden on agencies. We believe that the amendments to this section already address the commenter's concern about the documentation of complaints received against the agency.

Changes: None.

Comments: One commenter recommended that § 602.23(c)(1) be clarified so that, where a complaint's stated evidence includes institutional documents, policies, or records rather than solely a personal narrative, and the complainant does not seek an individual remedy, the agency's scope determination address whether the complaint identifies a potential institutional practice, separate from the fact that the complainant experienced that practice personally. The commenter further recommended that the Department clarify whether an agency's obligation under § 602.23(c)(1) to provide the institution a sufficient opportunity to respond applies only once a complaint has passed an agency's own scope screening, or whether that opportunity should also inform the screening determination itself when institutional records are at issue.

Discussion: We decline to accept the commenter's recommendation. We believe that the complaint process regulations are sufficiently robust. If the Department were to add more specific text, it would result in confusing regulatory language and overly rigid requirements that would constrain the process rather than make it more efficient.

Changes: None.

Comments: One commenter stated that whenever a recognized accrediting agency modifies a material policy within a defined period after receiving a complaint concerning that policy, it should preserve and publish the old version, the new version, the date, the stated rationale, whether the change applies prospectively or retrospectively, whether the complaint influenced the change, number of program complaints, number of complaints against the agency, issues raised, how many were screened out, average resolution time, number substantial, and number involving several areas (ex. conflicts, retaliation, etc.).

Discussion: The commenter did not specify which paragraph under § 602.23 is the subject of the comment. We believe that the complaint process outlined under § 602.23(c) is sufficiently robust and decline to make any further changes in the final rule.

Changes: None.

Comments: One commenter stated that some agencies have categorically refused third-party complaint submissions. The commenter stated that § 602.23(c)(1) should clarify that an agency may not refuse to review a complaint solely because it was submitted by a third party. At minimum, an agency should accept a complaint submitted by counsel or an

advocacy organization on behalf of an affected student or faculty member with that individual's authorization. And where a third party presents credible evidence of systemic noncompliance with an accreditation standard, the identity of the complainant should not immunize the underlying conduct from review. Finally, the commenter stated that § 602.23(l) should likewise include a structured means for receiving such information. Nothing requires an accrediting agency to become a general-purpose tribunal for every campus controversy.

Discussion: The Department does not believe that additional clarifying language is necessary. If an entity submits a complaint to an agency and does not believe that it has been sufficiently vetted, then the entity can submit a complaint to the Department for review of the agency's response to asrecordsmanager@ed.gov or call 202-453-7615. The commenters may also attend a NACIQI meeting and provide public comment regarding an accrediting agency. The Department encourages the commenters to consult the **Federal Register** and the NACIQI website for announcements and information regarding upcoming meetings and opportunities for public comment.

Changes: None.

Comments: One commenter suggested removing the newly revised language in § 602.23(d) stating that “[t]he agency must require its accredited institutions or programs to publicly disclose any action by the agency that begins the enforcement timeline in § 602.20(a) or (b).” The commenter asserts that this language is not necessary because it is redundant with language in § 602.26(e).

Discussion: We disagree and decline to accept the commenter's suggestion. This language at § 602.23(d) requires the public disclosure of any action by the agency that begins the enforcement timeline in § 602.20(a) or (b) which goes beyond the public disclosure requirements at § 602.26(e). We believe the additional public disclosure when an agency finds—at any time—that an institution or program is not in compliance with any standard is important for the transparency of agency actions and institutional or programmatic compliance with standards.

Changes: None.

Comments: One commenter stated that the expanded disclosure requirements proposed in § 602.23(d) should clearly distinguish preliminary or remediable findings of noncompliance from final adverse actions so that students and the public

receive timely and accurate information without creating a misleading impression about an institution's accreditation status.

Discussion: An agency can instruct institutions or programs how to distinguish between a preliminary and remediable finding of noncompliance from adverse actions in its requirements for public disclosure under § 602.23(d).

Changes: None.

Comments: One commenter stated that the proposed § 602.23(d) states that an agency “must require” institutions to publicly disclose any action by the agency that begins the enforcement timeline in § 602.20(a) or (b). The sentence that follows that language refers to an institution that “elects to make a public disclosure,” suggesting the disclosure is voluntary. The commenter recommends that the Department resolve the mandatory versus elective inconsistency.

Discussion: The public disclosure is mandatory for any action by the agency that begins the enforcement timeline in § 602.20(a) or (b) for an institution or program and the agency must ensure that the disclosure is accurate. Public disclosure of an institution's or program's accredited status otherwise is optional, but if an institution or program does disclose that status, the agency must ensure that it is an accurate disclosure.

Changes: None.

Comments: One commenter opposed changing “degrees” to “credentials” under § 602.23(f). The commenter stated that the omission of the term degree carries the potential to suggest to undergraduates that “credentials” and “degrees” are the same when earning a degree can have a significant impact on a student's future that mere credit accumulation cannot.

Discussion: The Department does not share the commenter's concern. We believe the change will be welcomed and as described in the NPRM, it will help confirm to employers that credentials from preaccredited institutions or programs carry the same validity and legitimacy as credentials from accredited institutions or programs.

Changes: None.

Comments: One commenter stated that requiring public disclosure of any agency action that begins the enforcement timeline could obscure the distinction between routine or readily correctable findings and serious concerns about quality, integrity, or student protection. The commenter recommended that the Department clarify what “any action” encompasses and establish a materiality threshold for

mandatory disclosure. When disclosure is required, public notices should clearly identify the nature and current status of the matter, including whether it has been corrected or resolved, so students and the public receive information proportionate to the underlying risk.

Discussion: We decline to accept the commenter's suggestion. The Department believes full transparency is paramount and adding further conditions to the public disclosure of agency actions would result in confusing rules for agencies and inconsistent application of the regulations.

Changes: None.

Comments: Several commenters supported the provision under § 602.23(h). One commenter stated that race-based metrics, including diversity, equity and inclusion (DEI) should end. Another commenter stated that accreditation standards should promote educational quality, accountability, and student success without compelling unlawful differential treatment or prohibited preferences.

Discussion: As noted in the NPRM, these regulations, in part, seek to implement *E.O. 14279*. A part of that order stated “Some accreditors make the adoption of unlawfully discriminatory practices a formal standard of accreditation, and therefore a condition of accessing Federal aid, through “diversity, equity, and inclusion” or “DEI”-based standards of accreditation that require institutions to “share results on diversity, equity, and inclusion (DEI) in the context of their mission by considering . . . demographics . . . and resource allocation.” Accrediting agencies have also abused their governance standards to intrude on State and local authority.”

Changes: None.

Comments: Some commenters opposed the provision under § 602.23(h) that states an agency must not have policies that require institutions or programs to violate any Federal or State law for the following reasons:

- Agencies are not civil right laws experts or law enforcement agencies. Commenters believe that this requirement is Federal overreach and could lead to constitutional issues such as agencies infringing on the free speech of institutions, programs, and students.
- Social cultural background should be considered in higher education policies because students from wealthy families have more opportunities to engage in extracurricular activities and influential networks than a student from a family with less means.

- Institutions are already bound by anti-discrimination laws. Making agencies independently responsible for policing it, amid the administration's public stance against diversity, equity, and inclusion (DEI), will predictably lead institutions to eliminate lawful programs—including minority pipeline programs in medicine, nursing, and public health that diversify the health workforce—simply to avoid regulatory risk.

- The regulations require agencies to ensure institutional compliance with applicable Federal and State laws. Accrediting agencies are educational quality reviewers, not courts, regulators, or law enforcement bodies. Legal compliance matters are already reviewed and adjudicated by Federal agencies, State agencies, courts, and other regulatory authorities. Expanding agency responsibilities into broad legal compliance oversight risks increasing costs, creating inconsistent findings, and diverting attention from educational quality.

- The language creates significant uncertainty for Historically Black Colleges and Universities (HBCUs) and other institutions attempting to comply with evolving Federal and State civil-rights requirements.

- Institutions will be confused about how to accredit institutions that have legal diversity, equity and inclusion aims as part of their institutional missions. For example, legally permitted targeted initiatives, including programs serving veterans, TRIO participants, and other populations authorized or protected under Federal or State law, lawful sex-specific scholarships or programs, on-campus voluntary student affinity groups.

- The rule ignores that institutions offer preferential admission for issues unrelated to merit, such as admission of student athletes at elite sporting institutions.

Commenters made several suggestions:

- Limit accrediting agency review to legal matters directly related to educational quality, institutional integrity, and student protection rather than broad legal compliance oversight.

- Limit the role of the accrediting agencies to determining whether an institution maintains appropriate policies and responds responsibly to final findings issued by a court or governmental authority with jurisdiction.

- Clarify that accrediting agencies and institutions may continue to collect and analyze demographic data; conduct recruitment and outreach efforts focused on rural, low income, first-generation,

and underserved communities; consider applicants' individual experiences consistent with applicable law; and deliver evidence-based instruction necessary to prepare students to care for diverse patient populations.

- Specify that institutions retain authority over employment, personnel, and research misconduct decisions in compliance with applicable Federal and State law and any existing collective bargaining agreements.

Discussion: The provision does not eliminate lawful admission or hiring practices, but instead it prohibits illegal diversity, equity, and inclusion requirements. The Trump Administration has sought to eliminate illegal diversity, equity and inclusion requirements throughout the Federal government and its programs, as demonstrated in E.O.s 14151¹¹ and 14398.¹² Further, E.O. 14279 states that “the Secretary of Education shall, as appropriate and consistent with applicable law, hold accountable, including through denial, monitoring, suspension, or termination of accreditation recognition, accrediting agencies who fail to meet the applicable recognition criteria or otherwise violate Federal law, including by requiring institutions seeking accreditation to engage in unlawful discrimination in accreditation-related activity under the guise of “diversity, equity, and inclusion” initiatives.”

These regulations do not dictate an institution's admission process. The Department is aware that many institutions have holistic application processes. Applications contain essays, statements, questions about extracurricular activity and awards, etc. Institutions may continue to collect and analyze demographic data and consider applicants' individual experiences consistent with applicable law. However, they cannot have policies that use race, color, or national origin as criteria for admissions, set percentage targets based on race, color, national origin, or use other information as proxies for race, color, or national origin.

Changes: None.

Comments: One commenter stated that the Department should clarify that “Federal or State law” includes the exemptions, exceptions, defenses, and

constitutional protections that are part of those laws. The commenter recommended to add the following language to § 602.23(h)—“Nothing in this part shall be construed to allow an accrediting agency to treat as unlawful any policy, practice, or decision permitted by an applicable statutory or constitutional exemption, exception, defense, or protection, including, but not limited to, the religious exemption in 20 U.S.C. 1681(a)(3).”

Discussion: We decline to accept the commenter's suggestion. We believe the regulatory text already accounts for exemptions, exceptions, defenses, and constitutional protections that are a part of Federal and State law. We do not intend to create an exhaustive list of each statute that must be considered because all relevant statutes must be considered by an agency in its standards, policies, and procedures.

Changes: None.

Comments: One commenter stated that an agency is currently violating regulations proposed under § 602.23 insofar that the agency has policies related to nondiscrimination.

Discussion: While the commenter did not provide the specific proposed paragraph the agency is accused of violating, the Department assumes the commenter is referencing § 602.23(h). Note that the regulations are effective on July 1, 2027, and most provisions will not be enforced until then. However, if the commenter believes that a Federal or State law is currently being violated, the commenter can file a complaint with the specific agency or the Department for further investigation.

Changes: None.

Comments: One commenter stated that the requirement under § 602.23(i) related to antitrust internal controls should be clarified so that ordinary peer review is not chilled. The commenter requested that the Department clarify that the development and application of published quality standards through a peer review process is not itself “coordination” within the meaning of the requirements under § 602.23(i) and should identify the conduct it actually intends to reach.

Discussion: Conducting peer reviews does not inherently violate antitrust laws, but agencies may wish to consult with an attorney(s) to ensure their review process does not violate antitrust laws. The Department cannot state definitively in the preamble that all peer review processes are exempt from § 602.13 and § 602.23(i).

Changes: None.

Comments: One commenter stated that under § 602.23(i) the Department should require complainants to refer all

¹¹ Ending Radical and Wasteful Government DEI Programs and Preferencing—<https://www.whitehouse.gov/presidential-actions/2025/01/ending-radical-and-wasteful-government-dei-programs-and-preferencing/>.

¹² Address DEI Discrimination by Federal Contractors—<https://www.whitehouse.gov/presidential-actions/2026/03/addressing-dei-discrimination-by-federal-contractors/>.

antitrust concerns about agencies to the Federal Trade Commission or the Department of Justice.

Discussion: The Department noted in the NPRM—and repeats here—that it is not the enforcer of antitrust law. As such, the Department may refer any potentially anticompetitive conduct to the federal antitrust enforcement agencies, but the Department does not need to make changes to the regulations herein to make such referrals.

Changes: None.

Comments: A few commenters supported the provisions under § 602.23(j). One commenter expressed strong support for the Department's recognition of State authority over public institutions.

Discussion: We thank the commenters for their support.

Changes: None.

Comments: Some commenters had concerns with § 602.23(j). The main concern from commenters was that these provisions could limit the ability of accrediting bodies to respond when State action interferes with academic freedom, institutional governance, curriculum, or established professional and educational standards. One commenter stated that an accrediting agency cannot simultaneously be instructed to verify an institution's constitutional compliance and be barred from reviewing the governance decisions through which that compliance is or is not maintained.

One commenter stated that it is unclear in § 602.23(j) what is included within the scope of “aspects of institutional governance of public institutions that are established by State law,” beyond the issue of “appointment of institutional directors or officers by elected or appointed State officials.”

Another commenter stated that under proposed § 602.23(j), the politically motivated appointment of regents established by State law would be outside the accrediting agency's review. This is a threat to independent accreditation, making it effectively a rubber stamp of whatever States decide to do—whether or not those actions materially weaken the quality of education for students at institutions within those States. The commenter asserted that the provision strips the ability of accrediting agencies to effectively enforce their standards in any meaningful way.

One commenter recommended revising § 602.23(j) to preserve accrediting agencies' ability to evaluate governance matters relevant to institutional quality, even where particular governance structures are established by State law. Another

commenter recommended revising § 602.23(j) to read: “The agency shall not penalize or place on probation any public or private nonprofit institution for actions taken by its governing board that fall within the board's statutory, charter, or legal authority” or “The agency must only review aspects of institutional governance of public institutions to ensure their compliance with State and Federal laws, including the appointment of institutional directors or officers by elected or appointed State officials.”

Another commenter stated that the Department should clarify the terminology in § 602.23(j) to expressly reference typical public institution governance bodies such as “boards of trustees,” as it does in the preamble language. The commenter indicated that the regulations should also make clear whether the provision protects only governance structures and appointments of institution or program leaders prescribed by State law, or whether it also protects decisions for which State law assigns decision-making authority to a public institution's governing board. The commenter requested that the final text not prevent an agency from reviewing a State law governance decision when the review concerns compliance with Federal law, the institution's own policies, or valid academic and institutional quality standards. The commenter also argued that the regulations should not authorize an agency to direct the outcome of a governance decision that State law reserves to the State or its governing bodies.

Discussion: We disagree with the commenters' assertions. The Department's intent is to ensure that an agency's standards do not supersede State law. For example, if a State passes a law that grants the Governor authority to appoint an administrator to an institution, then the agency may not review any subsequent decision by the Governor to make an appointment of the specific administrator. The Department intends this requirement to remain broad. We decline to prescribe an exhaustive list in regulation of the scope of § 602.23(j). As issues arise, the Department will work with agencies and States to clarify guidance and resolve issues.

We decline to add a reference to a “board of trustees” or specify that the regulations prevent accrediting agencies from reviewing decisions for which State law assigns decision-making authority to an institution's governing board because the list in regulation is not exhaustive. The regulation states that the agency must refrain from

reviewing aspects of institutional governance of public institutions that are established by State law, “including” any appointment to institutional governance established by State law; the Department does not intend for that to be the only item that cannot be reviewed.

The regulations under § 602.23(j) do not prevent an accrediting agency from reviewing concerns with an institution's compliance with Federal law or valid academic and institutional quality standards that are clearly under the direct purview of the agency under the law and regulations, even if those standards might be impacted by the policies of a State governance board. The requirements under § 602.23(j) are specifically intended to prevent accrediting agencies from intervening in governance matters that are under the clear and rightful purview of the State. Where there are governance matters that could affect academic quality but remain under the purview of the State, the accrediting agency may act as an advisor but not as the arbiter of the institution's policies.

Finally, we believe that § 602.23(h) already addresses the requested amendment related to State law compliance with Federal law.

Changes: None.

Comments: In the preamble, the Department explains that: “We propose § 602.23(j) to direct accrediting agencies to refrain from interfering with institutional governance decisions that fall within the rightful purview of State governments, boards of trustees, or similar governing bodies, limiting their role to advisory purposes only.” A few commenters stated that the Department should note what an agency's “advisory only” role permits and prohibits in practice.

Discussion: An advisor cannot make a final decision. An accrediting agency can give professional advice regarding matters that are clearly under the purview of State governance; however, it cannot interfere with a State government's statutory authority over institutional governance.

Changes: None.

Comment: One commenter asked if the requirement under § 602.23(j) applies to institutional, not specialized, accrediting agencies.

Discussion: The provision under § 602.23(j) applies to all accrediting agencies that are recognized by the Department.

Changes: None.

Comments: One commenter suggested removing § 602.23(k) because they stated that it is confusing. The commenter stated that the regulation

says “may” have a process for accelerating an institution’s ability to obtain accreditation status but then dictates minimum requirements for this optional process. The commenter asserted that mandating the requirements of a process that an agency is not required to have at all discourages an agency from having the process.

Discussion: We disagree with the commenter’s suggestion and assertion. The regulation provides flexibility to agencies to offer an accelerated process while establishing guardrails for implementation when agencies choose to do so. The Department has done this in several places throughout the regulations. For example, in the recent regulations published on eligible workforce programs under § 690.93(h), the Department permitted governors to enter into bilateral agreements and subsequently set parameters for the bilateral agreements.

Changes: None.

Comments: A few commenters stated that the Department should establish a common set of minimum safeguards that every recognized institutional accrediting agency must apply when reviewing an institution that changes or adds accrediting agencies. One of these commenters indicated that the Department could add a new paragraph to § 602.23(k) requiring the receiving agency to apply, at a minimum, the agency’s standards and procedures concerning student achievement, financial responsibility, consumer protection, complaints, institutional stability, teach-out planning, and compliance with Federal and State law. The commenter stated that the Department should also add a new monitoring requirement to § 602.23(k) or § 602.33 requiring heightened monitoring for at least two years after the change. The commenter asserted that this requirement would not prohibit legitimate institutional mobility or require the Department to assign an institution to a particular accrediting agency.

A different commenter requested that the Department state eligibility exclusions in regulatory text. The accelerated process should be unavailable to any institution under monitoring, probation, show-cause, or a negative action; in or recently emerged from a substantive change review; that has changed accrediting agencies within a defined lookback period; that is provisionally certified; or that is experiencing significant enrollment growth within the meaning of 20 U.S. Code § 1099b(c)(2).

Discussion: The Department disagrees with the commenters. The regulations

under § 600.11 are sufficiently rigorous and clear. These regulations provide the proper safeguards when an institution chooses to change agencies or seek out accreditation from multiple agencies. The final rule at section 602.23(k) reduces administrative burden when switching between recognized accrediting agencies, but still requires a comprehensive review of the institution by the agency against its standards.

The Department has also added requirements for the application of standards that require all agencies to review institutions. Commenters will note that agencies will need to have stronger policies to evaluate student outcomes. There are also the current safeguards, for example, the Department staff reports and NACIQI reviews of agencies.

Changes: None.

Comments: A few commenters suggested removing § 602.23(l) because the new requirements are redundant given the existing requirements for agencies in the regulations under § 602.23(b) and § 602.23(c). The commenter also stated that there is a typographical error in the amendatory language under § 602.23(l).

A separate commenter stated that numerous processes for complaints already exist for students and employees. For example, complainants may file grievances, such as Title IX, civil rights, and employment claims with appropriate Federal agencies. Accreditation should not create yet another process, in addition to already existing processes, for grievances. The commenter stated that the proposal creates a particular risk for religious institutions. A student or employee who disagrees with a doctrinal requirement, chapel expectation, conduct standard, hiring decision, student-life policy, or other religiously based policy may characterize the disagreement as an accreditation concern. The agency may then be drawn into a dispute about the substance of a lawful religious policy rather than the institution’s compliance with an accreditation standard. The commenter recommended that the Department include due process requirements. If information received through the grievance process may be used to support a finding of noncompliance or another adverse action, the institution should receive notice of the substance of the information and a fair opportunity to respond.

Another commenter requested that the Department clarify in § 602.23(l) that communications received through that provision do not constitute formal complaints under § 602.23(c) unless

they satisfy the agency’s established requirements for initiating a formal complaint. The commenter stated that nothing should prevent an agency from treating information received through § 602.23(l) as a complaint when appropriate under its policies.

Discussion: We decline the commenters’ suggestion to remove or substantively amend § 602.23(l). We believe that § 602.23(l) is necessary to explain the appropriate mechanisms for how students, staff, or faculty of an accredited institution or program communicate concerns about the agency’s standards directly to the agency. We thank the commenter for notifying us about the typographical error under § 602.23(l) and have corrected it, as described in the “Technical Corrections” section.

Regarding the concern about agencies inappropriately applying the provision to lawful policies of religious institutions, the Department is clear in the regulatory text that the concerns are limited to “concerns related to the agency’s accreditation standards or the institution’s or program’s compliance therewith,” not a religious policy of the institution or program. The mechanism in § 602.23(l) is simply about creating a direct channel for the student, staff, and faculty to voice concerns directly with the agency. Under § 602.23(c), institutions and programs have the right to respond to formal complaints made against the institution or program; therefore, a formal due process framework for § 602.23(l) is unnecessary.

Finally, communications received under § 602.23(l) do not constitute formal complaints under § 602.23(c) unless they satisfy the agency’s established requirements for initiating a formal complaint.

Changes: Please see the technical edit for this particular item under the “Technical Corrections” section.

Comments: Under § 602.23(l), one commenter recommended that the Department require randomized panels or independently administered surveys as a floor, with registration available as a supplement rather than a substitute. The commenter recommended that the Department delete or define “manageable in volume,” state that participation limits may not operate to exclude students who have raised concerns, require the channel to operate year-round rather than only during a site visit, and require agencies to report the volume and disposition of concerns received. The commenter suggested that the Department should also state plainly in the final rule that the student and veteran negotiators, who represent this

provision's intended beneficiaries, abstained rather than affirmed the text.

Discussion: We decline the recommendation; we believe that the Department's regulations are sufficiently rigorous. The commenter will note that these regulations do not currently exist and the Department's proposal already represented heightened consumer protections, safeguards, and guardrails. Per the protocols for the rulemaking session, abstaining does not equal disagreement. The Department achieved consensus on the regulations.

Changes: None.

Comments: One commenter stated that an accrediting agency whose standards are incorporated into Federal employment and program requirements is not merely a private association petitioning its government. The commenter stated that the agency is exercising delegated gatekeeping authority, and the Department should treat conduct that expands or entrenches that authority as conduct within the scope. The commenter requested that the Department add a new § 602.23(m) that reads: "The agency must not oppose the recognition of equivalent qualifications for graduates of programs accredited by another agency in any Federal or State employment, licensure, certification, or reimbursement requirement that names the agency."

Discussion: We decline to add the provision as requested. The Department is concerned about unintended consequences that may arise from adding this broad language to the regulations. There could be legitimate reasons for an accrediting agency to oppose recognition of a separate but equivalent qualification, and the blanket prohibition described by the commenter would foreclose those opportunities.

Changes: None

Comments: One commenter stated that the Department should require programmatic accrediting agencies to undergo independent legal and economic audits under § 602.14, § 602.15 and § 602.23 that are published publicly.

Discussion: The commenter did not specify the exact location in the regulations for the recommendation, so we will address the comment under § 602.23. We do not believe the Department has the authority to require agencies to go through these types of audits. We also believe that there are Federal and State requirements outside of Department of Education rules which agencies operate under, such as financial laws enforced by the Internal Revenue Service or civil rights laws enforced by the Department of Justice.

Changes: None.

§ 602.24 Additional Procedures Certain Institutional Agencies Must Have

Teach-Out Plans and Agreements, and Closed Institutions

Comments: Several commenters argued that if an institution is on provisional certification, that does not imply that they are at risk of closure. Commenters believed that institutions that undergo routine change-in-ownership reviews, operational or compliance issues, or are placed on provisional certification during Heightened Cash Monitoring do not indicate any real risk of closure and should be exempted from the teach-out requirements in § 602.24(c). Commenters urged the Department to only require teach-out plans when appropriate and that such requirements be tied directly to demonstrated institutional risk rather than being automatically triggered by broad status classifications like provisional certification. Commenters believed linking teach-out obligations to financial or operational risk would ensure that the requirement serves its intended purpose—protecting students from abrupt closures. One commenter noted that the changes in § 602.24(c)(1)(iii) will require large public institutions to identify teach-out partners across numerous programs, and the mandated student communications will create confusion by implying closure risks that do not exist. The commenter recommended maintaining the current language in § 602.24(c)(1)(iii), which requires a teach-out plan for a defined subset of institutions on provisional certification, rather than for every institution on provisional certification.

Another commenter suggested revising § 602.24(c)(1)(iii) to read: "The Secretary changes an institution's participation in the title IV, HEA programs from full certification to provisional certification based on circumstances that present a material risk to the institution's continued operation or its ability to provide instruction to enrolled students." A different commenter raised concerns about financial protection requirements, such as letters of credit, when an institution cannot secure a teach-out agreement. The commenter warned that these requirements will inadvertently create or worsen financial distress because letters of credit can be costly and can significantly constrain an institution's liquidity.

Discussion: The Department appreciates commenters' suggestions to

maintain the current language in § 602.24(c)(1)(iii) or revise the language, but we will not be adopting the suggestions. Provisional certification is, by definition, a status associated with elevated oversight and potential risk, whether financial, administrative, or related to consumer protection. The Department is strengthening early warning systems to ensure that students are protected when institutions encounter operational or financial challenges that may impair their ability to continue offering educational programs. In many cases, indicators that lead to provisional certification come before more significant problems. Requiring institutions in provisional status to develop a teach-out plan ensures that, if circumstances worsen, students will not face abrupt disruption or loss of educational continuity. The Department also emphasizes that a teach-out plan is a planning tool, not a presumption of closure, and an overall best practice to mitigate lost educational opportunities when unforeseen events or circumstances occur. Teach-out plans can be scaled appropriately to the institution's structure and circumstances, and institutions retain discretion to design plans that reflect their program offerings, size, and stability.

With respect to financial protection requirements such as letters of credit, the Department acknowledges the commenter's concern that these measures can be costly. Nonetheless, financial protection plays a critical role when an institution cannot secure a teach-out agreement, particularly in situations where operational or financial deterioration creates heightened student risk. These safeguards help ensure that resources will be available to support students if closure occurs. Moreover, institutions unable to secure a teach-out agreement must document the reasons for this difficulty, and the Department may require financial protection only when necessary to secure student continuity in the event of institutional disruption.

The Department agrees that regulatory obligations must be carefully calibrated to risk, and the final rule incorporates several mechanisms to strengthen early warning systems and align requirements with the conditions institutions face. At the same time, the Department declines to limit teach-out or financial protection requirements solely to instances of demonstrated closure risk because doing so could delay safeguards until risks become acute which may compromise student protections.

Changes: None.

Comments: Several commenters are concerned about the 30-day requirement for institutions to submit teach-out plans or teach-out agreements under §§ 602.24(c)(1) and (c)(3). One commenter suggested extending the 30-day timeline for submission of a teach-out plan and/or teach-out agreement(s) to at least 60 days. Another commenter argued that large, multi-campus institutions cannot produce comprehensive, high-quality teach-out plans within 30 days, especially when those plans must account for every educational program and site. The commenter cautioned that requiring rushed plans risks poor quality submissions that fail to adequately protect students and recommended applying the same flexibility currently afforded under § 602.24(c)(3) to § 602.24(c)(1). In addition, the commenter recommended the Department be required to notify accrediting agencies immediately when it places an institution on provisional certification or takes other teach-out triggering actions listed in §§ 602.24(c)(1) and (c)(2). A different commenter requested that the Department clarify that the 30-day timeline proposed in § 602.24(c)(1) can be shortened when circumstances warrant quicker action.

Discussion: The Department acknowledges the commenters' concern regarding the 30-day requirement for institutions to submit teach-out plans or teach-out agreements under §§ 602.24(c)(1) and (c)(3), but we will maintain the proposed language. The 30-day timeline reflects the Department's commitment to early and proactive intervention when institutions encounter circumstances such as a change from full to provisional certification. As stated before, provisional certification signals heightened oversight, and institutions will retain discretion to tailor the plan to their size, academic structure, and operations. Nothing in the regulation precludes an accrediting agency from requiring a teach-out plan at regular intervals, such as at each renewal of accreditation review, or at other points, which would relieve the 30-day timeline obligation, and agencies retain the discretion to do so.

Regarding the commenter's recommendation that the Department notify accrediting agencies right away when an institution gets provisional certification or faces other teach-out actions, the Department is committed to improving communication with accrediting agencies. However, we will not add new rules requiring immediate notification. In addition, the Department

agrees with the commenter's statement that there may be instances where a more expedited response is necessary to protect students or to ensure the integrity of the accreditation and oversight processes. The 30-day period in § 602.24(c)(1) represents the maximum time allotted for agencies to take the required action. Nothing in the regulation precludes an accrediting agency from acting sooner when circumstances justify a shorter timeframe, and agencies retain the discretion to do so.

Changes: None.

Comments: A few commenters recommended requiring teach-out plans (not just agreements) whenever statutory triggers occur, adopting a "reasonably similar program" standard, and prohibiting an institution from using its own branch campus as its sole teach-out partner. The commenters argued that research shows that records-retention and teach-out policies significantly increase the likelihood of post-closure reenrollment, especially when both are in place. One commenter suggested adding the following to § 602.24(c): "A teach-out plan must identify a teach-out opportunity in a program reasonably similar in content, structure, and scheduling to the program in which the student is enrolled, and may not rely solely on an additional location or branch campus of the closing institution."

Discussion: Although the Department appreciates the commenter's suggested additions, the Department believes the final regulatory text strikes an appropriate balance by enhancing protections for students, improving transparency, and strengthening continuity measures without imposing unnecessary rigidity. The Department emphasizes that the final rule requires accrediting agencies to ensure institutions include record-retention plans, maintain transcript access, and identify comparable program pathways in teach-out plans and agreements.

Changes: None.

Comments: A few commenters explained that once an institution loses accreditation, whether through adverse action or voluntary resignation, the accrediting agency no longer has any relationship with the institution and therefore cannot act on its behalf. One commenter stated that once the institution is no longer a member of the agency, the responsibilities envisioned in § 602.24(d)(i), securing teach-out options after closure, and § 602.24(d)(ii), establishing transfer options with institutions named in a teach-out plan, are not feasible. Commenters argued that an institution that closes without a

teach-out plan would not have pre-identified teach-out institutions, making the provision impossible to carry out and recommended narrowing § 602.24(d) to include only paragraphs (iii) and (iv).

Discussion: The Department appreciates the commenters' perspective on the scope of § 602.24(d), but the Department will not adopt the recommendation to limit the provision to paragraphs (iii) and (iv). As described in the NPRM, § 602.24(d) is designed to ensure that, when an institution closes without a teach-out plan, accrediting agencies, States, and the Department act promptly and cohesively to help students identify reasonable opportunities to complete their education without additional charges. § 602.24(d) does not require accrediting agencies to act on behalf of a closed institution; rather, it requires them to work, to the extent feasible, with the Department and appropriate State agencies to help students secure reasonable opportunities for educational continuation. Therefore, these provisions serve as expectations for coordinated student protection rather than as prescriptive requirements mandating specific teach-out arrangements.

Changes: None.

Comments: A few commenters argued that teach-out requirements should account for specialized programs, clinical placements, licensure pathways, employer partnerships, and rural areas with few comparable providers. Commenters urged the Department to consider reasonable extensions and provide clear transition protections, including continuity of Federal student aid when an accrediting agency's recognition changes or a decision remains under authorized review.

Discussion: The Department acknowledges the commenter's concerns about ensuring continuity of student support when an accrediting agency's recognition changes or when a recognition decision remains under authorized review. While statute governs the Department's ability to extend Federal student aid eligibility beyond what Congress permits, and does not permit the extensions contemplated by the commenters here, the Department reiterates that § 600.11 and § 602.10 establish the necessary framework to ensure orderly transitions between accrediting agencies and prevent disruptions to institutional eligibility for Federal programs during such periods.

Changes: None.

Comments: One commenter noted their concern regarding a student's

ability to access a transcript once their institution closes. The commenter recommended that, in addition to traditional arrangements, the Department require institutions to fulfill a portion of their transcript access obligations by providing students with durable, independently verifiable copies of their academic records prior to the institution closing. The commenter asserted that the proposed rule relied heavily on institutions maintaining and providing transcript access after closure, and argued that this model is inherently fragile due to the reasons institutions shutter—limited staff, funding, and no successor to maintain administrative functions, such as transcript availability.

Discussion: The Department agrees that ensuring students can access their academic records during and after institutional closure is an essential component of student protection, and nothing in § 602.24(c)(4) prevents accrediting agencies from adopting supplemental measures to strengthen that access. Institutions have a fundamental responsibility to ensure that students have access to their transcript. Although institutions and agencies may require additional safeguards, that does not mean standards or practices should abdicate the fundamental responsibility that requires such distribution and access in the first place.

Changes: None.

Comments: One commenter urged the Department to not implement changes to § 602.24(c)(8) and asserted the revisions would substantially weaken student protections by removing concrete guidelines for equitable treatment of students. Further, the commenter requested the Department not implement changes to § 602.24(c)(10), as providing notice to accrediting agencies of teach-out-related communications helps to ensure transparency and that institutions are not making misrepresentations to students.

Discussion: With respect to § 602.24(c)(8), the Department's intent in revising this provision is not to reduce protections for students, but to ensure that accrediting agencies retain appropriate flexibility while maintaining a predictable Federal framework. The Department notes that the broader teach-out requirements continue to provide clear expectations for agencies to intervene early and ensure consistent safeguards for students across the Federal-State-accrediting agency triad. Regarding § 602.24(c)(10), the Department has concluded that the existing structure of

agency oversight, combined with the strengthened Federal framework elsewhere in the regulation, is sufficient to ensure that agencies have the information necessary to monitor institutional behavior and protect students. For these reasons, the Department will not make changes to the proposed regulations in the final rule.

Changes: None.

Comments: One commenter stated that teach-out requirements are already fully addressed by accrediting bodies, noting that current standards require institutions to identify comparable institutions, ensure transcript preservation, and support students during transitions.

Discussion: The final rule builds upon existing accrediting agency expectations by clarifying when institutions must submit teach-out plans versus teach-out agreements, establishing consistent timelines for initiating required actions, and reinforcing the importance of maintaining access to academic records during and after closure. These clarifications do not replace accrediting agency requirements; rather, they provide a predictable Federal framework to ensure early intervention and consistent safeguards across the triad.

Changes: None.

Transfer of Credit Policies

Comments: Several commenters support the proposed transfer of credit protections, emphasizing that students should not be denied credit simply because their coursework was completed at an institution accredited by a different accrediting agency. While supporting greater transparency and fairness in transfer of credit decisions, commenters stressed the need to preserve institutional authority to determine academic comparability, program coherence, sequencing, and specialized accreditation requirements.

Discussion: The Department appreciates the significant support for the proposed transfer of credit protections, and we recognize the concerns regarding the importance of preserving institutional authority over academic determinations. The Department clarifies that decisions related to comparability, program sequencing, coherence, and specialized accreditation requirements rest with institutions and their faculty, as they are responsible for maintaining academic quality and the integrity of degree pathways. The final rule does not require institutions to accept transfer credit that is not comparable or that would compromise program quality;

rather, they require institutions to apply their criteria transparently, consistently, and not reject credit solely due to differences in the recognized accrediting agency.

Changes: None.

Comment: Several commenters recommended that the Department clarify that the transfer of credit provisions do not create a presumption that credit from another accredited institution must be accepted, and that institutions retain meaningful academic discretion to determine whether prior coursework is comparable and applicable to their curricula, particularly at institutions with a religious mission. The commenters stated that these institutions must retain the ability to decline credit from institutions that do not share their theological commitments and should not be required to conduct individualized case-by-case reviews. Commenters requested explicit recognition of institutional mission, worldview, curricular coherence, program sequencing, residency requirements, professional accreditation and licensure standards, and similar academic considerations as valid bases for denying transfer credit.

One commenter stated that transfer of credits in STEM disciplines carries unique academic risks, such as courses with identical numbers and similar curricula varying significantly depending on the faculty member, instructional approach, and rigor. Because of these variations, the commenter argued that automatic or presumed acceptance of STEM credit is inappropriate and potentially harmful. The commenter recommended that the Department require every transfer student have a conversation with a faculty member for each STEM course to ensure the student is adequately prepared and placed appropriately.

Another commenter asked for clarification on the permissible types of academic criteria preserved by 602.24(e)(4)'s "academic standards or curricular requirements" qualifier for limiting transfer credit. A different commenter argued that § 602.24(e)(3–5) endangers the integrity of undergraduate courses and recommended that those paragraphs be removed. The commenter stated that it does students no favors to assume that all courses are equivalent, and that institutions should continue to carefully negotiate transfer credit criteria.

Discussion: The Department disagrees with the assertions that § 602.24(e)(3–5) presumes that all courses are equivalent or undermines academic quality. Likewise, the Department also disagrees

with the claim that the transfer of credit provisions in § 602.24(e) eliminate institutional discretion or prevents institutions from considering mission-based factors when determining whether coursework is comparable and applicable. The regulations under § 602.24(e) do not require institutions to accept coursework that does not meet their academic standards, curricular requirements, or program specific expectations. Instead, the regulations require institutions to apply published criteria consistently and prohibit the denial of credit solely based on the institution or its recognized accrediting agency. The Department recognizes that institutions retain discretion to establish and apply academic criteria when evaluating transfer credit. Such criteria may include, for example, determining whether prior coursework is sufficiently comparable in content, learning outcomes, level, prerequisites, accreditation-related program requirements, or degree-specific curricular expectations. These examples are illustrative rather than exhaustive and are intended to reflect institutions' authority to make individualized academic determinations consistent with their educational mission and program requirements.

Further, the Department recognizes the concerns stated by the commenter while noting that all credits are not created equal. The Department believes this rule establishes appropriate checks and balances to ensure that institutions accept those credits that are equal through careful evaluation, and ensuring that students are provided the appropriate, additional education where it deems, with a reasoned explanation, that these credits are not equal. These requirements do not override institutional judgment regarding comparability or academic fit; therefore, the Department declines to add new regulatory language enumerating all possible academic bases for denying credit.

The Department appreciates the commenter's concerns regarding the unique challenges when evaluating transfer credit in STEM fields; however, these requirements do not require institutions to provide "blind" acceptance of STEM credit as the commenter asserted, nor do they interfere with faculty judgment regarding whether a student is adequately prepared for advanced coursework. Institutions may, and should, continue to engage faculty in evaluating demanding STEM courses and determining appropriate placement or support to protect student success. At the same time, the Department

maintains that students deserve clear explanations when credit is not accepted and timely information about how their prior coursework will count before committing financially to enrollment at the transfer institution. This transparency supports informed decision-making and reduces the likelihood of students repeating coursework unnecessarily. The Department believes the final rule appropriately balances institutional discretion with the need for fair, transparent, and consistently applied transfer credit practices, and ensures that students receive clear explanations for credit determinations while institutions maintain full authority over academic requirements.

Changes: None.

Comment: A few commenters requested a process to evaluate several categories of coursework, including Registered Apprenticeship-related instruction, pre-apprenticeship and noncredit occupational training, industry-recognized credentials, dual enrollment, military training and service-related learning, documented employment-based learning, pre-pharmacy coursework, direct-entry pathways, integrated undergraduate-professional curricula, and competency assessments. One commenter emphasized that the regional accrediting agency affiliation remains important for evaluating transfer credit, especially across States, as standards and coursework may not align with local licensure expectations. Another commenter asked whether institutions may maintain differentiated transfer policies based on enrollment status, modality, or instructional setting.

Discussion: The Department recognizes that institutions and accrediting agencies play a central role in determining whether coursework aligns with local programmatic or licensure expectations. The final rule does not alter institutions' ability to assess comparability of content, rigor, and learning outcomes, including State-specific requirements in fields such as teacher education or health programs. Institutions may continue to apply differentiated transfer policies where distinctions reflect legitimate academic considerations and are applied transparently and consistently. As a reminder, the Department no longer recognizes "regional" accreditation as a separate Federal category; all recognized institutional accrediting agencies are held to the same standards and therefore no longer held to an arbitrary geographic distinction. Therefore, the commenter's concerns here are not

applicable, and the Department declines to make such changes.

Changes: None.

Comments: Several commenters urged flexibility in establishing transcript submission and review timelines, using business days rather than calendar days for appeals, and allowing institutions at least 30 business days for appeals requiring additional faculty review. One commenter warned that the 15-day appeal window requirement is significantly more restrictive than existing State frameworks, which may lead to rushed and error prone evaluations. Another commenter suggested § 602.24(e)(5) to read:

"Provide the student an opportunity to appeal the decision or request a competency-based or direct assessment evaluation of the student's knowledge of the subject-matter within 15 calendar days of receipt of the institution's written notification if an institution declines to award transfer credit under paragraph (4)." A different commenter asserted their belief that the Federal appeals process was unnecessary, as institutions already publish transfer credit policies and maintain procedures for addressing student concerns. According to the commenter, imposing a mandatory Federal process would add administrative burden and costs without improving educational quality.

Discussion: The Department disagrees that 30 business days are needed to carry out the appeal requirements in the regulations. Timely and transparent communication to students is essential, including the resolution of credit transfer appeals within a predictable and consistent timeframe. Therefore, the Department will not adopt the recommendations to replace calendar-day deadlines with business-day deadlines or provide 30 business days for appeals requiring additional faculty review. The Department believes a clear and accessible appeal opportunity is an important safeguard for students, particularly to those who may otherwise be required to retake coursework unnecessarily or who may not understand the basis for denial. Although institutions may already have internal complaint or appeals processes, those processes differ widely. A minimum Federal requirement helps ensure that students' rights are protected consistently across institutions, as well as provide necessary information timely to students so they can make informed decisions about their education. The Department encourages institutions to adopt efficient transcript review systems, standardized explanation templates tied to academic criteria, and

collaborative transfer pathway agreements that support student mobility.

Changes: None.

Comment: One commenter recommended revising § 602.24(e)(5) so that the 15-calendar day period begins on “the date the institution issues the notification,” rather than the date of “receipt.” They noted that the definition “receipt” is operationally unfeasible, as institutions cannot reliably document when a student opens or receives the communication. The commenter argued that using the date the institution sends the notification would create a clear, administratively feasible standard, reduce burdens on students to prove receipt of an email, and avoid ambiguity that could undermine the fairness of the appeal process.

Discussion: The Department acknowledges there could be some practical challenges, as described by the commenter, regarding verification of receipt and administrative tracking. However, the Department notes that the purpose of the regulatory language is to ensure that students receive the full benefit of the appeal period and are not disadvantaged by delays in communication systems or institutional processes outside their control. Aligning the appeal timeline to the date the institution issues the notification could, in some cases, unintentionally shorten the time available to students, particularly those experiencing delays in email access, inconsistent connectivity, or other barriers.

Changes: None.

Comments: A few commenters noted that some institutions are evading the Department’s proposed interpretive rule, which eliminated the use of “regional” accreditation categories, requiring both institutions and accrediting agencies to relabel or reword their policies. The commenters stated that colleges continue to block credit by using terms like “regionally accredited,” “formerly regional,” or listing only the seven former regional accrediting agencies as locations or institutions from which it will accept credit. The commenters urged the Department to clarify that any policy conditioning transfer of credit on the old “regional” group or on a subset of recognized accrediting agencies constitutes a decision that is prohibited under the criteria, as it is based on “solely” on an accrediting agency.

Discussion: The Department acknowledges the concerns of institutional practices relying on the former “regional” accreditation construct. The final rule ensures that institutions do not deny credit transfer

based solely on the identity of the institution’s recognized accrediting agency, and that credit transfer determinations focus on the comparability of coursework, rather than outdated accreditation categories. The Department clarifies that conditioning transfer credit on accreditation by specific agencies or on any subset of recognized accrediting agencies is a form of denial based “solely” on accrediting agency and is prohibited under § 602.24(e)(3). Institutions must evaluate transfer credit using transparent, academically grounded criteria that are unrelated to the branding or historical categorization of accrediting agencies.

Changes: None.

Comments: A few commenters argued that the new transfer of credit provisions should not extend to graduate or professional programs; and recommended that the Department explicitly delineate that such policies only apply to undergraduate education. Commenters requested that the final rule explicitly affirm that graduate institutions retain authority to evaluate transfer credit based on program coherence, sequencing, clinical integration, and degree outcomes.

Discussion: Graduate and professional programs are not included within the scope of these transfer of credit requirements. Institutions retain full discretion, consistent with their published policies, to evaluate graduate-level prior learning using appropriate criteria for specialized, advanced, or professionally regulated programs.

Changes: None.

Comment: One commenter recommended extending these protections to graduate programs, noting that accrediting agency-based discrimination similarly affects graduate admissions and graduate transfer credit. The commenter proposed adding a new § 602.24(g) that would bar graduate programs from denying admission or transfer credit solely because of the accrediting agency of the applicant’s prior institution. The commenter proposed the following: “Graduate admission and graduate transfer of credit policies. For agencies that accredit institutions offering graduate or professional programs, the accrediting agency must confirm, as part of its review for initial accreditation or preaccreditation, or renewal of accreditation, that the institution does not deny admission to a graduate or professional program, or deny the award of graduate transfer credit, solely on the basis of the accreditation status of the agency that accredited the applicant’s or student’s prior degree-granting

institution, provided that institution was accredited by an agency recognized by the Secretary under this part at the time the degree was awarded.”

Another commenter argued that universities apply inconsistent credit transfer standards between American and international students. According to the commenter, institutions often deny American students’ transfer credits without explanation, forcing them to retake courses unnecessarily. In contrast, the commenter claimed that universities accept full credits from international institutions, such as those in India, without comparable scrutiny, which results in more international students entering taxpayer-funded graduate programs. The commenter further asserted that, because many American colleges now offer fully online undergraduate programs, international students also earn regionally accredited degrees which eliminates any justification for treating their credits differently. The commenter suggested that transfer of credit compliance be enforced equally, regardless of national origin.

Discussion: The Department appreciates the concern that accrediting agency-based discrimination also affects graduate students; however, the Department declines to add proposed § 602.24(g). The transfer of credit framework in § 602.24(e) is intentionally scoped to undergraduate coursework, reflecting both the predominant volume of student mobility at the undergraduate level and the need to maintain institutional discretion for programmatic and discipline-specific graduate admission standards. Regarding the inconsistency of international credit transfer, the Department agrees that institutions should apply their transfer of credit policies consistently and transparently. The final rule does not prescribe specific academic standards for accepting or rejecting transfer credit, nor do they require institutions to evaluate coursework from different States or countries in any specific manner. However, what the regulations do require is that an institution apply the standards it determines appropriate to its mission, programs, students, and content consistently, across all students, regardless of international status. Institutions retain responsibility for establishing and applying their transfer of credit policies consistent with applicable law and accrediting agency requirements.

Changes: None.

Comment: One commenter suggested that, when evaluating program length, accrediting agencies and the Department

account explicitly for differences between semester credit and quarter credit systems. The commenter stated that a 180-quarter-credit bachelor's degree is equivalent to a 120-semester-credit bachelor's degree, and suggested that program length be assessed based on actual academic work and expected time to completion, rather than nominal credit values.

Discussion: The Department agrees that program length evaluations must account for differences between semester-credit and quarter-credit systems. Accrediting agencies should determine whether a program's credit structure, instructional time, and expected student workload are appropriate to the credential awarded.

Changes: None.

Comments: One commenter asked the Department to clarify whether the presumption to award credit under § 602.24(e)(4) and the per-course written-rationale requirement under § 668.43(c)(4) applies only to credit earned at other title IV institutions.

Discussion: Yes, the requirements in § 602.24(e)(4) and § 668.43(c)(4) apply only to credits earned at title IV institutions that are accredited by a Department recognized agency.

Changes: None.

Comment: One commenter asked whether accrediting agency recognition in 602.24(e)(3) is measured at course completion or at evaluation. The commenter also asked the Department to address transcript delays beyond the students' and receiving institution's control.

The commenter requested confirmation that late transcripts would not reopen prior evaluations or appeal periods. On the other hand, another commenter request clarification that a school cannot reject a timely, well-supported appeal solely due to circumstances beyond the student's control that caused them to miss the standard deadline.

Discussion: Recognition is determined based on the accrediting agency's status at the time the student completed the course or program. One of the purposes of the Database of Accredited Postsecondary Institutions and Programs (DAPIP) is to provide students, employers, licensing bodies, and other stakeholders with a historical record that can be used to verify whether an institution or program was accredited at the time a student attended or completed the program. Maintaining recognition determinations based on the accrediting agency's status during the period of attendance promotes transparency, consistency, and the reliability of accreditation

records. DAPIP serves as an important resource for validating the accreditation status applicable to a student's course of study or credential at the time it was earned.

We understand the commenters' concerns regarding transcript delays that are outside the control of the student or the receiving institution. Timelines for transcript review may vary widely across institutions, and delays can arise from staffing limitations, prior institutions' processing schedules, or mail delivery issues. The Department acknowledges these practical concerns and clarifies that late-arriving transcripts do not reopen prior evaluations or restart appeal periods, provided the institution made its determination based on the information available at the time and in accordance with its established criteria. The Department agrees that appeals processes must offer meaningful student protection and confirms that institutions may not dismiss an otherwise valid appeal purely because external circumstances impeded a student's ability to meet an administrative timeline. This principle is reflected in Departmental due process expectations, which require agencies and institutions to afford students reasonable opportunities to respond or supply supporting evidence before adverse determinations are finalized.

Changes: None.

Comment: One commenter requested the Department clarify in the final rule's preamble or the Accreditation Handbook that § 602.24(e) is not meant to discourage institutions or accrediting agencies from applying the same principles—transparency, consistency, comparability—to standardized examination credit, and other forms of prior learning, where appropriate. The commenter argued that such clarification would not expand institutional obligations or interfere with accrediting agency authority, but that it would instead prevent an overly narrow interpretation.

Discussion: § 602.24(e) is focused on ensuring that students receive clear, academically grounded explanations of credit transfer determinations, particularly involving coursework completed at institutions accredited by title IV gatekeeper agencies. The Department notes that this requirement does not limit institutions or accrediting agencies from applying similar evaluative principles to other forms of learning, including standardized examination credit, credit for prior learning, or other competencies, provided such practices remain within accrediting agency standards and

institutional authority. The Department agrees that applying these principles consistently across credit-evaluation contexts can promote student understanding and institutional fairness. The final rule establishes baseline expectations for transfer credit determinations while preserving institutional and accrediting agency flexibility to adopt broader frameworks where appropriate. This is consistent with the Department's intention to ensure clarity for students while allowing accrediting agencies and institutions to accommodate variation in academic structures and evaluation practices.

Changes: None.

Comment: One commenter recommended that the preamble clearly differentiate the teach-out and institutional closure provisions from the transfer of credit provisions. The commenter suggested that the summary be revised to state that the appeal process applies only to credit transfer denials. The commenter expressed concern that the discussion of student protections during institutional disruption flows directly into a statement that students would have "an appeals process," which they believed could be misread as an appeals right related to closure or teach-out decisions.

Discussion: The Department appreciates the commenter's concerns and agrees that greater clarity could be provided in the preamble. Accordingly, we have separated the summary of requirements in § 602.24 into two sentences. See the "Summary of Major Provisions" for the changes.

Changes: None.

Comments: One commenter urged the Department to strike the phrase "comparable in content" from the regulatory section here. The commenter asserted that the phrase shifts focus away from learning outcomes and could encourage institutions to invoke extraneous criteria, such as course modality or accrediting agency of the sending institution. The commenter believed that credit should be awarded if there is 70 percent or more alignment in learning outcomes. If the 70 threshold is not met, the commenter recommended institutions focus on whether the learner is sufficiently prepared to succeed in subsequent education.

Discussion: The purpose of § 602.24(e) is to ensure that students receive clear, academically grounded explanations when transfer credit is denied, not to prescribe a uniform evaluative methodology across institutions or mandate specific thresholds. The Department recognizes that institutions

increasingly rely on learning outcome-based evaluation models and affirms that accrediting agencies and institutions may rely primarily on learning outcomes when determining equivalency. Nothing in § 602.24(e) prohibits or discourages such practices.

However, the Department does not believe that removing the phrase “comparable in content” or establishing a Federally mandated percentage threshold would be appropriate or consistent with statutory limits on the Secretary’s authority. Accrediting agencies and institutions must retain discretion to determine appropriate academic criteria based on institutional mission, program structure, content, learning outcomes, sequencing, licensure requirements, or other academically relevant factors. For some disciplines, content comparability remains an essential component of academic quality, even when learning outcomes are also evaluated. Accordingly, the Department declines to revise the regulation to remove the phrase “comparable in content” or to substitute a fixed percentage standard.

Changes: None.

Comments: A few commenters argued that the proposed rule requires transfer criteria that go beyond what is allowable in statute. The commenters asserted that the HEA does not authorize the Secretary to require policies, procedures, or practices by institutions of higher education with respect to transfer of credit. If the final rule does include new requirements for transfer of credit policies, the commenters urged the Department to maintain the language in the proposed rule that allows colleges to factor in comparative evaluations of content and learning outcomes to the institution’s own course offerings in its decision-making.

Discussion: The Department’s final rule is grounded in its long-standing authority to establish criteria for accrediting agency recognition, and to ensure that accrediting agencies apply standards consistently and transparently. The transfer of credit provisions in § 602.24(e) do not mandate how institutions must award credit, nor do they dictate academic judgments. Rather, they require accrediting agencies to confirm that institutions publicly disclose their transfer of credit policies and apply their stated criteria consistently and without arbitrary discrimination. These provisions fall squarely within the Department’s statutory authority to oversee accrediting agency recognition and to protect students through transparent, fair, and predictable institutional processes. The Department

agrees that institutions must retain academic discretion to evaluate comparability and applicability of coursework, and confirms that the final rule continues to allow consideration of content, outcomes, and other academically relevant factors as part of an institution’s decision-making framework.

Changes: None.

Comment: A few commenters opposed the proposed transfer of credit provisions entirely, and requested they be removed from the amended regulations. Commenters cautioned that these changes could unintentionally broaden the acceptance of credits from accrediting agencies with weaker standards, and emphasized that credit transfer decisions should continue to rest with institutional academic judgment.

Discussion: The Department declines to remove § 602.24(e). These changes preserve institutional autonomy and academic standards while addressing longstanding problems students face when transferring between institutions, including the potential for a loss of large portions of earned credit and difficulty progressing through a degree program.

Changes: None.

§ 602.25 Due Process

Comments: One commenter stated that the proposed changes to § 602.25 should be reconsidered because they are unnecessary and risk weakening meaningful due process. The commenter stated that the Department should preserve the current due process framework, which sufficiently protects institutions without recreating the burdens of litigation inside the accreditation process.

Discussion: We decline the commenter’s recommendation. The Department believes the changes satisfy due process while also reducing prescriptive requirements on accrediting agencies that are not required by statute. The changes to § 602.25 are limited to the administration of the appeals process by an agency and do not weaken or fail to satisfy due process.

Changes: None.

Comments: One commenter asserted that institutions face informal expectations from accrediting agencies that are unwritten and only verbally communicated through evaluators, staff, guidance, or prior decisions. The commenter stated that institutions face pressure to comply with these verbal directives and requested that the rule clearly state that adverse actions must be provided in writing and based on a written identified accreditation standard

and accurate information, not an unwritten expectation.

Discussion: The regulations in this section currently require written notification and specification regarding adverse action. If an institution receives an informal adverse action based on an unwritten expectation from an agency, then the institution should submit a formal complaint against the agency to the Department.

Changes: None.

Comments: One commenter recommended revising § 602.25(c) to read: “Provides the institution or program with a written specification of any deficiency identified, including the applicable accreditation standard, policy, or requirement; the material institution- or program-specific findings supporting the deficiency; and, when the agency requires additional information, documentation, corrective action, or other evidence of compliance, a sufficiently specific description of the information, documentation, evidence, or showing that the institution or program must provide to demonstrate resolution of the deficiency.” The commenter stated that the language would close the principal gap in the current formulation.

Discussion: We decline the recommendation. We believe that the spirit of the commenter’s recommendation is sufficiently covered under § 602.25. The regulation already requires “. . . written specification of any deficiencies . . .”. We believe the language proposed by the commenter would be overly prescriptive and burdensome. If an institution or program believes that the agency has not provided sufficient information under § 602.25(c) the institution or program can communicate with the agency requesting more specificity.

Changes: None.

Comments: One commenter requested that the Department strengthen § 602.25(e) to read: “The notice must provide an institution- or program-specific explanation of the basis for the action, identify each accreditation standard, policy, or requirement material to the action, describe the material findings supporting the action, state applicable deadlines, and, for a status or action that may be removed through corrective action, describe the criteria or showing the agency will use to determine whether the deficiency has been resolved and the action or status may be removed.” The commenter believed more precise language would remove uncertainty surrounding what an adequate description entails.

Discussion: We decline the commenter’s suggestion. We believe the

regulation is sufficient to require detailed notice from the agency on adverse actions. The Department does not want to be overly prescriptive with this regulation, and notes that this portion of the regulation was not modified in the proposed rule. Instead, we allow agencies to determine their adverse action notification requirements and believe that provides accrediting agencies sufficient flexibility, while maintaining appropriate oversight of its institutions or programs.

Changes: None.

Comments: One commenter requested that the Department clarify that under § 602.25(f)(1)(iii) and (iv), in the event of a decision by the appeals panel that differs from that of the original decision-making body, the original decision-making body must act in a manner consistent with the appeals panel's decision or instructions.

Discussion: We decline the recommendation; the commenter's request is implied in the nature of an appeal. The mere difference of opinion implies that the appeal was lost, and that the findings of the initial decision-makers are upheld.

Changes: None.

Comments: In order to require material oral instructions or clarifications to be memorialized in writing, one commenter requested the Department add a new paragraph to read: "If the agency or its authorized representatives communicate orally a material institution- or program-specific instruction or clarification concerning an identified deficiency, required special or follow-up report, evidence of compliance, corrective action, deadline, or criteria for removing or reversing an accreditation status or action, the agency must promptly memorialize the substance of that instruction or clarification in writing and provide it to the institution or program. The agency may satisfy this requirement through electronic communication. The written confirmation must be provided within a reasonable period, not to exceed 10 business days, and sufficiently before any applicable response deadline to permit a meaningful response."

Discussion: We decline to add the new paragraph. Oral instructions from an agency to an institution are not authorized under the due process regulations. All requirements must be in writing; the Department declines to imply that an agency can offer any instruction to an institution or program orally.

Changes: None.

§ 602.26 Notification of Accrediting Decisions

Comments: Most commenters broadly disagreed with the revised § 602.26. Commenters stated the following as rationale for opposition to the provisions:

- The final rule would weaken the consumer information role and effectiveness of accrediting agencies;
- The final rule would weaken safeguards surrounding institutions that change accrediting agencies;
- The Federal government would be weaponizing title IV, HEA funding eligibility;
- The Department could keep an institution's title IV eligibility active for an unreasonable or unlimited period while an adverse accreditation action is under appeal;
- The standard or discretion is unclear for keeping an institution's title IV eligibility active while an adverse accreditation action is under appeal;
- The final rule would constrain accrediting agencies and reduce the standing of the U.S. globally;
- The final rule should require fair and specific procedures before an accrediting agency takes adverse action;
- The Department could second-guess accrediting agency decisions; and
- Rapid disclosure of agency actions may affect enrollment decisions, transfer activity, employee recruitment, philanthropy, etc., before an underlying dispute is resolved.

Discussion: The Department disagrees with these comments. Our intention in amending this regulation, and our expectations for institutions and accrediting agencies after this rule is promulgated, is that this rule will establish a uniform disclosure framework of accreditation actions, enhance transparency, and strengthen consumer protection. Regarding new § 602.26(h), we feel the stated timeframe allows appropriate latitude when needed, and provides limits regarding the length of time an institution's eligibility may be extended. We do not expect this provision to be employed as frequently as some commenters expressed. The Department may provide additional guidance in the future regarding the process for an institution to request a continuation of eligibility for title IV, HEA program funds when it is challenging an agency's decision to end its accreditation.

Regarding the concern of rapid disclosure of agency actions adversely affecting enrollment decisions, the Department reasserts its desire to enhance transparency and strengthen consumer protections. Finally, the

Department disagrees that a new review framework overseeing recognized accrediting agencies that serve as the primary gatekeepers for the Federal student aid programs equates to weaponizing the title IV, HEA programs. Rather, these revisions ensure that students are protected from misuse of these funds, and that their continuing education is protected. The review framework ensures that all institutions that receive title IV, HEA program funds are worthy, and also allows institutions that believe they were wrongly judged to continue educating their students while legal actions proceed. The final rule is needed to improve educational quality, protect students and taxpayers, and promote a higher education accreditation system that supports innovation, accountability, and legal compliance. We do not see any reason to believe that these changes will undermine the world standing of the United States, nor did the commenter provide a persuasive argument that this would occur.

Changes: None.

Comments: Several commenters agreed with the Department's changes to § 602.26, specifically regarding the provisions that require an agency to note a probation or adverse decision in its public website directory within one business day of notifying the institution, and maintaining a five-year record of every action taken for each institution it accredits. The commenter emphasized these are specific duties on a fixed timeframe and should be easily reviewed for compliance. The commenter also recommended that the Department further modify § 602.26(h) to add a variable time limit based on published agency findings, require a determination that weighs student and taxpayer harm, and notify enrolled students that aid is continuing provisionally. Other commenters affirmed this approach should limit disruption during a review period and could correct erroneous decisions related to accreditation, thus allowing for an objective review and preserving the integrity of the process.

Discussion: We appreciate the commenter's support. The recommendation to further modify § 602.26(h) would add significant complexity and burden to both institutions and agencies when weighing a temporary continuation of eligibility for title IV, HEA funds until due process is exhausted. The Department believes the new § 602.26 will provide increased transparency and will provide effective implementation of the directives set forth in E.O. 14279.

Changes: None.

Comments: Another commenter suggested that the requirements of § 602.26(f) be limited to the actions listed in § 602.26(b) and § 602.26(c). The commenter further stressed there should not be a reference to § 602.26(e) in § 602.26(f), as § 602.26(e) does not delineate any actions that could be disclosed.

Discussion: The Department disagrees. The intent of § 602.26(f) is to broaden transparency and notification efforts to convey all actions taken for the specified period. We feel this expanded requirement will benefit any interested person or entity seeking recent accrediting agency actions at a specific institution or program.

Changes: None.

Comments: One commenter stressed the Department should clarify that “clear explanation in writing” under § 602.26 means more than identifying a general standard or reproducing standard language. The commenter opined that the written communication should contain institution-specific findings.

Discussion: The changes to § 602.26(b), (c), (d) and (e) are designed to improve transparency and clarify the notice requirements (e.g., clear explanations in lieu of brief summarizing statements). The Department declines to define the term “clear explanation” but expects accrediting agencies to, in lieu of a decision letter, provide specific information consistent with what is included in a decision letter for the institution or program. The Department reserves its authority and capability to regulate further on this topic as, and if, needed.

Changes: None.

Comments: One commenter requested clarification regarding the requirement in § 602.26(f) that would require an accrediting agency to maintain on its website “a clear record of all actions taken” for each institution or program it accredits or preaccredits for a period of at least five years. Specifically, the commenter asked if this five-year requirement would be from the effective date of the final rule or retroactive for the past five years.

Discussion: The Department thanks the commenter for this request for clarification. We note that this requirement is not retroactive; it will apply beginning on the effective date of these regulations.

Changes: None.

§ 602.28 Regard for Decisions of States and Other Accrediting Agencies

Comments: Several commenters expressed concern that the final rule

would allow for disputed political or ideological viewpoints to become conflicts in the accreditation process. The commenters stressed that students should not risk losing access to higher education or title IV, HEA program funds due to any disagreement between political officials and a university regarding its policies or activities. The commenters emphasized that accreditation decisions should be based on educational quality and established accreditation standards.

Discussion: The Department disagrees with the commenters. The intent in revising § 602.28(d) is to protect the consumer—students. The final rule does this by broadening the circumstances under which an accrediting agency must promptly review an institution or program to include when adverse or certain negative actions are taken by other State or Federal agencies.

Changes: None.

Comments: Many commenters expressed concerns about the expansion of this regulation that includes adverse actions or probation or equivalent statuses by State and Federal agencies. Some commenters suggested limiting State and Federal agencies to State approving/authorizing agencies. Other commenters suggested that the revised rule should apply only to final, written findings that are issued after notice and an opportunity to respond.

Discussion: The final rule is intended to increase accountability for institutions or programs subject to adverse or certain negative actions by State and Federal authorities by requiring accrediting agencies to promptly review those institutions or programs for continued compliance with the agency’s standards. If a compliance issue exists or existed, even if only tangentially, it should be promptly reviewed by the agency.

Changes: None.

Comments: One commenter urged the Department to add language to § 602.28 that clarifies the process outlined in § 602.20 for institutions, should an accrediting agency review an institution’s accreditation or preaccreditation due to being placed on probation, or equivalent status, by a state or Federal agency. The commenter stressed that institutions should be able to provide evidence that may indicate the issue has been resolved before any final decision is made.

Discussion: The Department believes that the amendments to this section do not impact the enforcement requirements in § 602.20. This section includes the actions taken by recognized accrediting agencies, State agencies, or Federal agencies that trigger a prompt

review of an institution’s or program’s preaccreditation or accreditation by their accrediting agency. The Department expects that any agency’s review of an institution or program would include correspondence with the institution or program under review before making a compliance determination.

Changes: None.

Comments: A few commenters requested the Department provide a definition of the term “adverse action.” The commenters warned that the final rule could be abused or misapplied without an explicit definition of this term.

Discussion: The Department clarifies that the definition of adverse action is found in § 602.3(b), which reads:

Adverse accrediting action or adverse action means the denial, withdrawal, suspension, revocation, or termination of accreditation or preaccreditation, or any comparable accrediting action an agency may take against an institution or program.

Changes: None.

§ 602.30 Agency Applications and Reports to be Submitted to the Department

Comments: Two commenters requested that the Department specify a review process for confidential information submitted by accrediting agencies to ensure agencies can submit information without risking any inappropriate disclosure.

Discussion: The final rule specifies that accrediting agencies must redact all personally identifiable information for individuals acting as agents of the agency, or of an institution or program under review, and the names and any other personally identifiable information of students or others who are not agents of the agency or of an institution or program the agency is reviewing. The Department already has in place processes for the review of information that the agency designated as exempt from disclosure; and therefore further changes in the regulations were not required.

Changes: None.

§ 602.31 Procedures for Submitting Applications for Recognition and Renewal of Recognition

Comments: Several commenters expressed concern that changing the review timeline to the proposed shorter timeline would make the review less rigorous. Two commenters suggested that the Department should include time ranges, including establishing minimum and maximum time periods for each stage of the review process. The

commenters also requested that the Department apply those same timelines to all agencies or provide criteria for differentiated periods of review and suggested that without such written rules, the Department would enforce timelines inequitably.

Discussion: The Department respectfully disagrees. The new regulations benefit both the Department and accrediting agencies under review by allowing for greater flexibility in the review process and the ability to accommodate various situations. The establishment of strict timelines for each stage of the review process would eliminate the ability for the Department to make good faith judgments on the complexity of petitions and the corresponding length of time available for review. Given that the regulations are meant to be a general framework, the Department does hold the ability, should the need arise, to provide subregulatory guidance as necessary to inform the implementation of the regulations. The Department is confident that the shortened review period will continue to provide meaningful and appropriate oversight. In addition, the shortened period will ensure that both accrediting agencies submit and the Department analyze the most current information. The timeline of two years means Department staff, NACIQI, and the SDO rely on out of date information in the current review process. The proposed timeline still provides for an iterative and rigorous review process. The revised recognition review timeline also helps to reinforce the expectation that accrediting agencies are in compliance with the regulations when they submit a petition for renewal of recognition.

Changes: None.

Comments: Several commenters stated that the Department's usage of the amount of title IV, HEA funds distributed as a basis for the type of review it conducts does not hold sufficient specificity. Comments were concerned about this definition due to the lack of an explicit definition for "substantial portion" in the new regulations. One commenter also expressed concern that institutions may specifically have a direct interest in the determination of "substantial portion." One commenter questioned whether using the amount of title IV, HEA funds for the determination of risk would accurately determine which accrediting agencies present the most risk or permit abbreviated review. One commenter questioned whether the Department is permitted to abbreviate reviews under 20 U.S.C. 1099b(n)(1), further requesting the Department establish "substantial

portion" as a specific percentage with a corresponding annual publication of the applicable agencies. The commenter also requested that the Department amend the interval for comprehensive applications for agencies who have not met the Department's "substantial portion" trigger to every other cycle of review, rather than every third cycle of review as noted in the proposed regulations. Two commenters expressed concerns that utilizing funding as the benchmark for review could ignore smaller institutions that could be prone to additional risk. One commenter requested that every agency undergo a comprehensive petition at its first renewal and that any agency that had accepted institutions previously subject to adverse action by another agency be reviewed through a comprehensive petition.

Discussion: Accrediting agencies serve as gatekeepers in determining which institutions may participate in title IV, which currently provide more than \$100 billion in Pell Grants and Federal loans to students annually. The Department is seeking to balance its oversight of agencies while ensuring it can significantly decrease burden for most accrediting agencies. The "substantial portion" element noted in the new regulations allows for the Department to accomplish this, in balance, by enabling flexibility in the determination of the review of agencies. The Department does not agree with the commenter who stated that institutions would have a direct interest in understanding whether or not an agency would be comprehensively reviewed, as there would be no effect on any specific institution. We believe that holding the comprehensive review as every third review will be sufficient, given that the agencies will be reviewed under focused review applications in the interim, satisfying the requirements noted in 20 U.S.C. 1099b(n)(1). While the Department understands the commenters' concern regarding greater risk for smaller institutions, the Department has an obligation to use its resources to provide oversight as broadly as possible by following the distribution of title IV, HEA funds. The focused review applications, together with the Department's ability to investigate issues and appropriately monitor agencies, ensure sufficient oversight in the interim period. Given that the regulations are meant to be a general framework, the Department does hold the ability, should the need arise, to provide subregulatory guidance as necessary to inform the implementation of the regulations.

Changes: None.

Comments: Several commenters expressed support for the Department's intention to prevent accrediting agencies from causing credential inflation. One commenter expressed concern that the Department would not be able to determine when scope inflation was necessary or unnecessary.

Discussion: We thank the commenters for their support. By amending the requirements in the new regulations for a change of scope, the Department will be able to collect and analyze detailed information when an agency seeks to expand credential requirements. By requiring such a review for all changes of scope, the Department will have a comprehensive review process that will ensure that an informed decision is made on the necessity of the expansion.

Changes: None.

Comments: One commenter requested accrediting agencies be specifically permitted to "authorize external providers to prepare, validate, format, and transmit applications, reports, and supporting data, subject to written authorization, oversight, agency review and certification, and applicable privacy and security requirements," and "reference previously submitted or authoritative data rather than resubmitting identical information."

Discussion: The Department does not prescribe the methods that accrediting agencies must use to complete any petition or to complete any response to a request for information. However, the accrediting agency is fully responsible for any and all submissions made to the Department.

Changes: None.

Comments: Two commenters requested that the proposed regulations be amended in § 602.31(a)(3) to only refer to legal actions, complaints, or other compliance issues that have been resolved or have some sort of final judgment given that the regulation could be interpreted as including pending issues. One commenter also requested that the Department establish an evidentiary threshold for when complaints are reviewed by the Department.

Discussion: The Department believes that pending legal actions, complaints, or other compliance matters would indeed be appropriate to report to the Department. The Department holds appropriate expertise to make judgments regarding information that is sufficiently significant to require additional review and oversight. Additionally, such oversight is necessary to ensure that pending issues that could significantly affect the accrediting agency, its institutions or programs, or its students, would be

appropriate to review prior to any final judgment or conclusion.

Changes: Please see the technical edit under the “Technical Corrections” section. The Department is clarifying that any determination if legal actions, complaints, or other compliance issues that individually or in the aggregate raise substantial concerns regarding the agency’s compliance would be made by the Secretary.

Comments: One commenter requested that the Department clarify anticompetitive conduct to not include an agency’s competency framework and assessment tools, given that some outcomes-based requirements could prevent certain institutions or programs from gaining or maintaining accreditation. One commenter requested that the preamble to the final rule include specific information regarding when anticompetitive conduct has occurred.

Discussion: The Department does not consider an agency’s standards related to outcomes-based assessment as being related to anticompetitive conduct. Instances of anticompetitive conduct are generally complex and require judgment-based decisions grounded in a review of agency activity and documentation. The Department holds appropriate expertise to make judgments on when information is sufficiently significant to require additional review and oversight. The regulations are meant to be a general framework, though the Department does hold the ability, should the need arise, to provide subregulatory guidance as necessary to inform the implementation of the regulations.

Changes: None.

Comments: One commenter stated that the Department failed to specify how it would comply with Section 496(n)(1)(A) of the HEA, which mandates that the Department’s “. . . evaluation [of an accrediting agency] shall include the solicitation of third-party information concerning the performance of the accrediting agency or association . . .” The commenter elaborated that the removal of this requirement may render the Department’s evaluation of accrediting agency changes in scope deficient under applicable law.

Discussion: Under § 602.31(b), the Department publishes the agency’s application for initial or renewal of recognition in the **Federal Register**. The public is invited to comment on the agency’s application, thereby satisfying the requirement that the Department solicit third-party information in such instances.

Changes: None.

§ 602.32 Procedures for Review of an Expansion of Scope, a Contraction of Scope, Compliance Reports, or Increases in Headcount Enrollment

Comments: One commenter stated that the proposed changes could allow accrediting agencies to easily change their scope to avoid Department oversight.

Discussion: The Department believes that the commenter may have misread the proposed regulations. The regulations increase the types of changes to scope reviewed than those that were previously reviewed to fully capture any change in scope. The regulations also allow for flexibility by the Department to determine when the review of any change in scope is reviewed.

Changes: None.

Comments: One commenter noted a concern regarding timelines and stated their concern that 90 days was not sufficient for a review petition, and 45 days for an agency response may also be insufficient.

Discussion: The Department believes that the commenter may have misread the proposed regulations. The regulation timelines regarding 90 days and 45 days are related to the review of compliance reports, not an agency’s petitions for recognition.

Changes: None.

§ 602.33 Procedures for Review of Agencies During the Period of Recognition, Including the Review of Monitoring Reports

Comments: A few commenters expressed concerns over the proposed elimination of the requirement for the Department to publish a notice in the **Federal Register**. The notice typically includes an invitation for the public to comment on an agency’s compliance with any criteria identified by Department staff that the agency may not be following.

Discussion: The Department has not proposed eliminating the requirement to finalize an analysis for presentation to NACIQI in the event a compliance concern is identified under the provisions of § 602.33. Doing so requires submitting the matter for review in accordance with § 602.34, which itself prescribes publication of a notice of the NACIQI meeting in the **Federal Register** which invites interested parties to make oral comments.

Changes: None.

Comments: Two commenters expressed concerns over the proposal to shorten the amount of time an accrediting agency has to provide a response to a staff analysis.

Discussion: The Department is focused on increasing the efficiency of the review process, which necessitates tighter timelines, not only for accrediting agencies, but also for Department staff. Additionally, accrediting agencies can continue to raise issues or concerns related to a final staff analysis when appearing before NACIQI and the entirety of the record, including a transcript of the meeting, will be available to the senior Department official prior to reaching a decision.

Changes: None.

Comments: One commenter suggested the Department first require documented findings prior to undertaking a review under § 602.33(a)(2).

Discussion: The commenter is referencing a subsection of the regulation that has not been proposed for change. However, the commenter may wish to review a related change, proposed under § 602.33(c) that would require the Department to provide an accrediting agency with documentation concerning an inquiry that arises under (a)(2) and provides the agency an opportunity to respond within a reasonable period of time.

Changes: None.

Comments: One commenter stated that following the Department’s changes, monitoring during the period of accreditation would become the primary means of oversight, and thus in-period monitoring should be strengthened. The commenter requested specific data-based triggers for review as well as decreasing the maximum period of recognition.

Discussion: The focused review applications, together with the Department’s ability to investigate issues and appropriately monitor agencies, ensure sufficient oversight in any interim period. The Department foresees greater emphasis on the review of information received between petition reviews and has appropriately included processing information for the review of agencies during the period of recognition. Given that the regulations are meant to be a general framework, the Department does hold the ability, should the need arise, to provide subregulatory guidance as necessary to inform the implementation of the regulations.

Changes: None.

§ 602.36 Senior Department Official’s Decision

Comments: Two commenters expressed concerns related to § 602.36. Both commenters expressed concerns related to recognition of accrediting

agencies that have limited experience. One of the commenters was also concerned that allowing the senior Department official to reach a recognition decision if a quorum of NACIQI members is not achieved results in the Department somehow being able to pressure accrediting agencies to adopt the Department's positions on compliance matters.

Discussion: Only cross-reference changes were proposed for § 602.36 in the NPRM. The Department included a paragraph in the amendatory language section of the NPRM for reference purposes only.

Changes: None.

§ 668.43 Institutional and Programmatic Information; Reporting and Disclosure of Information

Comments: Several commenters expressed concern about the administrative burden associated with course-specific determinations and written explanations that would be required by the regulations prior to enrollment or financial commitment. Commenters emphasized these concerns were specifically formulated based on smaller or newer institutions without extensive articulation databases or dedicated transfer evaluation staff. Several commenters suggested permitting standardized, criteria-based explanations tied to published academic policies instead of individualized narratives for each course, technology and data sharing infrastructure for resource constrained institutions, and Statewide articulation agreements and transfer partnerships between community colleges and HBCUs. A few commenters also asked if institutions were permitted to use categorical rules for groups of courses—including Bible and theology courses, core curriculum, upper-level major requirements, clinical courses, laboratories, and capstone experiences—rather than being required to apply individualized determinations for each course.

Discussion: The Department recognizes commenters' concerns about administrative burden, but we emphasize the importance of students receiving prompt decisions that support their informed enrollment planning and reduce uncertainty that may affect program progression. Institutions may establish reasonable timelines for transcript review and course material evaluation, provided they supply prospective students with clear and timely information about credit transfer policies. Institutions may also use structured or standardized templates tied to academic criteria when explaining course specific denials, so

long as the reasoning remains specific enough for students to understand the academic basis for determination. This flexibility supports clarity for students while accommodating variations in institutional size and staffing. The Department also supports efforts by States, systems, and institutions, including HBCUs and community colleges, to build articulation frameworks that facilitate smoother transfer and reduce barriers for students.

Changes: None.

Comments: A few commenters asked the Department to establish a specific timeframe for when an institution must receive a student's transcript to ensure a timely review, while other commenters urged the Department to remove the pre-enrollment disclosure entirely. These commenters believed it would lead to rushed, error-prone evaluations, especially when an official transcript has not been received. Some commenters were concerned that without a defined deadline, students would not know when they need to submit their transcripts to allow sufficient processing time. One commenter suggested that, similar to the explicit timeframe for filing an appeal under § 602.24(e)(5) "within 15 calendar days of receipt," § 668.43 should likewise include a clearly defined period to provide consistency and clarity for students.

Discussion: The Department declines to remove the pre-enrollment disclosure requirement, and we decline to add a specific timeframe for transcripts to be received. The Department believes the pre-enrollment disclosure requirement is an essential element in promoting clarity and avoids situations in which students enroll without necessary information about how their earned credit will apply. Institutions have the flexibility in designing their transcript review systems, including assigning review responsibilities to academic units in a timely manner, using structured templates tied to academic criteria, and adopting technology solutions and articulation agreements. Institutions are required to disclose the date by which a student must submit transcripts for review in their transfer of credit policies. This approach provides transparency while maintaining flexibility for institutions to account for differences in program offerings, enrollment cycles, and administrative processes. While § 602.24(e)(5) includes an explicit timeframe for appealing a transfer of credit denial, "within 15 calendar days of receipt," that provision addresses the appeals process rather than the initial submission of transcripts. The Department does not

believe that applying a uniform Federal deadline to transcript submission would appropriately reflect the diversity of institutional practices or support the efficient administration of credit evaluations across institutions.

Changes: None.

Comments: Several commenters urged the Department to clearly distinguish between transferability (whether a course can be accepted for credit) and applicability (whether the accepted credit applies to specific degree requirements). One commenter believes this distinction will help clarify the confusing use of "awarded for courses" in § 668.43. A few commenters pointed out that a credit that transfers as an unassigned elective does not necessarily shorten a student's path to a degree and that students need to know whether accepted credits satisfy elective, general education, or major requirements. One commenter also urged the Department to extend disclosures to include learning earned through registered apprenticeships. The commenter recommended that § 668.43(c)(3)(i) read: "Inform the student of the credit that will be awarded for courses on that transcript, inclusive of related technical instruction as appropriate, and how that credit will apply toward the student's intended program of study, including whether it satisfies elective, general education, or major requirements."

Discussion: The Department agrees that transferability and applicability have distinct meanings and that clarity between awarding credit and applying credit is important to help students make informed decisions about their educational pathways. § 668.43 ensures that students receive clear information about both which credits may be accepted and how those credits will apply to the program they intend to pursue. The regulation does not prohibit institutions from distinguishing transferability from applicability in their policies and the Department encourages institutions to do so.

The Department acknowledges that institutions may maintain different applicability standards across categories (e.g., major requirements, general education, electives), as commenters noted. While the Department supports expanded transparency regarding credit for prior learning, including apprenticeship-related learning, the Department must also ensure that any additional disclosure requirements remain aligned with statutory authority and are administratively feasible. Therefore, the Department declines to revise the regulatory text to incorporate additional prescriptive applicability requirements or to mandate specific

disclosure language related to apprenticeships in § 668.43, as these additions exceed the scope and purpose of this rule.

Changes: None.

Comments: One commenter noted a potential contradiction between § 668.43(a)(11)(i), which requires institutions to disclose any criteria used for evaluating transfer credit, including identifying types of institutions or sources from which they will not accept credit, and the Department's proposed prohibition in § 602.24(e)(3) against denying credit based on the sending institution. The commenter argued that § 668.43(a)(11)(i) implies that institutions may legitimately refuse credit from certain sources and asked for clarification on how both provisions would function together.

Discussion: The Department does not view these provisions as contradictory. The disclosure requirements in § 668.43(a)(11)(i) are intended to promote transparency by ensuring that students understand the criteria an institution uses when evaluating transfer credit. § 602.24(e)(3), by contrast, addresses the substance of transfer credit determinations that states that institutions may not deny transfer credit solely based on the sending institution or its recognized accrediting agency. Institutions remain free to evaluate transfer credit using academically relevant factors, including course content, learning outcomes, level, applicability to program requirements, prerequisites, sequencing, or other legitimate academic considerations. However, institutions may not rely exclusively on the identity of the sending institution or its recognized accrediting agency as the basis for denying credit. Accordingly, the disclosure requirements in § 668.43(a)(11)(i) and the requirements in § 602.24(e)(3) serve complementary purposes. The former promotes transparency regarding institutional policies, while the latter establishes limits on the criteria that institutions and accrediting agencies may use in credit transfer decisions. Institutions must disclose their transfer of credit policies, but those policies must remain consistent with the requirements of § 602.24(e)(3).

Changes: None.

Comments: A few commenters requested that the Department revise the timing requirement so that institutions are not required to complete individualized transfer-credit determinations before a nonrefundable enrollment deposit when verified records or necessary faculty review are not yet available. Commenters stressed

the strain institutions may face by preparing credit transfer determinations for prospective students who ultimately may not enroll.

Discussion: The Department recognizes that credit transfer evaluations can involve complex academic judgments and that institutions may require time to obtain and review official transcripts, course descriptions, and other supporting documentation. The Department does not intend to compel institutions to make credit transfer determinations based on incomplete information or to sacrifice academic rigor in favor of speed. As noted elsewhere in the preamble, institutions may establish reasonable processes and timelines for transcript review and course evaluation, provided they furnish students with clear and timely information regarding credit transfer policies and determinations. At the same time, the Department remains committed to students receiving meaningful credit transfer information before making financial commitments that could expose them to unexpected costs or extended time to completion. The timing requirement will improve transparency and enable students to make informed enrollment decisions, particularly where transferability of prior coursework may affect educational affordability and degree progress. Nothing in the regulation requires institutions to disregard legitimate academic review processes or to reach final determinations in the absence of information necessary for an accurate evaluation. Further, the Department expects institutions to communicate clearly to students when a determination remains pending because additional documentation or faculty review is required. The Department continues to believe that students should receive credit transfer information before enrollment, registration, or other significant financial commitments whenever reasonably possible while preserving institutional discretion to conduct appropriate academic reviews.

Changes: None.

Comments: One commenter suggested that, in addition to disclosing credit transfer policies and evaluation criteria, institutions should also transparently disclose all critical information about transfer practices, including decision-making authority and workflows, timelines, and appeal processes. Another commenter argued that also institutions should distinguish direct equivalency, general-education credit, elective credit, and rejected credit in student notices.

Discussion: The Department is mindful of the need to balance transparency with regulatory flexibility. Institutions vary significantly in their governance structures, credit transfer review processes, academic programs, and administrative systems. The Department does not believe it is necessary to prescribe specific disclosure formats or require institutions to provide detailed descriptions of all internal workflows and decision-making processes.

Changes: None.

Comment: One commenter asked the Department to consider publishing transfer credit data in a publicly accessible database, stating that metrics could include the percentages of credits that are accepted and denied at each institution per year.

Discussion: The Department notes that the regulations in this final rule are focused on institutional and accrediting agency requirements regarding credit transfer policies, disclosures, and decision-making processes. The regulations do not establish Federal reporting requirements for institution-level transfer of credit acceptance and denial rates, nor do they create a framework for the collection, validation, and publication of such data. The Department may continue to explore opportunities to improve information available to students regarding transfer outcomes and student mobility, but such efforts are beyond the scope of this rule.

Changes: None.

Comments: One commenter urged the Department to eliminate § 668.43(a)(11)(ii) and (v). The commenter argued that paragraph (ii) is too broad, and that paragraph (v) is too narrow to be meaningful. The commenter noted that § 668.43(a)(11)(v) would only apply to the Workforce Pell Grant program where non-credit programs are required to be accepted for credit in at least one certificate or degree program.

Discussion: The Department does not agree that § 668.43(a)(11)(ii) is unnecessarily broad. The purpose of this provision is to ensure that prospective and current students have access to clear information regarding the criteria institutions use when evaluating transfer credit. Transparency regarding institutional policies and practices enables students to make informed enrollment and transfer decisions. The Department also disagrees that § 668.43(a)(11)(v) lacks value. Although the commenter notes that the provision may be particularly relevant in contexts involving Workforce Pell, information about whether an institution recognizes or articulates non-degree and non-credit

learning may be important to students seeking pathways from workforce training, certificate programs, prior learning experiences, or other educational experiences into degree programs. Providing this information promotes transparency and may help students better understand opportunities for academic progression before making enrollment decisions.

Changes: None.

Comments: One commenter asked the Department to clarify what counts as a “nonrefundable financial commitment”, specifically when a refund is required on tuition payment, payment plan, required deposits, and application fees. The commenter asked whether the relevant date for refund on tuition is the date payment is due, is made (if the individual pays after the due date), or the date after which a full refund is no longer available. For a refund on a payment plan, the commenter asked if an individual establishes a payment plan months before classes begin, does that constitute a nonrefundable financial commitment? The commenter also asked if the plan provides a generous refund option when enrollment changes but imposes a small cancellation fee, does that fee trigger a nonrefundable financial commitment? Additionally, the commenter asked if a payment plan would only constitute a nonrefundable financial commitment if the institution itself manages the plan, or would it also constitute a nonrefundable financial commitment if the plan is managed by a third party? The commenter also asked if a deposit is refundable, would the Department no longer consider it a financial commitment for purposes of these regulations? As for application fees, the commenter asserted that they don’t believe it should count as a nonrefundable financial commitment to the institution.

Additionally, the commenter asked if an institution provides a refund option when a learner declines enrollment because transfer credit is denied, would that remove the payment from the definition of a “non-refundable financial commitment”? The commenter also asked if a learner voluntarily makes a nonrefundable financial commitment after being informed of the right to receive transfer-related information, but before an established deadline, would the institution be out of compliance if it had not completed the transfer credit review, or would the institution have to decline the payment? The commenter also requested that the Department elaborate on how these final rules would apply to foreign transcripts. The commenter asked if the implementation

of this requirement differs based on the learner’s status?

Discussion: The Department does not believe that it is necessary to prescribe in regulation every institutional practice relating to tuition payments, payment plans, deposits, application fees, or other enrollment-related charges. Whether a particular payment or obligation constitutes a nonrefundable financial commitment depends on the facts and circumstances of the arrangement and whether the student may recover the funds or terminate the obligation without financial loss. Generally, the relevant consideration is the point at which a student becomes subject to a charge, fee, deposit, or other obligation that is not fully refundable or otherwise cannot be avoided.

Changes: None.

Comments: The commenter recommended removing the terms “enrollment” and “registration” from the disclosure requirements to make clear that the priority is protecting students from making nonrefundable financial commitments before they have the information needed to make an informed enrollment decision.

Discussion: The Department declines to remove the references to “enrollment” and “registration” from the disclosure requirements. The Department’s objective is to ensure that prospective students receive important transfer of credit and consumer information before taking significant steps toward enrollment, including signing an enrollment agreement, completing registration, or making a nonrefundable financial commitment. The inclusion of enrollment and registration, in addition to nonrefundable financial commitments, recognizes that institutions use different admissions, enrollment, and registration processes and that students may become committed to attending an institution through mechanisms other than the payment of a nonrefundable fee.

Changes: None.

Comments: The commenter argued that § 668.43(c) is inconsistent with the organization of the existing regulations. The commenter noted that § 668.43(c) currently addresses requirements related to programs that prepare students for State licensure or certification. The commenter is concerned that adding new requirements to the same subsection could create confusion about whether they are related to licensure or certification or are separate requirements applicable more broadly. For clarity, the commenter recommended placing the new requirements in a new § 668.43(d) and

redesignating current § 668.43(d) as § 668.43(e).

Discussion: The Department does not believe that relocating these provisions to a separate subsection is necessary.

The Department notes that regulations frequently contain multiple related requirements within a single section, and the structure of § 668.43 is intended to consolidate disclosure obligations applicable to prospective and enrolled students. The final rule clearly identifies the transfer of credit review requirements as distinct provisions within § 668.43(c), and the Department believes that the regulatory text sufficiently distinguishes those requirements from the licensure and certification disclosures. As a result, institutions and students will be able to understand that the transfer of credit requirements apply independently of the licensure-related disclosures. This organization also preserves the overall structure of § 668.43 and avoids unnecessary redesignation of existing provisions.

Changes: None.

Comments: One commenter is concerned that § 668.43(c)(3)(iii) is confusing. The commenter pointed out that not every credit transfer denial corresponds directly to a course offered at the receiving institution or that institutions deny credit to require learners to retake their version of a course. The commenter noted that residency requirements may mandate students to complete a certain number of credits at the degree-granting institution and a transfer student who changes majors may have credits that no longer apply to the learner’s course of study.

Discussion: The regulation does not intend to suggest that every credit transfer denial is based on the existence of an equivalent course at the receiving institution or that institutions deny credit solely to require a student to complete the institution’s version of a course. The purpose of § 668.43(c)(3)(iii) is to promote transparency by ensuring that students receive a written explanation when credit is not awarded and information that helps them understand the institution’s credit transfer evaluation process. The Department believes that providing students with a clear rationale for why credit was not awarded is particularly important because credit transfer determinations may be based on a wide range of academic and institutional considerations. As discussed elsewhere in this rulemaking, institutions are required to provide a written explanation as to why they declined to award credit and provide information

and examples of courses that otherwise would be awarded credit. This requirement is intended to assist students in understanding the institution's standards and practices rather than to imply that every denied credit has a direct equivalent within the institution's curriculum.

The Department further notes that the regulation does not prohibit institutions from explaining that a credit was accepted but did not apply toward specific degree requirements, or that a credit was not awarded due to residency requirements, program requirements, changes in a student's course of study, or other legitimate academic reasons. Institutions retain discretion to apply their academic policies and degree requirements, provided they clearly communicate the basis for their determinations to students.

Changes: None.

Comments: One commenter recommended adding a new § 668.43(a)(11)(vi) to read: "The institution's existing transfer of credit determinations, published in a publicly accessible location on the institution's website. For each determination, the institution must identify the sending institution, the sending institution's course identifier and title, and how the institution treated the course: the specific course equivalency awarded, the type of credit awarded where no specific equivalency has been established (such as elective credit), or a statement that the institution declined to award credit. The institution must publish these determinations in the form in which it maintains them, updated no less often than annually. The determinations published under this paragraph consist of course-level and institution-level information only and must not include personally identifiable information about any student. Nothing in this paragraph requires an institution to adopt a particular format or data standard, to create determinations it has not made, or to represent that a published determination will apply to any particular student. The determinations must be accessible without a login, account, application, fee, or agreement to terms of use, and an institution that licenses a third party to maintain its determinations remains responsible for their publication under this paragraph."

Discussion: The Department believes that the final regulation appropriately balances transparency for students with institutional flexibility by requiring institutions to disclose their transfer of credit policies, the criteria used to evaluate transfer credit, any categories of institutions or sources from which

credit will not be accepted, applicable transcript-submission deadlines, articulation agreements, and information about transfer-credit determinations made for individual students who timely submit transcripts. The Department's focus in these regulations is ensuring that prospective students receive institution-specific information relevant to their own educational records before signing an enrollment agreement, completing registration, or making a nonrefundable financial commitment. The Department does not believe that requiring institutions to publish all prior credit transfer determinations is necessary to achieve that objective.

Changes: None.

VII. Regulatory Impact Analysis

1. Regulatory Planning and Review Including Regulatory Impact Analysis

Executive Orders 12866 and 13563

Under Executive Order 12866, the Office of Management and Budget (OMB) must determine whether this regulatory action is "significant" and, therefore, subject to the requirements of the Executive Order and subject to review by OMB. Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities;

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise legal or policy issues for which centralized review would meaningfully further the President's priorities, or the principles stated in the Executive Order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

As indicated in the Net Budget Impact section of this RIA, the Department estimates that there will be no significant change in transfers between the Federal government and student loan borrowers and Pell Grant recipients as a result of the final rule. Quantified annualized costs include updates and reporting costs for accrediting agencies, institutions, and individuals detailed in the *Paperwork Reduction Act* section of

this final rule of \$3.4241 million and \$3.8180 million at 3 percent and 7 percent discounting, respectively. Therefore, based on our estimates of quantified and non-quantified costs and benefits, OIRA has determined that this regulation is significant under Section 3(f)(1) of Executive Order 12866 and subject to OMB review.

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and considering—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." OIRA has emphasized that these techniques may include "identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes."

Executive Order 14192 directs agencies of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and to alleviate unnecessary regulatory burdens placed on the American people. This action is not expected to be considered a regulatory action under Executive Order 14192 because it imposes no more than de minimis net regulatory costs.

Consistent with OMB Circular A–4, we compare the final rule to the current regulations. In this regulatory impact analysis, we discuss the need for regulatory action, potential costs and benefits, net budget impacts, and the regulatory alternatives we considered.

Elsewhere in this section under Paperwork Reduction Act of 1995, we identify and explain burdens specifically associated with information collection requirements.

Regulatory Impact Analysis

a. Need for Regulatory Action

The Department proposes this regulatory action to align the Secretary of Education’s (Secretary) criteria for recognition of accrediting agencies to promote high-quality, high-value, and affordable education for students as outlined in E.O. 14279, titled “Reforming Accreditation to Strengthen Higher Education,” issued on April 23,

2025, by President Trump.¹³ E.O. 14279 directs the Secretary to take several actions related to the Department’s recognition of accrediting agencies or associations to ensure agency standards and enforcement actions are focused on student outcomes and free from unlawful discrimination and other potential violations of Federal and State law.

The Higher Education Act of 1965, as amended (HEA), requires the Secretary to establish criteria for determining whether an accrediting agency is a reliable authority, for purposes of the HEA and for other Federal purposes, on the quality of education or training offered by the institutions or programs that they accredit. Consistent with the statute, the Secretary has established regulations for recognition of

accrediting agencies and has revised these regulations periodically.

The final reduces barriers that limit competition among accrediting agencies and recognition of new accrediting agencies. Similarly, via changes to accrediting agency requirements, the final rule will likely increase educational innovation and foster new education models that advance credential and degree completion. To improve student outcomes on student loan repayment, graduate earnings, and financial value and affordability, the final rule requires that recognized accrediting agencies assess member institutions on program-level student outcomes, without reference to race, ethnicity, or sex.

b. Summary of Comments and Changes From the NPRM

Table 2.1 provides a summary of the proposed provisions.

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¹³ Executive Order 14279. “Reforming Accreditation to Strengthen Higher Education.” The White House. April 23, 2025. www.whitehouse.gov/presidential-actions/2025/04/reforming-accreditation-to-strengthen-higher-education/.

Table 2.1 - Summary of Key Changes in the Proposed Regulations

Provision	Regulatory Section	Description of proposed provision
Accreditation, Innovation, and Modernization		
Special rules regarding institutional accreditation or preaccreditation .	§ 600.11	Amend § 600.11 to make it less burdensome for institutions that are changing accrediting agencies or wish to utilize more than one accrediting agency.
How do I know which agencies the Secretary recognizes?	§ 602.2	Amend § 602.2 to require the Department provide public notice on its accreditation website if the Secretary denies continued recognition to a previously recognized agency, or if the Secretary limits, suspends, or terminates the agency's recognition before the end of its recognition period.
What definitions apply to this part?	§ 602.3	Amend § 602.3 to define and use the term "institution" in these regulations instead of "institution of higher education" which is defined in the HEA, and elsewhere in the Department's regulations, and refers to a narrower subset of institutions, and to add a definition for "related, associated, or affiliated trade association."
Link to Federal programs.	§ 602.10	Amend § 602.10 to clarify the Secretary's recognition extends only to those accrediting agencies whose institutions or programs actively participate in a Federal program.
Extent of Accrediting activities.	§ 602.11	Amend § 602.11 to require accrediting agencies to clearly describe the scope of their accrediting activities and remove geographic restrictions on institutions' and program's

		ability to choose an accrediting agency.
Accrediting experience.	§ 602.12	Amend § 602.12 to remove references to geographic areas and geographic constraints, and require review of contractions of scope. Additionally, amend the regulations to clarify the policies and capacity an accrediting agency must have to seek initial recognition, and eliminate the "two-year rule" for initial recognition due to lack of statutory requirement.
Effect of recognition.	§ 602.13	Unreserve and amend § 602.13 to specify that an accrediting agency's recognition by the Department does not provide any immunity from antitrust laws.
Purpose and organization.	§ 602.14	Amend § 602.14 to strengthen the fiscal and administrative criteria an accrediting agency must meet to prove it is fully separate and independent from any related, associated, or affiliated trade or membership organization.
Administrative and fiscal responsibilities .	§ 602.15	Amend § 602.15 to require accrediting agencies to administer their standards, policies, and procedures in a manner that minimizes unnecessary compliance costs and administrative burdens on accredited institutions, as well as requires agencies to maintain appropriate conflict of interest controls and policies.
Accreditation and preaccreditation standards.	§ 602.16	Amend § 602.16 to require accrediting agencies to assess clear institutional and program level student achievement requirements aligned with § 602.17, and to

		clarify that any additional standards must be lawful and consistent with ensuring institutional and programmatic quality and integrity.
Application of standards in reaching accreditation decisions.	§ 602.17	Amend § 602.17 to clarify expectations for reviewing student achievement and faculty related policies, including academic freedom and intellectual diversity. There are also new requirements for cost-benefit analysis, institutional flexibility and mission, program length review, and safeguards against misrepresentation.
Ensuring consistency in decision-making.	§ 602.18	Amend § 602.18 to require accrediting agency decisions to be neutral with respect to viewpoint and ideology, except for those with a religious mission.
Enforcement of standards.	§ 602.20	Amend § 602.20 to provide guidance to accrediting agencies on how to structure their arbitration procedures and remove overly prescriptive requirements.
Review of standards.	§ 602.21	Amend § 602.21 to remove overly prescriptive requirements.
Substantive changes and other reporting requirements.	§ 602.22	Amend § 602.22 to refine the list of changes requiring accrediting agency approval, add prison education programs as a defined substantive change, and remove outdated and overly prescriptive requirements.
Operating procedures all agencies must have.	§ 602.23	Amend § 602.23 to require accrediting agencies to ensure institutions comply with all applicable Federal and State laws and remove overly prescriptive requirements.
Additional procedures	§ 602.24	Amend § 602.24 to strengthen accrediting agencies'

certain institutional agencies must have.		oversight of institutional changes, expand requirements for teach-out planning, including transcript access, and increase transparency and support for students when institutions face disruptions. These regulations would also establish clearer, fairer transfer of credit rules by defining consistent criteria, prohibiting discriminatory denials, requiring acceptance of comparable credits, and providing students with an appeals process.
Due process.	§ 602.25	Amend § 602.25 to remove overly prescriptive requirements.
Notification of accrediting decisions.	§ 602.26	Amend § 602.26 to update and modernize the required content of agency notices and better align these requirements with contemporary methods of disclosure and allow temporary continuation of eligibility for title IV, HEA funds after erroneous decisions on the part of the accrediting agency.
Other information an agency must provide the Department.	§ 602.27	Amend § 602.27 to require that the Department's website is updated on a regular, timely basis to display the current accreditation status of all institutions and programs.
Regard for decisions of States and other accrediting agencies.	§ 602.28	Amend § 602.28 to broaden the circumstances under which an accrediting agency must reevaluate an institution or program following negative actions by other authorities.
Agency applications and reports to be	§ 602.30	Amend § 602.30 to modernize how accrediting agencies submit applications and

submitted to the Department.		required reports to the Department.
Procedures for submitting applications for recognition and renewal of recognition.	§ 602.31	Amend § 602.31 to modernize and streamline the procedures accrediting agencies must follow when submitting applications for initial or renewed recognition.
Procedures for review of an expansion of scope, a contraction of scope, compliance reports, or increases in headcount enrollment.	§ 602.32	Amend § 602.32 to modernize and clarify the processes used to review an accrediting agency's expansions or contractions of scope, compliance reports, and increases in headcount enrollment.
Procedures for review of agencies during the period of recognition, including the review of monitoring reports.	§ 602.33	Amend § 602.33 to modernize and streamline the procedures for review of agencies during the period of recognition, including the review of monitoring reports.
Advisory Committee meetings.	§ 602.34	Amend § 602.34 to require the National Advisory Committee on Institutional Quality and Integrity (NACIQI or Advisory Committee) to review applications for contractions of scope, and for accrediting agencies to post public notice of upcoming NACIQI reviews for transparency and consistency.
Responding to the Advisory Committee's recommendation.	§ 602.35	Amend § 602.35 to update cross references.
Senior Department official's decision.	§ 602.36	Amend § 602.36 to update cross references.

Appealing the senior Department official's decision to the Secretary.	\$ 602.37	Amend \$ 602.37 to update cross references.
Institutional and programmatic information.	\$ 668.43.	Amend \$ 668.43 to require transfer of credit disclosures and direct written notice to students.

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Summary of Comments From the NPRM

The Department received comments related to the Regulatory Impact Analysis in the NPRM. This section responds to these comments. Some commenters submitted alternatives that were substantially similar to remarks submitted by other commenters; in these cases, we grouped those comments and responded to them collectively.

Comments: One commenter argued that the Department had not produced sufficient analyses to substantiate its claims that the proposed rule would help lower college costs and prices for students.

Discussion: The Department believes that the credit transfer policies in the proposed and final rule will help reduce costs for students. The Department included an analysis in the Regulatory Impact Analysis in the proposed rule that showed how many students and Title IV aid dollars could potentially be affected when a greater share of students' credits transfer when they change institutions. However, that analysis did not estimate potential changes in total or per-student aid distributions.

Changes: The Department has expanded the data and analysis regarding credit transfer to estimate reductions in Title IV aid disbursements due to the credit transfer policies in this final rule. These estimates help to illustrate the potential savings to both taxpayers and students that are likely to result from the credit transfer policies in this final rule.

Comments: The Department received several comments raising concerns that women, students from minority groups, and low-income students will be disproportionately and negatively affected by the proposed rule. Commenters argued that these students will lose access to educational opportunities due to the proposed rule.

Discussion: The Department disagrees. The Department believes that the final rule will help create greater educational opportunities by fostering innovation and new educational delivery models. The Department has included additional analysis in this final rule that estimates the potential growth in short-term credential programs and exclusively online programs as a proxy for the increased educational opportunities that are likely to arise under the final rule. Data from the National Postsecondary Student Aid Study show that women represent a larger share of enrollment in these programs compared with other programs. Black students are also more likely to enroll in short-term programs than are other groups. The data therefore suggest that the final rule will, in fact, increase education opportunities for certain groups of students.

Changes: None.

Comments: One commenter argued that the Department failed to consider the effects of the proposed rule on different sectors of higher education and requested that the Department consider these differentiated effects.

Discussion: The Department included a breakdown of the effects on different sectors of higher education in various sections of the Regulatory Impact Analysis in the NPRM. The analysis detailing Title IV aid disbursements made to transfer students (which the Department has expanded in the final rule to include estimates of potential changes in disbursements) is broken out by public, private non-profit, and private for-profit institutions.

Changes: None.

Comments: One commenter noted that community colleges serve different students than other sectors of higher education and recommended that the Department allow accrediting agencies to use different outcome measures for evaluating programs at community colleges than for other institutions.

Discussion: The final rule requires accrediting agencies to review their criteria for assessing whether an institution is successful in achieving its stated objectives at both the institutional and program levels, including minimum expectations regarding student outcomes. The Department notes that accrediting agencies have wide latitude in determining expectations for student outcomes and can tailor those measures to community colleges and their students or specific programs and enrollment patterns if they deem it appropriate.

Changes: None.

Comments: Several commenters raised concerns that the proposed rule would encourage accrediting agencies to use students' post-enrollment earnings to assess whether an institution or program is successful in achieving its stated objectives. Commenters argued that earnings vary by field of study, geography, labor markets, and other factors and are therefore an unreliable proxy of educational quality. Other commenters argued that only long-term earnings, for which data are difficult to obtain, are appropriate for measuring outcomes.

Discussion: The Department believes that post-enrollment earnings can be one of many valuable measures of whether an institution or program meets quality standards and stated objectives. Moreover, these data are increasingly available and reliable. The Department notes, however, that under the final rule, accrediting agencies maintain considerable discretion in how they develop and apply standards using earnings outcomes. The final rule does not prevent accrediting agencies from considering the issues that the commenters raise.

Changes: None.

Comments: A commenter raised concerns that institutions of higher education lack access to comprehensive and reliable data on retention, completion, and post-enrollment

outcomes of their students and would therefore not be able to meet any accreditation requirements on these factors.

Discussion: The Department notes that institutions of higher education already report significant data and statistics on student completion and retention rates to the Department and to other agencies. This RIA also includes analyses of outcomes by accrediting agency that were produced using public data, further demonstrating that these data are available. Moreover, the Department of Education will publish annual statistics on the earnings of program completers drawn from Federal tax records (who are Title IV recipients) starting in 2027, which could serve as additional outcome information for institutions, programs, and accrediting agencies.

Changes: None.

c. Discussion of Cost, Benefits, and Transfers

The final rule will likely affect students, institutions of higher education, accrediting agencies, and the Federal government. The Department expects students and the Federal government to benefit from the final rule. The final rule is likely to impose new costs on institutions and accrediting agencies.

This analysis focuses on four major policy areas within the final rule that are likely to have the most significant costs and benefits:

- (1) changes to accrediting agencies' transfer of credit policies;
- (2) a new requirement that agencies adopt policies that assess program-level student outcomes;
- (3) regulatory changes that will allow for greater competition among existing and newly recognized accrediting agencies; and
- (4) reforms that align accreditation standards with efforts to reduce college costs and credential inflation.

We discuss the costs and benefits associated with each of these areas below. The Department notes that there is little critical data available on which to base estimates of the proposed regulation's effect on the accrediting agency marketplace and responses by institutions and students. For this regulatory impact analysis, the Department has relied primarily on the publicly available Database of Accredited Postsecondary Institutions and Programs (DAPIP) and its own administrative data on title IV, HEA student aid recipients in the National Student Loan Data System (NSLDS) and the Common Origination and Disbursement (COD) System.

Transfer of Credit

The final regulation would make it easier for students to transfer credits to continue their postsecondary enrollment at a new institution. Under Section 602.24(e)(3), accrediting agencies would be required to ensure member institutions adopt several policies regarding transfer of credit that should increase the number of credits students are able to retain when transferring to a new institution. For example, the final rule would require that accrediting agencies prohibit an institution from denying transfer of credit based on the recognition of the institution, or type of institution, at which the student completed the coursework, so long as the agency accrediting that institution is recognized by the Secretary. Accrediting agencies must also require an institution to award transfer credit for undergraduate programs for coursework that has been successfully completed at another institution, is accredited by an agency recognized by the Secretary, and is comparable in content and learning outcomes to the institution's own course offerings, unless the institution provides a written basis for denial.

Students could benefit from these changes because they may spend less time and money retaking courses that failed to transfer. A 2017 study by the U.S. Government Accountability Office using Department of Education data found that transfer students typically lose 43 percent of their credits when they transfer.¹⁴ Under the proposed rule, it is more likely that students will retain more of their credits earned at prior institutions, allowing them to complete their postsecondary education faster.

It is difficult to estimate the precise effect this policy may have on enrollment and title IV, HEA student aid disbursements, and the Department acknowledges a variety of outcomes could occur. First, the policy may induce more students to enroll in higher education because students will have more flexibility to switch programs without losing a substantial amount of credit earned at prior institutions. The policy may also reduce the dropout rate as students are able to maintain more of their prior credits when transferring, thereby reducing the total cost and enrollment duration of their program which should facilitate credential

completion. It may also make transfer more desirable, allowing students to better match themselves to different programs and enhancing their ability to continue their education. If this occurs, the policy may ultimately increase enrollment and title IV, HEA student aid disbursements, imposing new costs on taxpayers and the Federal government. Additionally, higher education institutions may benefit, as they would likely receive additional revenues due to higher enrollment levels.

Alternatively, the policy may result in a reduction in title IV, HEA disbursements, providing a benefit to the Federal government and taxpayers and a new cost for higher education institutions. This would occur if higher education enrollment remains constant and if the proposed provision allows students to finish their credentials faster, resulting in fewer title IV, HEA disbursements. If this occurs, institutions may experience costs because their transfer students will likely spend less time enrolled (because they will not need to retake the credits that the institution previously did not accept in the transfer).

To better understand the potential impact of the transfer of credit policies for accrediting agencies in this rule, the Department is providing information from the National Student Loan Data System on the number of undergraduate students who transferred institutions between the 2023–24 and 2024–25 award years and the title IV, HEA student aid they received. This information is presented in Tables 3.1 and 3.2. Specifically, Table 3.1 shows that, between the 2023–24 and 2024–25 award year, a total of 1.8 million title IV, HEA students transferred institutions, and among those students, roughly 60 percent received title IV, HEA student aid in the award year they transferred (2024–25). Table 3.2 shows that these title IV, HEA recipients received a total of \$8.8 billion in title IV, HEA funds at their new institution in 2024–25, or an average of approximately \$8,300 per transfer student.

While the Department lacks readily available data to determine how much title IV, HEA disbursements could change due to the transfer of credit provisions, these data help establish a method to gauge the potential impact for both students and taxpayers. For example, if the Department assumes that 43 percent of title IV, HEA student aid received by transfer students was spent covering tuition and fees for course credits that failed to transfer (which is what prior research indicates is the average share of credits that fail to transfer), and under further assumptions

¹⁴ U.S. Government Accountability Office, Report to Congressional Requesters, "Higher Education: Students Need More Information to Help Reduce Challenges in Transferring College Credits", GAO-17-574, August 14, 2017, <https://www.gao.gov/assets/gao-17-574.pdf>.

that overall enrollment remains constant and transfer students do not change other aspects of their enrollment behavior, this would suggest that title IV, HEA disbursements would decline by an average of approximately \$3,600 per transfer student during the 2024–25 award year if 100 percent of the lost credits now successfully transfer.

Less than 100 percent of credits may transfer, however, in cases where institutions provide written reasoning for denying credit based on the credit

failing to meet institutional standards. In Table 3.3, the Department estimates the potential reduction in title IV, HEA student aid disbursements that could occur under different scenarios depending on the extent to which institutions utilize their ability to deny credit transfer through written statements. Specifically, the table provides a range of potential reductions in disbursements under a scenario where all, three quarters, and half of credits that did not transfer in the past

now transfer.¹⁵ We estimate that title IV disbursements would decline by \$3.8 billion annually if 100 percent of credits that students typically lost when transferring are now successfully accepted by institutions and students spend less time enrolled re-taking classes and course work. Comparatively, if only half of credits that were typically lost during transfer are successfully accepted, we estimate that title IV disbursements would decline by \$1.9 billion annually.

Table 3.1 – Total Title IV Transfer Students in 2024-25 and the Percent that Received Title IV Disbursements

Control	All Title IV Undergraduate Transfer Students in 2024-25	Undergraduate Transfer Students who Received Title IV Aid in 2024-25	Percent of Undergraduate Transfer Students who Received Title IV Aid in 2024-25
Public	1,325,800	727,200	55%
Private	265,200	196,500	74%
Proprietary	191,700	143,200	75%
Total	1,782,700	1,066,900	60%

Note: “Transfer Student” is defined as a student who enrolled as an undergraduate in both 2023-24 and 2024-25 and was enrolled at different institutions across those award years. These students are counted as transfer students at the institution where those students enrolled in 2024-25. This includes students who complete an undergraduate credential during 2023-24 and continue their enrollment as an undergraduate student in 2024-25. Some double counting may occur if students transferred to two or more institutions in 2024-25. “All Title IV Undergraduate Transfer Students” includes any title IV, HEA transfer student in 2024-25, regardless of whether or not title IV, HEA student aid was received in 2024-25.

Source: Department of Education using NSLDS data from the 2023-24 and 2024-25 award years.

¹⁵ For these estimates, we begin with the assumption that 43 percent of credits are currently lost at transfer, which is the average found by the GAO. Further, we assume no other changes occur

in student enrollment and borrowing decisions. U.S. Government Accountability Office, Report to Congressional Requesters, “Higher Education: Students Need More Information to Help Reduce

Challenges in Transferring College Credits”, GAO–17–574, August 14, 2017, <https://www.gao.gov/assets/gao-17-574.pdf>.

Table 3.2 - Total and Average Title IV Disbursements to Undergraduate Transfer Students During the 2024-25 Award Year

Control	Undergraduate Transfer Students who Received Title IV Aid in 2024-25	Total Title IV Aid Disbursed to Undergraduate Transfer Students in 2024-25	Average Title IV Disbursement
Public	727,200	\$5,389,718,800	\$7,400
Private	196,500	1,957,207,000	10,000
Proprietary	143,200	1,490,474,600	10,400
Total	1,066,900	8,837,400,400	8,300

Note: "Transfer Student" is defined as a student who enrolled as an undergraduate in both 2023-24 and 2024-25 and was enrolled at different institutions across those award years. These students are counted as transfer students at the institution where those students enrolled in 2024-25. This includes students who complete an undergraduate credential during 2023-24 and continue their enrollment as an undergraduate student in 2024-25. Some double counting may occur if students transferred to two or more institutions in 2024-25. Title IV aid includes Pell Grants and student loans.

Source: Department of Education using NSLDS data from the 2023-24 and 2024-25 award years.

Table 3.3 – Estimated Reduction in Title IV Disbursements to Undergraduates Due to Increased Credit Transfer Rates under Final Rule

Control	Total Title IV Aid Disbursed to Undergraduate Transfer Students in 2024-25	Estimated Annual Reduction in Title IV Aid Disbursements under Final Rule		
		All Lost Credits Transfer	Three Quarters of Lost Credits Transfer	Half of Lost Credits Transfer
Public	\$5,389,718,800	-\$2,317,579,084	-\$1,738,184,313	-\$1,158,789,542
Private	1,957,207,000	-841,599,010	-631,199,258	-420,799,505
Proprietary	1,490,474,600	-640,904,078	-480,678,059	-320,452,039
Total	8,837,400,400	-3,800,082,172	-2,850,061,629	-1,900,041,086

Note: Estimates are based on 2024-25 disbursements and assume 43 percent of credits failed to transfer prior to the final rule. "Transfer Student" is defined as a student who enrolled as an undergraduate in both 2023-24 and 2024-25 and was enrolled at different institutions across those award years. These students are counted as transfer students at the institution where those students enrolled in 2024-25. This includes students who complete an undergraduate credential during 2023-24 and continue their enrollment as an undergraduate student in 2024-25. Some double counting may occur if students transferred to two or more institutions in 2024-25. Title IV aid includes Pell Grants and student loans.

Source: Department of Education using NSLDS data from the 2023-24 and 2024-25 award years.

Standards for Program-Level Student Outcomes

Under the final regulation, accrediting agencies are required to review the use of additional student outcome metrics in their standards for institutions. Under Section 602.17, accrediting agencies must review their criteria for assessing whether an institution is successful in achieving its stated objectives at both the institutional and program levels, including minimum expectations regarding student outcomes such as graduation rates, post-completion employment and educational and economic returns using earnings data for former students relative to the total cost of attendance.

Requiring accrediting agencies to review their standards and criteria may impose new costs on both accrediting agencies and institutions. Some accrediting agencies may review their usage of student outcome criteria and ultimately make no adjustments to the

standards they use because they have found, in their evaluation, that their standards are sufficiently rigorous and properly evaluate student success. In these cases, the cost to accrediting agencies and institutions is likely to be small.

In other cases, accrediting agencies may review and then adopt new standards related to student outcomes for the institutions they accredit. Agencies that choose this action may experience costs from several factors. First, for agencies that do not have a mechanism in place to assess the student success metrics of the institutions or programs they accredit, they will need to develop these new standards and apply them routinely in the accreditation process. Second, accrediting agencies may also need to develop systems and processes that allow them to collect new data from institutions, and to invest in new analytical capacity to assess the extent

that institutions meet minimum requirements related to student outcomes.

Institutions accredited by agencies who review and adopt new standards may also incur new costs as those institutions work to comply with the new standards and requirements from their accrediting agency. This is likely to include new reporting costs between institutions and accrediting agencies. Institutions are also likely to incur costs as they work to change and improve any programs that fail to achieve compliance with any new standards related to student achievement imposed by an accrediting agency. Some institutions may ultimately decide to close noncompliant programs, which will also cause institutions to incur new costs, both in operational costs to shutter a program, and in reduced enrollment and revenue associated with those closed programs.

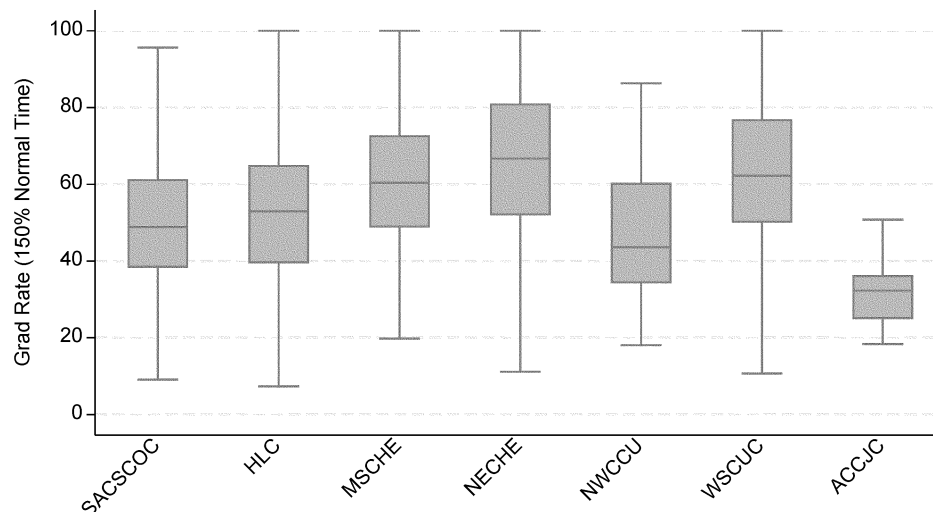
Accrediting agencies have considerable discretion in designing their own standards regarding student outcomes under the final regulation, and the Department cannot anticipate which metrics agencies will consider revising or adopting when making determinations regarding recognition. This makes it difficult for the Department to estimate the impact of the proposed change. To inform the potential impact of the requirement, the Department compiled data on the variation in several student outcome metrics among institutions accredited by seven institutional accrediting agencies.¹⁶ These metrics include graduation rates, post-enrollment

earnings, and student loan delinquency rates. Data were drawn from DAIP, the College Scorecard, and the Program Participation Data 2026 file released for the Accountability in Higher Education and Access Through Demand-Driven (AHEAD) rulemaking. The results are presented in Figures 3.1, 3.2, and 3.3. These box plots show the variation in student outcomes for institutions recognized by the same accrediting agency.

These figures show a wide variation in student outcome metrics among the institutions each agency accredits. For example, the Higher Learning Commission recognizes both institutions with near perfect graduation

rates and institutions with graduation rates well below 20 percent. The Higher Learning Commission also accredits institutions with both extremely high (over 80 percent) and very low student loan delinquency rates. The variation in outcomes across institutions recognized by the same agency suggest that, in practice, accrediting agencies have few meaningful standards on student outcomes. If the final rule results in agencies adopting more rigorous or consistent standards, some institutions or programs might be at risk of noncompliance and could therefore face pressure to improve or risk losing recognition.

Figure 3.1 - Variation in Institutional Graduation Rates by Accrediting Agency



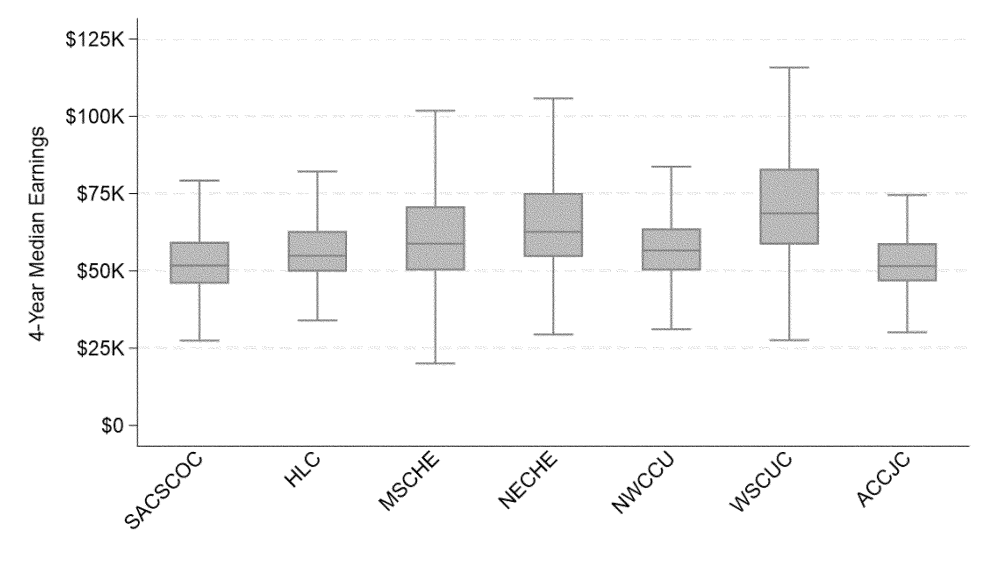
Notes: Graduation rates are for the 2025 Award Year. Graduation rates are defined as the completion rate for first-time, full-time students at four-year institutions (150 percent of expected time to completion). The box plots show the outcome at the 25th, 50th, and 75th percentile and the whiskers show the observation at 1.5 times the interquartile range. Southern Association of Colleges and Schools Commission on Colleges (SACSCOC); Middle States Commission on Higher Education (MSCHE); WASC Senior College and University Commission (WSCUC); Accrediting Commission for Community and Junior Colleges (ACCJC); Higher Learning Commission (HLC); New England Commission of Higher Education (NECHE); Northwest Commission on Colleges and Universities (NWCCU). Source: Department of Education calculations using DAIP, PPD:26, and College Scorecard.

¹⁶ These include the Accrediting Commission for Community and Junior Colleges, Higher Learning Commission, Middle States Commission on Higher

Education, New England Commission of Higher Education, Northwest Commission on Colleges and

Universities, and Southern Association of Colleges and Schools Commission on Colleges.

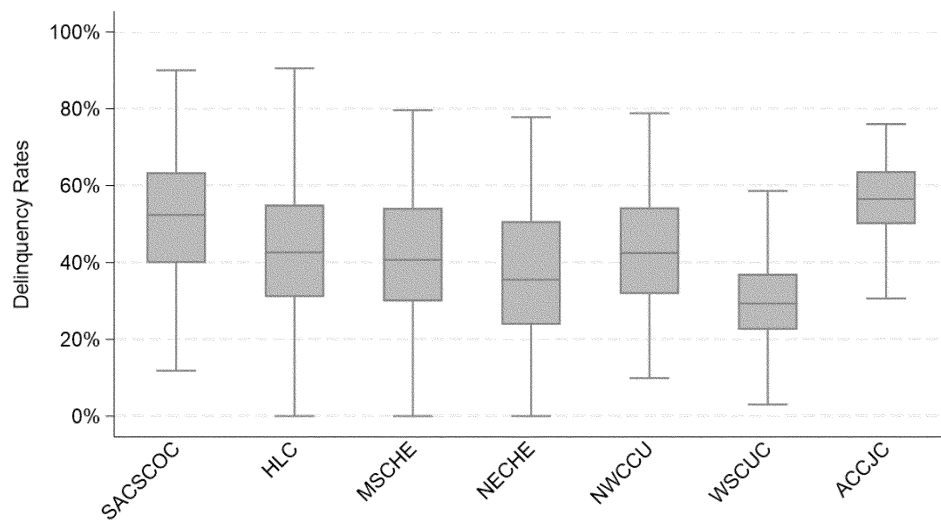
Figure 3.2 - Variation in Institutional Completer Earnings by Accrediting Agency



Notes: Earnings are the median earnings of title IV undergraduate students who graduated from the institution during the 2017-18 or 2018-19 academic year measured four years after completion. Students who are not working and students who are enrolled in college when earnings are measured are omitted from the median. The box plots show the outcome at the 25th, 50th, and 75th percentile and the whiskers show the observation at 1.5 times the interquartile range. Southern Association of Colleges and Schools Commission on Colleges (SACSCOC); Middle States Commission on Higher Education (MSCHE); WASC Senior College and University Commission (WSCUC); Accrediting Commission for Community and Junior Colleges (ACCJC); Higher Learning Commission (HLC); New England Commission of Higher Education (NECHE); Northwest Commission on Colleges and Universities (NWCCU).

Source: Department of Education calculations using DAPIP, PPD:26, and College Scorecard.

Figure 3.3 - Variation in Institutional Loan Delinquency Rates by Accrediting Agency



Notes: Delinquency Rates are for borrowers who entered repayment during AY2016. Borrowers are counted as delinquent if they were ever delinquent (90+ days late) on a Federal student loan payment by the end of 2019. See the PPD:26 Technical Data Appendix for additional details. The box plots show the outcome at the 25th, 50th, and 75th percentile and the whiskers show the observation at 1.5 times the interquartile range. Southern Association of Colleges and Schools Commission on Colleges (SACSCOC); Middle States Commission on Higher Education (MSCHE); WASC Senior College and University Commission (WSCUC); Accrediting Commission for Community and Junior Colleges (ACCJC); Higher Learning Commission (HLC); New England Commission of Higher Education (NECHE); Northwest Commission on Colleges and Universities (NWCCU). Source: Department of Education calculations using DAPIP, PPD:26, and College Scorecard.

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Accrediting Agency Competition and New Agencies

The final rule will remove barriers for new accrediting agencies to emerge and obtain Department recognition. Specifically, the rule simplifies and streamlines the Department's regulations for recognition and review of accrediting agencies, including eliminating superfluous requirements for recognition of new accrediting agencies that reduce competition and institutional choices when selecting an accrediting agency. The final rule also simplifies procedures for institutions to change accrediting agencies so that institutions are not forced to comply with standards that are antithetical to their values and missions. For example, the rule would remove the Department's current requirement that an accrediting agency grant or deny accreditation or preaccreditation to an institution for at

least two years prior to seeking recognition by the Department. This two-year requirement is not statutory and represents an unnecessary burden for new accrediting agencies. Similarly, the final rule streamlines the process for institutions to change accrediting agencies by clarifying that the Secretary may not delay, condition, or otherwise adversely affect an institution's participation in the title IV, HEA programs solely because the institution seeks accreditation from, or changes accreditation to, another agency recognized by the Secretary. Under Section 602.13, the final regulation also specifies that recognition by the Department does not confer immunity from antitrust laws, which may further stimulate competition among accrediting agencies.

Reducing barriers to entry may also facilitate innovation by making it easier for new accrediting agencies to emerge

and for institutions offering new educational models to obtain appropriate accreditation. To the extent such models attract students who receive Pell Grants or Federal student loans, the rule could affect Federal student aid outlays. The Department has provided estimates for the potential increases in enrollment and title IV, HEA student aid disbursements that could arise from new models and innovations. These estimates, which are based on historical growth rates among short-term certificate programs and exclusively online programs, are discussed later in this Regulatory Impact Analysis and are shown in Tables 3.6 and 3.7.

The Department also believes that reducing barriers to entry may improve contestability in the market for accrediting services. Contestability refers to the extent to which potential

competitors can realistically enter a market and existing customers can switch providers, even if relatively few firms currently compete or customers actually switch. Economic theory suggests that incumbent organizations respond not only to actual competition but also to the credible possibility of new entry or customer mobility. Baumol's theory of contestable markets predicts that reducing barriers to entry encourages incumbent firms to improve quality, reduce unnecessary costs, and become more responsive to consumers, while Demsetz emphasized that competition for a market can discipline incumbent firms even in concentrated industries. See William J. Baumol, "Contestable Markets: An Uprising in the Theory of Industry Structure," 72 *American Economic Review* 1 (1982); Harold Demsetz, "Why Regulate Utilities?," 11 *Journal of Law and Economics* 55 (1968). The Department believes that reducing unnecessary barriers to the recognition of new accrediting agencies and facilitating institutional mobility among recognized agencies is therefore likely to improve accrediting agency performance even if relatively few institutions ultimately change accrediting agencies. Accordingly, to the extent that these changes increase the credible possibility of new accrediting agency entry or institutional mobility, economic theory suggests they may improve accrediting agency performance even if relatively

few institutions ultimately change accrediting agencies.

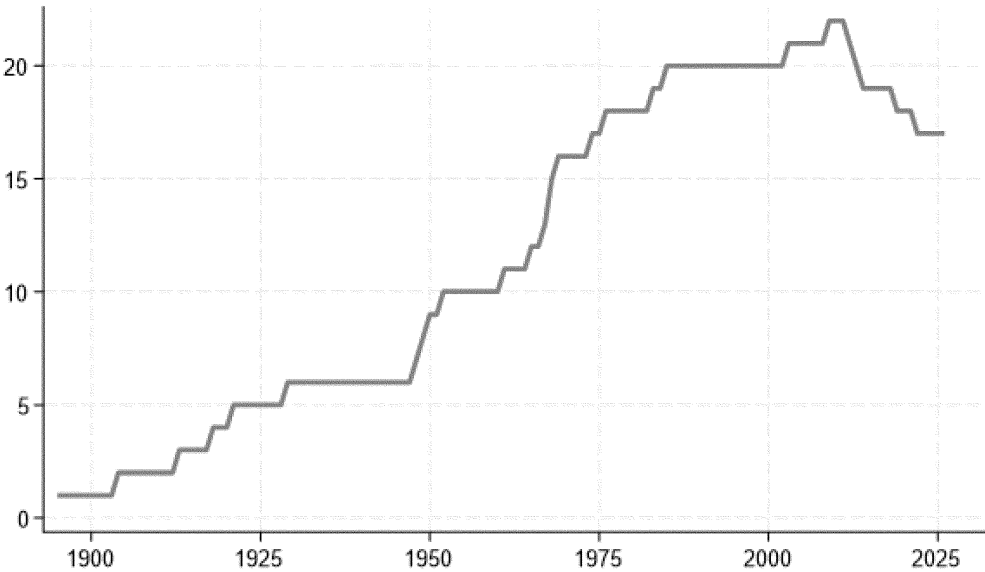
Although the Department lacks sufficient data to estimate how these changes will affect the accreditation marketplace, the changes will likely increase the number of institutional accrediting agencies recognized by the Department and may increase the number of institutions seeking to change agencies. To provide context regarding the potential impact of the changes, the Department used information from DAIP to examine the growth and contraction in the number of institutional accrediting agencies and the rate and number of institutions that switch agencies over time. This analysis adds evidence to the Department's view that both new accrediting agency recognition and changes in agency by institutions are rare. For example, Figure 3.4 and Table 3.4 show that there has been little change in the number of institutional accrediting agencies over the past 30 years, and that in recent decades the number of recognized agencies has actually declined, despite the large increases in higher education enrollment over this time. Additionally, Table 3.5 shows that since 2020, only 10 institutions have voluntarily switched from one of the agencies formerly known as a regional accrediting agency, and that fewer than 50 have ever voluntarily switched away from these accrediting agencies.

One of the key goals of the final rule is that, through reforms to reduce

burden and enhance competition among accrediting agencies, more institutional agencies will choose to be recognized and greater numbers of institutions will decide to change institutional accrediting agencies, thereby enhancing competition. While prior regulatory reforms may not have resulted in a descriptive change in the number of accrediting agencies and amount of accrediting agency switching that takes place (see Figure 3.4 and Table 3.5), the final rule includes additional provisions aimed at spurring competition, which may ultimately enhance the ability for accrediting agencies to enter and institutions to switch. Specifically, the reduction in time from initial petition to review for recognition by the senior Department official is likely to ultimately result in additional accrediting agencies applying for recognition, providing more options for institutions. These proposed changes also coincide with regulatory efforts by some States that require the State's institutions to switch accrediting bodies. Ultimately, accrediting agencies may benefit from the final rule because they will likely experience less burden to gain initial recognition and maintain recognition. Institutions, similarly, could benefit from these regulations if they value the ability to choose from a greater number of potential agencies, or if the new agencies that may emerge are better aligned with the institution's mission.

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Figure 3.4 - Number of Institutional Accrediting Agencies 1895- Present



Notes: Counts exclude state approval agencies and other accrediting agencies that predominantly accredit programs but are classified as institutional accrediting agencies because they can accredit single-purpose institutions. Source: Department of Education calculations using DAPIP, PPD:26, and College Scorecard.

Table 3.4 - Institutions & Accrediting Agencies 1950, 1975, 2000, & 2025

Year	1950	1975	2000	2025
Institutional Accreditors	9	17	20	17
Accredited Institutions	970	2,710	4,840	4,630
Postsecondary Students (Millions)	2.3	11.2	15.3	19.6

Notes: Enrollment is defined as Total Fall Enrollment at degree-granting institutions that participate in title IV student aid programs. Number of accredited institutions is rounded to the nearest 10. Includes all institutions from the corresponding year (in the column header), regardless of whether the college still exists in 2026. Source: DAPIP, National Center of Education Statistics Digest of Education Statistics.

Table 3.5 - Number of Institutions Voluntarily Switching Accrediting Agency

Type of Switch	Total	Before 2020	2020 or After
Total Voluntary Switches (1965-Present)	189	134	55
Former-Regional → Former-Regional	11	5	6
Former-National → Former-National	75	52	23
Former-National → Former-Regional	71	49	22
Former-Regional → Former-National	32	28	4

Notes: The sample is limited to institutions that are still in operation in 2026. "Voluntary Accrediting Agency Switching" is when institutions change their institutional accrediting agencies across two consecutive years excluding cases where the institutions' accrediting agency dissolved, split, changed name, or lost recognition. The seven "Former-Regional Accrediting Agencies" include: (1) Southern Association of Colleges and Schools Commission on Colleges (SACSCOC); (2) Middle States Commission on Higher Education (MSCHE); (3) WASC Senior College and University Commission (WSCUC); (4) Accrediting Commission for Community and Junior Colleges (ACCJC); (5) Higher Learning Commission (HLC); (6) New England Commission of Higher Education (NECHE); and (7) Northwest Commission on Colleges and Universities (NWCCU). "Former-National Accrediting Agencies" include all other institutional accrediting agencies. Note that North Central Association of Colleges and Schools (NCACS) voluntarily dissolved in 2013, and accrediting functions migrated to HLC.

Source: Department of Education calculation using DAPIP.

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Affordability and Innovation

The Department’s final rule would require accrediting agencies to adopt several new policies and procedures that aim to increase college affordability. Specifically, under Section 602.17 (Application of standards in reaching accreditation decisions), the final rule would require accrediting agencies to consider efficiency in their review of institutions and to conduct cost-benefit analyses to ensure institutions’ activities justify the associated financial, administrative and opportunity costs, and the impact of capital expenditures on future operating expenses. Such analyses could put downward pressure on institutional costs and, by extension, tuition prices. If some institutions prove to be incapable of conducting credible cost/benefit analyses, the number of

accredited institutions could fall, but this is unlikely.

Similarly, the final rule could put downward pressure on student costs by helping to reduce excessive program length by requiring that accrediting agencies apply standards that ensure program length is appropriate to the objectives of the program and credential awarded at the institution. The final rule also aims to reduce credential inflation and prevent agencies from restricting institutions from offering short-term programs, which may help reduce costs for students because they will be able to pursue fewer or shorter credentials to work in a given occupation. This may ultimately increase enrollment and title IV, HEA student aid disbursements if more students pursue postsecondary education as a result of the improved affordability and reduced time to completion.

The final rule would also specify in Section 602.17 that accrediting agencies’ standards related to student achievement may include credit for prior learning. Granting credits for prior learning should reduce costs for students because it allows them to earn credit from skills obtained outside the institution, such as service in the armed forces, employment, or other demonstrated competency.

While these provisions would likely provide benefits to students through lower prices and less time enrolled, they could also reduce revenues for institutions and transfers of Federal title IV, HEA funds to institutions. Institutions may therefore bear additional costs as they adjust their programs and policies to align with new accreditation standards. Accrediting agencies will bear new costs as they work to incorporate these proposed

changes into their standards and practices.

The final rule includes several provisions that ensure accrediting agencies do not unnecessarily constrain innovations that could further reduce costs to students and institutions, and may also increase program quality. For example, Section 602.15 (Administrative and fiscal responsibilities) would be amended to require that accrediting agencies provide training to all agency representatives and staff that includes topics related to best practices in various educational delivery methods, models, and modalities; innovative or lower-cost educational delivery models that may provide high-quality education to students; and avoiding unnecessary costs to institutions in the accreditation process. These innovations may make higher education more accessible for students, thereby increasing postsecondary enrollment and title IV, HEA student aid disbursements.

The Department has estimated the potential increase in enrollment and title IV, HEA student aid disbursements that could result from the innovations that the final rule helps facilitate. Specifically, the Department examined historical enrollment growth rates among short-term certificate programs and, separately, the growth rates among exclusively online programs (excluding changes in exclusively online programs during the COVID-19 pandemic).¹⁷ The

¹⁷ The Department analyzed historical growth rates using Integrated Postsecondary Education Data System (IPEDS) data. To calculate growth rates in exclusively online programs, we used IPEDS data on distance enrollment from 2012–13 to 2024–25. For each academic year, we calculated the average share of degree/certificate-seeking undergraduate and graduate students enrolled exclusively in online programs. We then computed the annual percent change in the share of students in exclusively online programs for each year from 2013–14 to 2024–25. We acknowledge that between 2019 and 2020, the distance enrollment IPEDS file changed from Fall Enrollment to 12-Month FTE enrollment; however, the change in definition does

Department used these two categories as proxies for innovative educational models, although the Department acknowledges that innovation can take many forms not necessarily captured in these categories. Given the uncertainty around potential innovations that may arise under the final rule, the Department has produced estimates using a low, medium, and high enrollment growth rate.¹⁸ After calculating the historical growth rates, the Department then used data on title IV, HEA student aid disbursements (Pell Grants and student loans) made to students in 2023–24 (for students in exclusively online programs) and 2024–25 (for students in short-term certificate programs).¹⁹

not influence our estimates because we compute annual percent changes, and we exclude this year due to its overlap with the Covid-19 pandemic. To calculate growth rates in short-term programs, we used IPEDS data on student charges for vocational programs from 2014–15 to 2023–24, the most recent year of data available at the time when this analysis was conducted. We defined short term programs as programs that were at least 600 clock hours in length but shorter than 12 months. After identifying this set of programs, we then merged this IPEDS data to Department data on title IV enrollments using common OPEID6, credential level, and 6-digit CIP codes. We then calculated the annual percent change in title IV enrollment for each award year between 2014–15 and 2023–24.

¹⁸ For exclusively online programs, the minimum growth rate was 1.7 percent; the median growth rate (excluding Covid-19 years), was 5.2 percent, and the maximum growth rate was 10.1 percent. For short-term programs, the minimum positive growth rate was 1.3 percent, the median growth rate (using years with positive growth) was 4.5 percent, and the maximum growth rate was 13.0 percent. We use these minimums, medians, and maximums for the low-, medium-, and high-growth rates for our analysis of exclusively online enrollment and enrollment in short-term certificate programs.

¹⁹ We use these years because they were the most recently available data at the time this analysis was conducted. Pell Grant and Federal student loan disbursement data are from IPEDS for our analysis of exclusively online programs. Specifically, we assume that students in exclusively online programs receive a proportional share of title IV, Federal student aid at an institution. For example, if 50 percent of students at an institution were enrolled in exclusively online programs, we assume

The estimated increase in potential Title IV, HEA recipients and disbursements are shown in Tables 3.6 and 3.7. Under a low-growth assumption for the creation and expansion of online programs, we estimate there could be 26,400 new Pell Grant recipients annually relative to the baseline, resulting in a total increase in annual disbursements of \$136.4 million. Under high-growth assumptions for online programs, we estimate there could be as many as 157,000 new Pell Grant recipients annually relative to the baseline, resulting in a net increase of \$810.5 million in Pell Grants. Turning to short-term programs, using low-growth assumptions for the creation and expansion of short-term certificate programs, we estimate there could be 1,700 new Pell Grant recipients annually, resulting in an increase of \$7.5 million in total annual disbursements. Under high-growth assumptions for short-term programs, there could be 17,300 new Pell Grant recipients annually, resulting in a total increase in annual disbursements of \$75 million.

The Department reiterates that these projections are estimates based on historical trends in enrollment increases in exclusively online and short-term programs. However, due to the uncertainty in the type and format of possible innovations, we acknowledge that the amount of growth that may come about due to the final rule could differ in scale or magnitude from historical levels.

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that half of the institution's title IV aid (Pell Grants and student loans, obtained through IPEDS) was disbursed to students in exclusively online programs. Pell Grant and loan disbursement data for our analysis of short-term certificate programs are from the Department's administrative records. This data may include a small amount of double counting if the same students are enrolled at two or more short-term certificate programs at the same institution in the same award year.

Table 3.6 - Estimated Annual Increase in Exclusively Online Enrollment Due to Innovation Under the Final Rule

	Baseline	Increase (Low)	Increase (Medium)	Increase (High)
Exclusively Online Pell Recipients	1,554,700	26,400	80,800	157,000
Exclusively Online Pell Disbursements	\$8,024,638,300	\$136,418,500	\$417,281,600	\$810,488,100
Exclusively Online Loan Recipients	1,264,300	21,500	65,700	127,700
Exclusively Online Loan Disbursements	\$8,790,676,800	\$149,441,200	\$457,115,600	\$887,857,900

Note: Estimates reflect the annual enrollment and corresponding disbursement increase due to possible innovations related to online programs. The low, medium, and high enrollment increase scenarios are based on historical growth rates in exclusively online enrollment from 2013-14 to 2024-25. The low scenario reflects a 1.7 percent increase in enrollment; the medium scenario reflects a 5.2 percent increase; the high scenario reflects a 10.1 percent increase. Pell Grant and Federal student loan disbursement data are for the 2023-24 academic year, obtained from IPEDS.

Source: Department of Education estimates using data from the Integrated Postsecondary Education Data System.

Table 3.7 - Estimated Annual Increase in Short-Term Certificate Programs Due to Innovation Under the Final Rule

	Baseline	Increase (Low)	Increase (Medium)	Increase (High)
Pell Recipients	133,400	1,700	6,000	17,300
Pell Disbursements	\$576,943,700	\$7,500,300	\$25,962,400	\$75,002,700
Loan Recipients	108,000	1,400	4,900	14,000
Loan Disbursements	\$690,818,000	\$8,980,600	\$31,086,800	\$89,806,300

Note: Estimates reflect the annual enrollment and corresponding disbursement increase due to possible innovations in short-term certificate programs. Short term certificate programs are defined as programs that are at least 600 clock hours in length but shorter than 12 months. The low, medium, and high enrollment increase scenarios are based on historical growth rates in short-term certificates from 2016-17 to 2023-24. The low scenario reflects a 1.3 percent increase in enrollment; the medium scenario reflects a 4.5 percent increase; the high scenario reflects a 13.0 percent increase. Pell Grant and Federal student loan disbursement data are for the 2024-25 award year, obtained from FSA records on title IV disbursements.

Source: Department of Education estimates using data from the Integrated Postsecondary Education Data System and PPD 2026.

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The final rule also states that agencies should apply their standards in ways that seek to reduce unnecessary barriers that restrict the ability of institutions or programs from adopting instructional, programmatic, or delivery practices that improve or accelerate credential completion. By reducing unnecessary procedural requirements, encouraging accrediting agencies to minimize administrative burdens, recognizing

innovative educational delivery models, and discouraging unnecessary barriers to new instructional approaches, the final rule is expected to facilitate experimentation with new methods of delivering high-quality postsecondary education. Because many of these innovations have not yet been developed or implemented, the Department cannot estimate their future value, but expects that increased

flexibility may improve educational quality, enrollment, and affordability over time.

The provisions in the final rule related to innovation and new educational models are likely to provide benefits to students by increasing the range of available educational options and by reducing prices for those options. As noted in the Net Budget Impact section of this RIA and in the

2019 Accreditation regulations, these factors may have offsetting effects on loan and grant volumes as credit transfer or shorter programs could reduce the amount needed to complete a degree but others could encourage increased enrollment. Accrediting agencies will bear new costs in aligning their policies and practices to implement those new requirements.

Finally, the rule requires major new changes that mandate separation between trade associations or affiliated organizations and accrediting agencies. These relationships can result in credential inflation if trade associations seek to require additional credentials to enter into a profession and then use their affiliation with an accrediting agency to make those requirements a condition of accreditation for programs at institutions. One report finds that many Federally recognized programmatic accrediting agencies maintain deep structural ties with the professional and trade associations with which they are affiliated.²⁰

Accrediting agencies and affiliated organizations or associations will bear new costs under these provisions as they work to alter their legal, operational, and physical structures. Students may benefit from these changes because the policies could reduce excessive and unnecessary degree and time requirements to enter into certain professions.

Department Administrative Costs

The Department expects the final rule to impose only modest incremental administrative costs on the Federal government. Most provisions modify the criteria and procedures the Department uses when recognizing accrediting agencies rather than establishing new Federal programs or recurring operational responsibilities.

Implementation will primarily require Department staff to review new, or additional, accrediting agency recognition applications and petitions under the revised standards. These reviews are already part of the Department's regular recognition process, and the final rule generally changes the substance of those reviews rather than creating new review processes. As a result, the Department expects most implementation activities to be absorbed within existing recognition cycles and staffing levels.

Some additional staff time may be required during the initial

implementation period to review revised accrediting agency policies and procedures addressing issues such as conflicts of interest, independence from affiliated organizations, antitrust compliance, student outcomes, academic freedom, intellectual diversity, research integrity, and other revised recognition criteria. The Department also anticipates limited one-time costs associated with updating guidance documents, internal training materials, and information systems necessary to administer the revised regulations.

To the extent the final rule encourages the recognition of additional accrediting agencies or increases the number of institutions seeking to change agencies, the Department could experience a modest increase in recognition-related workload. However, these activities are expected to occur gradually over multiple recognition cycles and to remain manageable within existing administrative structures.

The Department also anticipates offsetting administrative savings. Since the Department announced its accreditation reform efforts, three accrediting agencies have voluntarily withdrawn from Department recognition.²¹ As additional agencies determine that they no longer wish to maintain Federal recognition under the revised regulatory framework, the Department expects the number of Federally recognized accrediting agencies requiring recognition reviews, interim monitoring, compliance reporting, and other oversight activities to decline. A smaller number of recognized agencies would reduce the Department's workload associated with recognition petitions, staff reviews, National Advisory Committee on Institutional Quality and Integrity (NACIQI) proceedings, monitoring, and related administrative actions, thereby partially offsetting the implementation costs associated with the final rule.

The final rule may also generate longer-term administrative efficiencies by establishing clearer recognition standards and focusing Department oversight on areas presenting the greatest risk to students and taxpayers. To the extent these reforms improve the efficiency of the recognition process, they could reduce both Federal administrative costs and private-sector compliance burdens over time.

Accordingly, the Department does not anticipate that implementation of the

final rule will require significant additional Federal resources. Over time, the Department expects that the offsetting of administrative savings and efficiencies described above may reduce the overall Federal administrative burden associated with oversight of Federally recognized accrediting agencies.

4. Additional Benefits

The Department expects the final rule to produce several important benefits that cannot be reliably quantified but that are nevertheless relevant in evaluating the overall effects of the rule.

First, the final rule is expected to increase competition among recognized accrediting agencies. The Department anticipates that reducing unnecessary barriers to the recognition of new accrediting agencies, simplifying the process by which institutions may change accrediting agencies, and eliminating unnecessary geographic distinctions will increase institutional choice and create stronger incentives for accrediting agencies to innovate, improve responsiveness to institutions, and reduce unnecessary costs. While the Department cannot reliably estimate the magnitude of these effects, economic theory and experience in other quality-assurance markets suggest that increased competition is likely to improve quality and efficiency over time.

Second, the final rule is expected to improve transparency and accountability. The new requirements regarding transfer-of credit policies, public disclosure of accrediting actions, institutional representations, and research integrity will provide students, taxpayers, employers, and policymakers with more complete and reliable information regarding institutional quality and performance. Greater transparency improves decision making by prospective students and encourages institutions to maintain high standards. Although these benefits cannot readily be expressed in monetary terms, the Department expects them to improve the functioning of the higher education marketplace.

Third, the final rule is expected to strengthen academic freedom, intellectual inquiry, and the free exchange of ideas. The Department believes that institutions providing an environment in which lawful viewpoints may be expressed and examined, faculty are evaluated without regard to viewpoint or ideology, and students are exposed to a range of scholarly perspectives are better positioned to fulfill the educational purposes recognized by the Higher

²⁰ Bryan Cutsinger and Siri Terjesen, *Captured gatekeepers: Structural conflicts of interest in U.S. higher education accreditation*, European Economic Review, Vol. 190, 2026.

²¹ 3 Programmatic Accreditors Withdraw From Federal Recognition—<https://www.insidehighered.com/news/governance/accreditation/2026/07/24/3-programmatic-accreditors-withdraw-federal-recognition>.

Education Act. While these educational benefits cannot be quantified, the Department considers them an important component of institutional quality and student learning.

Fourth, the final rule is expected to reduce regulatory uncertainty by more clearly distinguishing the Department's recognition criteria from accrediting agencies' own substantive accreditation standards. The Department expects that clearer recognition standards, streamlined procedures, and more transparent expectations will reduce unnecessary disputes, improve the efficiency of the recognition process, and allow both accrediting agencies and institutions to devote greater resources to educational quality rather than regulatory compliance. Although these benefits cannot be quantified, they are expected to improve the administration of the Federal recognition process over time.

Finally, the final rule will likely strengthen public confidence in the accreditation system. By emphasizing educational quality, lawful administration of accreditation standards, research integrity, objective measures of student outcomes, transparency, and institutional accountability, the Department expects the final rule to reinforce public confidence that accreditation serves students and taxpayers while respecting institutional diversity, including intellectual diversity, and mission. Although these effects are inherently difficult to quantify, they are central objectives of the proposed rule.

5. Net Budget Impact

The Department continues to estimate that the changes to accreditation implemented by the final rule will not have a significant net Federal budget impact. However, we present the effects of the middle scenarios in Tables 3.3, 3.6, and 3.7 here for illustrative purposes. The transfer scenario from Table 3.3 is a reduction in volume that offsets the increases from innovation, which would result in a net budget impact of –\$131 million in loans and –\$4.2 billion in Pell Grants. Consistent with the requirements of the Credit Reform Act of 1990, budget cost estimates for the student loan programs

reflect the estimated net present value of all future non-administrative Federal costs associated with a cohort of loans. A cohort reflects all loans originated in a given fiscal year. The baseline for estimating the cost of these regulations is the President's Budget FY2027 baseline that includes effects of the Working Families Tax Cuts Act and final regulations related to loan limits, repayment plans, and other areas published May 1, 2026²² and related to earnings accountability published July 1, 2026.²³

Rules governing accreditation and the roles of actors in the Federal-State-accrediting agency triad have been the subject of several recent rules, including a rule published November 1, 2019²⁴ that shared the goals of reducing barriers that limit competition, innovations, and new educational models. Adjustments from the earlier regulations are in the current budget baseline.

The final rule will build on and further those initial efforts to foster innovation and remove regulatory barriers in the accreditation process. This could have offsetting effects on Federal student loan and Pell Grant volumes. If some schools are able to begin or extend their participation in the title IV, HEA programs by finding accrediting agencies that support their innovative approaches or missions, that could increase volumes compared to the baseline. On the other hand, accrediting agencies requiring more acceptability of transfer credits or approving experiential credits may allow some students to complete programs faster and reduce loan and grant volumes. The proposed mandate that accrediting agencies require institutions to use data on student-level outcomes to improve performance mitigates concerns that making accreditation changes less burdensome would result in greater defaults or other negative outcomes.

As noted in the NPRM published August 20, 2026,²⁵ the Department does not anticipate a significant budget impact of the final rule. Several commenters responded to the estimate of no budget impact in the NPRM published August 20, 2026 suggesting additional analysis and that the rule should have a significant net budget

impact. Some compared this estimate with analysis for the 2019 rule regarding accreditation as support for the current rule having a significant impact. Commenters pointed out that the Congressional Budget Office estimated increases of \$225 million in loans, \$212 million in mandatory Pell, and \$1.13 billion in discretionary Pell Grant volume over 2026–2035 from proposed legislation with similar provisions.²⁶ Many comments referenced the removal of accreditation constraints leading to volume, including new volume, flowing to institutions that may have had difficulty maintaining accreditation under existing rules. Other commenters noted the potential decrease in volume associated with transfer students from the provisions regarding acceptance of credits that is discussed around Table 3.3 of this RIA. While the Department still believes that the effects of these provisions will not lead to an appreciable net budget impact on title IV, HEA programs, we have included estimates of alternative scenarios to illustrate potential effects.

Alternate Scenarios

As described in the Costs, Benefits, and Transfers section of this RIA, there are possibilities that the changes in the final rule related to acceptance of transfer credits, encouraging innovation, and other aspects could result in volume increases or reductions. Therefore, we have considered two alternative scenarios based on the medium scenarios for transfers and innovation presented in Tables 3.3 and 3.6–3.7. To estimate the budget impact on student loans, we took the estimated reduction in Table 3.3 and distributed to budget risk groups (2-yr proprietary, 2-year non-profit and public, 4-yr fr/so, 4-yr junior/senior, graduate) and loan types using 2024–25 Q4 year-to-date school level loan disbursements from the FSA data center²⁷ with 4-year reductions split in half between risk groups. As the transfer scenarios in the Costs, Benefits, and Transfers section of this RIA analyzed undergraduate enrollment, we focused the sensitivities on exclusively undergraduate risk groups and distributed the reduction as shown in Table 5.1.

²² 84 FR 23768.

²³ 91 FR 40136.

²⁴ 84 FR 58834.

²⁵ 91 FR 160 p. 53940 available at <https://www.Federalregister.gov/documents/2026/08/20/>

2026-17001/accreditation-innovation-and-modernization-the-secretarys-recognition-of-accrediting-agencies.

²⁶ Congressional Budget Office, Cost Estimate for H.R. 4054, Accreditation Choice and Innovation

Act, June 25, 2025, <https://www.cbo.gov/publication/61826>.

²⁷ 2024–2025 Award Year Direct Loan Volume by School, Federal Student Aid Data Center, available at <https://studentaid.gov/data-center/student/title-iv>.

Table 5.1A. Distribution of Estimated Reduction in Direct Loans by Risk Group

Sector	Percent of Reduction Applied	Amount with Full Ramp-Up
2-yr Proprietary	8.3%	(112,393,032)
2-yr Non-Profit & Public	9.1%	(107,338,813)
4-yr FR/SO	41.3%	(655,561,728)
4-yr JR/SR	41.3%	(655,561,728)
Total		(1,530,855,302)

Pell Grants are estimated by type and control, not loan risk groups and Table 5.1B provides the distribution of the reduction for Pell Grants.

Table 5.1B. Distribution of Reduction in Pell Grants by Type and Control

Institution Type and Control	Percent of Reduction Applied	AY 2024-25 Reduction
2-yr Proprietary	6.0%	78,809,280
2-yr Non-Profit	1.0%	13,338,954
2-yr Public	16.6%	219,910,370
4-yr Proprietary	8.0%	106,162,449
4-yr Non-Profit	15.4%	204,039,659
4-yr Public	52.9%	698,623,089
Total		1,320,883,800

We ramped the estimated effects up over time as seen in Table 5.2 because the final rule involves accreditation changes that institutions will gradually respond to over time.

Table 5.2 Ramp-up Effects for Alternative Scenarios for Transfer and Innovation

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036
Transfer Scenario	-	-	0.25	0.25	0.50	0.50	0.75	0.75	1.00	1.00
Innovation Scenario	-	-	-	0.25	0.25	0.50	0.50	0.75	0.75	1.00

The estimated volume reduction from transfers of \$2.85 billion annually in Table 3.3 was distributed as \$1.53 billion in loans and \$1.32 billion in Pell Grants based on volumes associated

with transfer students in AY 2024–25. The loan reduction results in approximately –\$162 million in net budget impact in the Direct Loan program. As seen in Table 5.3B, the

reduction in transfers is estimated to reduce Pell Grant costs by approximately \$5.7 billion over the budget window from 2027–2036 with effects starting in FY 2029.

Table 5.3A Transfer Scenario Analysis - Estimated Annual Net

Budget Impact for Direct Loans, Outlays in Millions \$

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Subs.	-	-	(16)	(21)	(36)	(40)	(55)	(59)	(72)	(73)	(373)
Unsub.	-	-	(13)	(17)	(28)	(27)	(36)	(43)	(51)	(52)	(267)
PLUS (Parent)	-	-	22	31	53	59	68	79	94	111	517
Consol	-	-	(0)	(1)	(2)	(3)	(6)	(8)	(8)	(11)	(39)
Total for Loans	-	-	(7)	(8)	(12)	(12)	(28)	(32)	(37)	(25)	(162)

Table 5.3B Transfer Scenario Analysis - Estimated Annual Net

Budget Impact for Pell Grants, Outlays in Millions \$

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Discretionary	-	-	(83)	(274)	(360)	(551)	(637)	(830)	(916)	(1,108)	(4,759)
Mandatory	-	-	(16)	(53)	(69)	(106)	(122)	(158)	(174)	(209)	(907)
Total for Pell	-	-	(99)	(327)	(429)	(657)	(759)	(988)	(1,090)	(1,317)	(5,666)

The innovation scenario assumes an increase in loan and Pell grant volume as seen in Tables 3.6 and 3.7. Combining the medium scenarios in those tables, the increases associated with these examples of educational

innovations were approximately \$488 million in Direct loan volume and \$443 million in Pell grants. The estimated volume increase from innovation results in approximately \$31 million in outlays in the Direct Loan program over 10

years. As seen in 5.4B, the increased volume associated with innovation is estimated to increase Pell Grant costs by approximately \$1.5 billion over the budget window from 2027–2036 with effects starting in FY 2030.

Table 5.4A Innovation Scenario Analysis - Estimated Annual Net

Budget Impact for Direct Loans, Outlays in Millions \$

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Subs.	-	-	-	5	7	11	13	17	18	22	92
Unsub.	-	-	-	3	4	9	11	10	13	15	64
PLUS (Parent)	-	-	-	(7)	(10)	(16)	(17)	(24)	(26)	(34)	(134)
Consol	-	-	-	0	0	0	1	2	3	4	10
Total for Loans	-	-	-	1	(0)	5	8	5	7	5	31

Table 5.4B Innovation Scenario Analysis - Estimated Annual Net

Budget Impact for Pell Grants, Outlays in Millions \$

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Discretionary	-	-	-	28	92	121	185	214	278	308	1,226
Mandatory	-	-	-	5	18	23	36	41	53	58	234
Total for Pell	-	-	-	33	110	144	221	255	331	366	1,460

d. Accounting Statement

As required by OMB Circular A–4, we have prepared an accounting statement

showing the classification of the benefits, costs, and transfers associated with the provisions of these regulations. Table 5.4 provides our best estimate of

the changes in annual monetized benefits, costs, and transfers as a result of the final rule.

Table 5.5 - Accounting Statement

Annualized Impact (millions, \$2026)		
	Discount rate = 3%	Discount rate = 7%
Benefits		
Increased transfer credits allowing for faster completion of credentials	Not quantified	
Focus on student-level outcomes in accreditation	Not quantified	
Reduced barriers for new accrediting agencies to obtain Department recognition	Not quantified	
Increased choice of accrediting agencies for institutions	Not quantified	
Encouragement of innovation and new educational models	Not quantified	
Separation of trade associations or affiliated organizations and accrediting agencies may benefit students by reducing unnecessary degree and time requirements to enter certain professions	Not quantified	
Costs		
	Discount rate = 3%	Discount rate = 7%
Reporting costs to borrowers, institutions and accrediting agencies to comply with Paperwork Reduction Act requirements	\$3.41	\$3.80
Costs to accrediting agencies of developing and applying standards related to student outcomes	Not quantified	
Accrediting agency costs to align policies and practices to consider efficiency, include credit for prior learning, and other provisions related to innovation	Not quantified	
Accrediting agency costs to alter legal, operational, and physical structures to separate from trade associations or affiliated organizations	Not quantified	
Institutional costs to improve programs that do not meet new student outcome standards	Not quantified	
Operational costs to close programs that cannot comply with new standards	Not quantified	
Department administrative costs to update guidance documents, internal training, and information systems to administer the final rule.	Not quantified	
Transfers		
	Discount rate = 3%	Discount rate = 7%
Potential reduced payments from students to institutions as increased transfer credits or experiential credit reduces time students need to complete degree	Not quantified	

e. Alternatives Considered

As a part of the development of these regulations, the Department engaged in a negotiated rulemaking process in which we received comments and proposals from non-Federal negotiators representing numerous impacted constituencies on a variety of issues. The proposals were submitted from the constituencies listed under the “Negotiated Rulemaking” heading of the NPRM. Information about these proposals is available on our rulemaking website at <https://www.ed.gov/laws-and-policy/higher-education-laws-and-policy/higher-education-policy/negotiated-rulemaking-higher-education-2026>. Furthermore, the Department received 7,051 total comments during the public comment period. We considered them all as possible alternatives.

This section summarizes two alternatives that were considered but ultimately declined by the Department.

Application of Standards in Reaching Accreditation Decisions (§ 602.17(a)(1) and (2))

During negotiated rulemaking and the public comment period the Department received extensive feedback on the application of accreditation and preaccreditation standards related to student achievement and faculty. While the rulemaking committee came to consensus on the entire proposal, the Department received varied commentary during the public comment period. Some commenters supported the provisions stating that the provisions focus on student outcomes and prioritize intellectual diversity amongst faculty. Alternatively, some commenters also opposed the provisions stating that the Department exceeded its statutory authority and that it will use the regulations as a mechanism to punitively target agencies and institutions that do not align with the Administration’s own political agenda.

The Department considered amendments to provisions under § 602.17, however, we believe the application of standards are important considerations in evaluating the quality of higher education. The new regulations require accrediting agencies, when applying their standards, to consider institutional policies and practices relating to student achievement and faculty. They do not prescribe the content of such policies, require institutions to adopt particular policies, or require accrediting agencies to establish separate substantive standards in these areas.

An accrediting agency must consider relevant institutional policies and practices in the context of its existing standards and the institution’s mission. Where an agency has adopted standards addressing these matters, it must apply and enforce those standards consistently.

These provisions govern the process by which accrediting agencies evaluate institutions, rather than prescribing particular accreditation standards.

Arbitration (§ 602.20(e))

During the public comment period the Department received a few substantive comments arguing that arguing that prohibiting binding arbitration agreements between would undermine efforts to resolve disputes between institutions and accrediting agencies through negotiation and result in an increase in costly, protracted litigation. Commenters argued that binding arbitration agreements can provide institutions and agencies with a more efficient and less costly way.

The Department considered changes to the provision, however, we have consistently concluded that under Section 496(e) of the HEA arbitration cannot be binding, because the statute only refers to “initial” arbitration and provides that the institution may still instigate “any other legal action” after arbitration.

2. Regulatory Flexibility Act

This section considers the effects that the final rule may have on small entities in the Educational Sector as required by the Regulatory Flexibility Act (RFA, 5 U.S.C. *et seq.*, Pub. L. 96–354) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The purpose of the RFA is to establish as a principle of regulation that agencies should tailor regulatory and informational requirements to the size of entities, consistent with the objectives of a particular regulation and applicable statutes.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA) or any other statute unless the agency certifies that the rule will not have a “significant impact on a substantial number of small entities.”

This final rule implements regulatory changes to realign the Secretary’s criteria for recognition of accrediting agencies.

Congress has prohibited the Department from intervening in the curricular decisions of an institution or

attempting to exert control over its faculty, administration, or academic programs. Instead, under the HEA, accrediting agencies oversee the quality and academic sufficiency of instructional programs at institutions participating in the title IV, HEA programs. Accrediting agencies are independent, membership-based organizations that review member institutions or programs to ensure they meet certain standards for academic quality and rigor.

The HEA requires the Secretary to establish criteria for determining whether an accrediting agency is a reliable authority, for purposes of the HEA and for other Federal purposes, on the quality of education or training offered by the institutions or programs that they accredit. Such criteria are required to include appropriate measures of student achievement. Consistent with statute, the Secretary has established regulations for recognition of accrediting agencies at 34 CFR part 602 and has revised these regulations periodically.

E.O. 14279 directed the Secretary to take several actions related to the recognition of accrediting agencies or associations by the Department. Some of these actions require changes to existing regulations. The goal of these regulatory changes is to realign the Secretary’s criteria for recognition of accrediting agencies to promote high-quality, high value, and affordable education for students.

The Department estimates that the final rule would have a significant economic impact on a substantial number of institutional accrediting agencies that meet the definition of small entities. However, the Department believes that the final rule will only indirectly impact institutions of higher education.

Description of, and, Where Feasible, an Estimate of the Number of Small Entities to Which the Regulations Will Apply

The Department believes that institutions of higher education are not directly regulated by the final rule and could only be indirectly impacted by actions accrediting agencies take in response to the final rule. For this reason, the Department does not examine the possible impact of the final rule on small entities that are institutions of higher education. The Department also notes that it is difficult to estimate the impact of the final rule on institutions of higher education that are small entities because accrediting agencies have wide discretion in how they implement the final changes, and

data on the impact of accreditation regulations on institutions are not available. Moreover, as explained in Section 5 of this RIA (“Net Budget Impact”), several of the final regulatory changes are likely to have offsetting revenue effects for institutions, including on institutions of higher education that are small entities. For example, institutions will be subject to new student outcome standards for recognition purposes, which could force some institutions to reform or close programs, negatively affecting their revenues. Policies aimed at increasing credit transfers for students could have similar negative revenue effects on small entities. On the other hand, the final rule includes several provisions meant to prevent accrediting agencies from unnecessarily restricting innovation in educational models, which should allow institutions—including small entities—greater operational flexibility, which could increase their revenue. The final reforms

to increase new entrants and agency switching should also promote greater operational flexibility by creating a more favorable environment for institutions looking to innovate. The group directly affected by the final rule is accrediting agencies. Most accrediting agencies are organized as nonprofit entities that are defined as “small entities” if they are independently owned and operated and not dominant in their field of operation. While dominance in accreditation is hard to determine for institutional accrediting agencies, as it currently stands, the Department believes programmatic accrediting agencies—that is, recognized agencies that accredit specific programs within an institution—very often have dominance in their field. This is because there are usually, at most only one or two, and in rare cases multiple, programmatic agencies that provide recognition for a given field or occupation, that is used not only for Federal programs, but also

as for educational requirements related to professional licensure.^[20] Therefore, we do not consider programmatic accrediting agencies to be small entities for the purposes of this analysis. This determination is consistent with the Department’s past position on accrediting agency size standards. The Department believes that institutional accrediting agencies, which function as gatekeepers to title IV, HEA program funds and are subject to many of the policy changes in the final rule, meet the standard for small entities. The Department considers these agencies to be “professional organizations” as classified under the North America Industry Classification System (813920). The SBA defines small professional organizations as businesses having less than \$24 million in total annual revenue. Each accrediting agency recognized by the Department as institutional accrediting agencies report annual revenue below this threshold (Table 6.1).

Table 6.1 - Institutional Accrediting Agency Revenues

Agency	Year	Revenue (\$ millions)
Higher Learning Commission (HLC)	2025	17.5
Southern Association of Colleges and Schools Commission on Colleges (SACSCOC)	2025	14.8
WASC Senior College and University Commission (WSCUC)	2025	9.0
Accrediting Commission of Career Schools and Colleges (ACCSC)	2025	8.6
National Accrediting Commission of Career Arts and Sciences, Inc. (NACCAS)	2025	6.6
Northwest Commission on Colleges and Universities (NWCCU)	2024	6.1
New England Commission of Higher Education (NECHE)	2024	5.6
Accrediting Commission for Community and Junior Colleges (ACCJC)	2025	4.9
Council on Occupation Education (COE)	2025	4.8
Distance Education Accrediting Commission (DEAC)	2025	4.7
Middle States Commission on Higher Education (MSCHE)	2025	4.1
Accrediting Council for Continuing Education and Training (ACCET)	2024	3.2
Association for Biblical Higher Education (ABHE)	2025	2.4
Transnational Association of Christian Colleges and Schools (TRACS)	2025	2.0
Association of Advanced Rabbinical and Talmudic Schools (AARTS)	2025	1.6
Association of Institutions of Jewish Studies (AIJS)	2025	0.6

Source: Internal Revenue Service Form 990, PROPUBLICA. This table reports annual revenues from Form 990 for the most-recently available year at the time in which these data were collected. For some entities, this was 2025, while for others it was 2024.

To determine whether the final rule would have a significant economic impact on a substantial number of institutional accrediting agencies, the Department uses information on the burden the final rule would impose on institutional accrediting agencies included in the Paperwork Reduction Act section of this final rule. The final rule is estimated to require 352 hours of labor per institutional accrediting agency to comply with the final

regulations because institutional accrediting agencies will need to update their processes, data collection efforts, and reporting activities. Using the median hourly wage for Education Administrators, Postsecondary (11–9033) from the U.S. Bureau of Labor Statistics (\$50.29 in 2025) and then doubling that figure to account for overhead costs and employee benefits, results in an average annual burden imposed on an

institutional accrediting agency of \$35,404.²¹ These new costs will create a significant economic impact on a substantial number of institutional accrediting agencies. For the purposes of this analysis the Department has defined “significant economic impact” as increasing or reducing a small entity’s revenues by more than 3 percent, and a “substantial number of small entities” as more the 5 percent of

entities that meet the Department's definition of a small entity. The \$35,404 estimated burden for institutional accrediting agencies that result from the rule is about 6 percent of the Association of the Institutions of Jewish Studies' reported annual revenue of approximately \$600,000, exceeding the Department's threshold of 3 percent. All other agencies would experience less than a 3 percent effect on their revenues. Because there are fewer than 20 institutional accrediting agencies, a single accrediting agency represents over 5 percent of the accrediting agencies and the final rule exceeds the Department's threshold for a substantial number.

Alternatives Considered (Small Entities)

It is the Department's general policy to minimize compliance costs and regulatory burden for all regulated entities, especially small entities, and to develop regulations that are consistent with statutory requirements. The Department considered other options and changes to the proposed rule intended to reduce compliance costs and administrative burden for small entities such as whether institutional accrediting agencies who meet the definition of small entities could have fewer reporting requirements, or exemptions from certain aspects of the regulation. As explained above, each currently-recognized institutional accrediting agency is a relatively small non-profit voluntary membership organization and meets the definition of a small entity based on annual revenue volume (see Table 6.1). The Department determined that alternatives policies for small entities would diminish the effectiveness of the final rule for institutional accrediting agencies, which serve as quality gatekeepers for institutions participating in the Federal student assistance programs, under which approximately 13 million students will receive more than \$120 billion in the current year. Furthermore, the Department believes that such alternatives are inconsistent with the Higher Education Act, which establishes specific requirements for recognition of accrediting agencies that the existing regulations implement and which are further enhanced by the final rule, and E.O. 14279, which directed the Secretary to take specific actions.

Comments From the NPRM

Comments: Several commenters urged the Department to provide an estimate of the impact on institutions of higher education that meet its small entities definition in its Regulatory Flexibility Analysis for the proposed rule. One

commenter also argued that the Regulatory Flexibility Analysis should estimate the impact on programmatic accrediting agencies because they are consequential in affecting higher education policy.

Discussion: The Department did not provide a Regulatory Flexibility Analysis for institutions of higher education because it believes institutions are only indirectly affected by the rule; the rule applies to accrediting agencies and not institutions of higher education. Courts have held that the Regulatory Flexibility Act requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates small entities. On the issue of programmatic accrediting agencies, the Department maintains that these entities are dominant in their fields because there are usually, at most only one or two, and in rare cases multiple, programmatic agencies that provide recognition for a given field or occupation. They therefore do not meet the definition of a small entity. The Department has, however, provided an impact analysis for institutional accrediting agencies.

Changes: None.

Comment: Several commenters asked the Department to revisit its Regulatory Flexibility Act analysis, noting that the Department's paperwork and compliance burden was inaccurate and understated the burden imposed on institutional accrediting agencies.

Discussion: The Department used paperwork and compliance burden estimates to determine that the proposed rule would impose a significant economic impact on a substantial number of institutional accrediting agencies, which fit the Department's definition of small entities under the Regulatory Flexibility Act. The Department estimated in the proposed rule that only one institutional accrediting agency would experience a compliance burden that would exceed three percent of its annual revenue. The Department has reviewed and revised the Paperwork Reduction Act analysis and burden that will be imposed on institutional accrediting agencies in the final rule. Those changes (a slight reduction in the paperwork and compliance burden estimates for institutional accrediting agencies from those published in the proposed rule) are reflected in the Regulatory Flexibility Act analysis but they do not change the Department's estimates of the overall impact on small entities.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the Department consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not conduct or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

As part of its continuing effort to reduce paperwork and respondent burden, the Department provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps make certain that the public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

Discussion

The purpose of the regulations at 34 CFR part 602 is to ensure that accrediting agencies are, for purposes of the HEA and other Federal purposes, reliable authorities regarding the quality of education or training offered by the institutions or programs that they accredit. Accreditation in the United States has generally involved non-governmental entities that develop quality criteria and conduct evaluations, primarily through peer review, to determine whether or not those criteria are met. Reliance on the recognized accrediting agencies' quality assurance function is one of the three main elements of oversight for the HEA's Federal student aid programs. In order for students to receive Federal student aid from the Department for postsecondary study, the institution must be accredited by an accrediting agency (or, for certain vocational institutions, approved by a State approval agency) recognized under these regulations, be authorized by the State in which the institution is located, and receive approval from the Department through a program participation agreement.

As of October 1, 2026, the Secretary recognized 50 accrediting agencies that

are independent, membership-based organizations designed to ensure students have access to qualified faculty, appropriate curriculum, and other support services. Of these 50 accrediting agencies recognized by the Secretary, 34 are institutional for title IV HEA purposes and 16 are solely programmatic. Institutional accrediting agencies accredit entire institutions of higher education, while programmatic accrediting agencies accredit specific educational programs within institutions that prepare students for entry into a profession, occupation, or vocation. The Paperwork Reduction Act section will use these figures in assessing burden. Additionally, we use the number of title IV eligible institutions noted in the Regulatory Impact Analysis as the basis for assessing institutional burden in the Paperwork Reduction Act section.

General Comments

Some commenters believed that the burden estimates provided in the NPRM did not properly account for one-time and recurring costs for institutions and accrediting agencies. Some examples cited were: revising standards, developing processes, collecting and analyzing information, training personnel and reviewers, conducting additional reviews, reporting, and maintaining new requirements. Some commenters made suggestions that the Department assess the full institutional cost of the proposed regulation.

Discussion: The Department disagrees. The President's Executive Order specifically directed the Secretary of Education to take appropriate steps to reduce barriers that limit institutions in adopting practices that advance degree completion and new education models, as well as increasing the consistency, efficiency, and effectiveness of the accrediting agency recognition process, and streamlining the process for institutions to change accrediting agencies. Moreover, in doing this review directed by the Executive Order, the Department considered and reviewed the existing burden on accrediting agencies and institutions in the current regulations before considering additional changes to the existing requirements.

The final rule achieves the goals set forth in the Executive Order and further eliminates requirements that the Department identified as unnecessarily burdensome. These changes were proposed in negotiated rulemaking and included in the draft regulations that the negotiated rulemaking committee achieved consensus on.

This Paperwork Reduction Act analysis estimates the burden of both one-time implementation actions and any recurring requirements from new regulatory changes in the final rule.

Comments: Some commenters suggested that the burden estimates in the NPRM rested on unstated assumptions about future institutional academic records and to what extent such records are provided as structured documents. (In considering this comment, the Department assumed that in referring to "structured documents," the commenters were referring to electronic or physical documents that organize information using a predefined template, strict hierarchy, or markup or data schemas so that every piece of content appears in a predictable location and form.)

Discussion: The burden hour estimates for this final rule are based on a review of past estimates for requirements in each section, currently approved information collections, and the degree to which the final rule adds to or changes existing requirements. Additionally, while the Department did consider that certain records, such as institutional records, would generally be in electronic form, it did not assume that all documents, such as academic transcripts, were structured documents in uniform formats across varying institutions. The discussion in this section and in the description of the changes in the preamble clearly identify the basis for the Department's estimates, and no assumptions have been left unstated.

Comments: Several commenters noted that institutions are likely to already demonstrate compliance with some of the proposed regulations. They supported the new requirements in the recognition regulations and believed them to be best practices currently demonstrated by agencies or institutions. Other commenters suggested that the Department rely on institutions using their current practices rather than changing regulatory requirements for all.

Discussion: The Department appreciates these comments and the support for the regulations. However, the Department declines to rely solely on an institution's current practices and has included in the recognition criteria in the final rule accrediting agency best practices that promote transparency and consistency across recognized accrediting agencies and the institutions and programs that they accredit.

Comments: Several large institutions submitted comments stating their belief that the Department underestimated the burden on institutions of the new

regulations on credit transfers and the costs of implementing the regulations, such as the cost of changes to institutional policies and student information systems that will be needed. One commenter stated that applying the same 300-hour estimate to institutions regardless of the scale and complexity of their transfer operations significantly understated the burden on many institutions and does not adequately reflect the resources necessary for implementation. Commenters asked the Department to re-assess burden estimates to include all aspects of implementation and consider the complexity of the size and operations of the school.

Discussion: The Department disagrees with the commenters' statements that burden estimates did not consider changes to institutional policies and student information. As part of the NPRM, the Department published supplemental information documenting the burden analysis for transfer credits described in the Paperwork Reduction Act section.

The Department also declines to adjust the 300-hour burden estimate. We also note that 300 hours is an estimate, and we expect some institutions will incur more or less burden. The estimate is consistent with the Paperwork Reduction Act, which requires an estimate of burden based on the estimated number of responses multiplied by the estimated average hourly burden per respondent.

This action contains the following new information collection requirements and amendments to existing collections:

§ 600.11 Special Rules Regarding Institutional Accreditation or Preaccreditation.

Requirements

The final rule in § 600.11 will reduce burdensome requirements on institutions seeking to add or change recognized accrediting agencies. Currently, institutions are required to submit materials to the Department demonstrating a reasonable cause for changing accrediting agencies, and then wait for the Department's approval of the change in accrediting agency. The current regulations include several criteria for which the Secretary will not determine such change to be reasonable cause. Section 600.11 removes the approval step and the latter criteria unless the Secretary determines that the change is being sought to evade or circumvent a requirement of Federal law or regulation; avoid or delay enforcement or oversight by the

Department or an accrediting agency; obtain eligibility for title IV, HEA programs through misrepresentation or other unlawful means; or otherwise undermine the integrity of the title IV, HEA programs.

Institutions seeking accreditation from multiple recognized accrediting agencies will only be required to submit a brief, reasonable explanation to the Department for this request.

Additionally, the institution will be required to use all reasonable efforts to notify current students and recent graduates of any change of accrediting agency within 10 days.

Comments: We received two comments disagreeing with the proposed changes to § 600.11 citing increased burden and documentation on institutions when seeking to change accrediting agencies.

Discussion: The changes to § 600.11 in the final rule will not introduce new burden on institutions. Prior to the final rule the regulations in this section already required institutions to provide

documentation to the Department when seeking to change accrediting agencies. The changes in the final rule will decrease the amount of documentation and justification that institutions will be required to submit to the Department and will eliminate the requirement to wait for the Department's approval before seeking to change recognized accrediting agencies.

Burden Calculation

In the Paperwork Reduction Act section of the NPRM, the Department noted that institutions will be required to submit a form with required information on switching accrediting agencies and that burden for this requirement will be assessed under a new OMB control number and will be made available for public comment prior to the rule becoming effective.

However, the Department has re-evaluated this position in the final rule and will not be requiring a new form for institutions changing accrediting agencies. Since this notification is

currently required under prior regulations no burden calculation has been made for this change.

§ 602.3 What definitions apply to this part?

Requirements

The final rule in § 602.3 revises some key definitions and adds new definitions used in these regulations.

Burden Calculation

Accrediting agencies and institutions will be required to review the new definitions and update internal policies and procedures to ensure they are compliant with the new regulations. The Department estimates that it will take recognized accrediting agencies 20 hours and institutions 5 hours to review, update, and make any relevant changes not otherwise referenced in this section to be required to be in compliance with the regulations. The Department anticipates this will be a one-time burden.

Entity	Responses	Hours	Burden Hours
Agency	50 agencies	20	1,000
Public	1,806 institutions	5	9,030
Private	1,649 institutions	5	8,245
For Profit	1,546 institutions	5	7,730
Total	5,051		26,005

§ 602.12 Accrediting Experience Requirements

The final rule in § 602.12(a) requires that an agency seeking initial recognition demonstrate that it has sufficient accreditation experience prior to submitting an application for recognition.

Burden Calculation

Burden for the regulation is assessed elsewhere throughout the changes and in the burden estimates for requirements for recognition.

§ 602.14 Purpose and Organization Requirements

The final rule in § 602.14 strengthens the fiscal and administrative requirements that a recognized agency must meet in order for an agency to demonstrate that it is “separate and independent” from any related, associated, or affiliated trade association or membership organization. Section 496(a)(3) of the HEA requires an accrediting agency to operate “separate and independent” of any related, associated, or affiliated trade association or membership organization unless that agency is categorized as having a voluntary membership of institutions or

programs that utilize the agency's accreditation to access other Department or Federal programs. Section 496(b) of the HEA defines the term “separate and independent”.

Under the final rule, agencies subject to the “separate and independent” requirements are prohibited from any joint use of personnel, services, equipment, or facilities with a related, associated, or affiliated trade association or professional organization. In addition, such recognized agencies must establish and implement conflict of interest controls for each member of their decision-making body.

The final rule in § 602.14 will also require as part of the initial and renewal

of agency recognition process, an authorized representative of the agency to submit a signed statement certifying that it has met the requirements for being separate and independent. This certification must also include information regarding any complaints received during the current recognition period.

Burden Calculation

The change under § 602.14(b)(6) will require an authorized representative of the agency to submit a signed statement certifying that it has met the requirements to be “separate and independent.” The Department estimates that this change will take an agency five hours to complete the statement and obtain the necessary signature annually.

34 Institutional Accrediting Agencies ×
5 Hours = 170 Burden Hours

§ 602.15 Administrative and Fiscal Responsibilities Requirements

The final rule in § 602.15 will clarify that conflict of interest controls are an integral part of the administrative and fiscal capability criteria the Department uses for determining recognized accrediting agencies. Prior to this final rule, conflict of interest controls were not included in the administrative and fiscal responsibilities regulations. With this final rule, agencies will now be required to have conflict of interest controls.

Additionally, the final rule in § 602.15 will require training to be provided to agency representatives and staff, focusing on best practices and avoiding unnecessary costs. The final rule will also require an agency to cooperate with other agencies and the Department to develop common accreditation templates.

Burden Calculation

The Department estimates that it will take each accrediting agency 30 hours to create, review and update conflict of interest controls.

50 Accrediting Agencies × 30 Hours =
1,500 Burden Hours

Developing and conducting training for representatives and staff would create burden on accrediting agencies. We estimate it would take 18 hours for an agency to create or research appropriate training for their staff. The Department anticipates this will be an ongoing burden.

50 Accrediting Agencies × 18 Hours =
900 Burden Hours

§ 602.17 Application of Standards in Reaching Accreditation Decisions Requirements

The final rule in § 602.17 will clarify expectations for agency review of student achievement and faculty-related standards and policies, including those addressing academic freedom and intellectual diversity. They will also encompass agency review of institutional cost/benefit analyses, educational objectives, student success, faculty performance and evaluation, facilities, academic freedom, and intellectual diversity.

The final rule is consistent with Section 496(a)(6)(A) of the HEA which states that no accrediting agency may be determined by the Secretary to be a reliable authority as to the quality of education or training offered or for other Federal purposes, unless the agency meets criteria established by the Secretary. The statute states that such criteria shall include appropriate measures of student achievement and require that an agency establish and apply review procedures throughout the accrediting process, including evaluation and withdrawal proceedings, which comply with due process procedures.

Comments

Some comments submitted by institutions mentioned the burden estimate for the cost/benefit analysis in § 602.17, which the Department estimated in the NPRM to be 750,150 burden hours across Title IV-participating institutions. Some commenters disagreed with the estimate, asserting it was severely underestimated while others expressed concern it was too high. Other comments stated the burden of the cost/benefit analysis could not be estimated due to lack of instruction on specific requirements of such analysis. One comment stated the Department omitted burden on institutions for § 602.17 entirely and only considered it for accrediting agencies.

Discussion

None of the comments received from institutions included suggestions to improve the accuracy of the estimates of the administrative burden that were proposed to this section. However, the Department re-evaluated the burden estimate for institutions under this section in response to the comments. The Department has revised its analysis of reporting burden for the changes in Section 602.17 of the final rule. The changes in this section address how accrediting agencies seeking recognition

by the Department apply their standards and do not impose new requirements on institutions or programs, and the Department has removed calculation of institutional burden from the burden calculation below.

Burden Calculation

The regulations in § 602.17 that have already been in effect prior to the final rule require a recognized agency to have effective mechanisms for evaluating an institution's or a program's compliance with the agency's standards before reaching a decision to accredit or preaccredit the institution or program. Additionally, many agencies already have policies and procedures in place that are consistent with many of the requirements in this section of the final rule.

To comply with § 602.17, the Department estimates that all agencies will be required to review the final rule and assess whether or not their application of its current policies and procedures comply with the new requirements. As a result of this review, some agencies are likely to be required to make some changes to their policies and procedures, which will vary agency by agency. Based on the comments, we assume that most agencies currently do not review institutional cost/benefit analyses in the areas identified by the regulations. Thus, the estimate is an average amount of time across all agencies, with some agencies incurring more burden and some incurring less.

We estimate this would take an agency approximately 20 hours to review initial compliance with § 602.17.
50 Recognized agencies × 20 Hours =
1,000 Burden Hours

We estimate the change to existing policies and procedures would take an average of 40 hours; however, we do not estimate that the changes in this section would increase the overall time for an agency to review an institution or program. Thus, the estimate is an average amount of time to take steps to change policies across all agencies, with some agencies incurring more burden and some incurring less.

50 Accrediting agencies × 40 Hours =
2,000 Burden Hours

§ 602.18 Ensuring Consistency in Decision-Making

Requirements

The final rule in § 602.18(b)(4) will clarify that a recognized agency only meets the requirement in paragraph (a) of this section if the agency “has adopted and followed procedures to ensure that agency decisions are neutral with respect to viewpoint and ideology

that are unrelated to its accrediting policies or standards.”

Burden Calculation

Burden for this proposed regulation has already been accounted for elsewhere in this section.

§ 602.20 Enforcement of Standards Requirements

The final rule in § 602.20(e) will require an agency's arbitration standards or policies to be nonbinding, except that both parties may agree to binding arbitration after a dispute arises on a case-by-case basis. Section 602.20(h) will require an agency to have a policy for restoring accreditation, including retroactive restoration, to an institution.

Burden Calculation

The Department estimates that there will be a one-time burden on accrediting agencies that do not currently have retroactive accreditation policies. We estimate it would take an accrediting agency 30 hours to create such a policy.

$$50 \text{ Accrediting Agencies} \times 30 \text{ Hours} = 1,500 \text{ Burden Hours}$$

The accreditation guidance²⁸ on non-binding arbitration language has been in effect since December 5, 2023; therefore, we do not estimate this change to create additional burden.

§ 602.21 Review of Standards Requirements

The final rule in § 602.21 will streamline the prescriptive requirements in the prior regulations for an accrediting agency to maintain a comprehensive systematic program of review. Specifically, the final rule removes the requirements in paragraphs (b), (c), and (d) of § 602.21 that are not based on statute. Removing these paragraphs eliminates burdensome and complex regulations that are difficult for accrediting agencies to implement and difficult to enforce effectively and consistently. The final rule continues to retain the statutory requirement for accrediting agencies to regularly review their standards which, in totality, affords them the flexibility to innovate but also maintain essential requirements for a regular review process.

Burden Calculation

The Department estimates the changes to § 602.21 in the final rule will reduce

annual burden on recognized accrediting agencies. The last time burden was assessed for this regulation under OMB Control Number 1840–0788 the Department estimated that reviewing standards would take approximately 12 hours to complete each year. In the NPRM, we estimated a reduction of 4 hours per agency. However, after reviewing the requirements in response to comments, we now estimate that the requirement will take 6 hours per agency to complete, a 50 percent reduction in annual burden compared to the prior requirements. The Department is adjusting the annual burden hours under OMB Control Number 1840–0788 accordingly.

§ 602.22 Substantive Changes and Other Reporting Requirements

The final rule in § 602.22 will clarify, streamline, and reduce the types of situations that are defined in the agency's definition of substantive change.

Burden Calculation

The Department estimates that the changes to § 602.22 in the final rule will reduce burden on recognized institutional accrediting agencies. Under the final rule, the definition of substantive change will include a more precise set of situations, achieve a better balance of which changes require additional oversight, and provide deference to recognized accrediting agencies to make the decisions on the specific types of substantive changes they review and approve.

We estimate there will be a reduction of 16 burden hours per institutional agency annually.

$$34 \text{ Institutional Accrediting Agencies} \times 16 \text{ Hours} = 544 \text{ less annual Burden Hours}$$

§ 602.23 Operating Procedures All Agencies Must Have Requirements

The final rule in § 602.23(c)(1) will include preaccredited institutions. Prior to the final rule, the regulations only required that recognized accrediting agencies review complaints received for accredited institutions.

The final rule in § 602.23(c)(3) will require agencies to also review conflicts of interest and require agencies to document actions when complaints about institutions are reviewed.

The final rule in § 602.23(d) will require that a recognized accrediting agency have operating procedures that ensure that institutions or programs it

accredits will publicly disclose any action by the agency that triggers the enforcement timeline provision in § 602.20(a) or (b).

The final rule in § 602.23 will prevent recognized agencies from having policies that would require institutions or programs to act in violation of any Federal or State law. The agency will also be required to have internal controls to ensure compliance with antitrust laws.

The final rule in § 602.23(k) will require recognized agencies to have a timely procedure to accelerate the comprehensive accreditation process for an institution or program seeking initial accreditation.

Lastly, the final rule in § 602.23(l) will require recognized agencies to establish and maintain at least one structured mechanism through which currently enrolled students, employed staff, and employed faculty of accredited or preaccredited institutions or programs may communicate directly with the agency.

Burden Calculation

In 2019, the Department estimated that it would take 2 hours annually for each accrediting agency to comply with § 602.23. We now estimate that by adding these additional consumer protection provisions in the final rule, it would take each agency an additional two hours annually to comply.

$$50 \text{ Accrediting Agencies} \times 2 \text{ Hours} = 100 \text{ Burden Hours}$$

§ 602.24 Additional Procedures Certain Institutional Agencies Must Have Requirements

The final rule in § 602.24 would codify the current practice of most agencies that a peer or independent site visitor accompany accrediting agency staff during on-site reviews, clarify when institutions must submit teach-out plans and agreements, and establish clear timelines and documentation expectations.

The final rule in § 602.24 will also enhance transparency and student support by requiring accrediting agencies to coordinate teach-outs, ensure transcript access and transfer pathways, and notify other agencies when cross-agency agreements are approved. Additionally, institutions will be required to update and publicly disclose comprehensive transfer of credit policies, adopt consistent criteria for evaluating comparable credits, prohibit discriminatory denials, and provide students with an appeals process.

²⁸ DCL GEN–23–14—Regulations Governing the Recognition of Accrediting Agencies, Institutional Eligibility, and Arbitration—<https://fsapartners.ed.gov/knowledge-center/library/dear-colleague-letters/2023-11-03/regulations-governing-recognition-accrediting-agencies-institutional-eligibility-and-arbitration-updated-dec-5-2023>

Prior to this final rule, the regulations did not distinguish between the circumstances requiring institutions to provide teach-out plans versus teach-out agreements. Under the final rule, institutions will be required to submit a teach-out plan within 30 days when specified events occur, such as when an institution's certification status changes from full to provisional. On the other hand, teach-out agreements will be required within the same 30-day window when institutions experience triggering events that signal heightened operational risk, including financial concerns or adverse actions. To ensure institutions act promptly when they are unable to secure a teach-out agreement, the Department adds a new requirement mandating that institutions provide their accrediting agency and the State with documentation explaining why a teach-out agreement could not be secured within 30 days. In addition, institutions in this situation will be required to notify the Department, which may then require the institution to provide proof of financial protection to safeguard students in the event of closure.

Prior to the final rule, the regulations required institutional accrediting agencies to evaluate teach-out agreements based on elements that went beyond what the HEA requires, and provided insufficient contingency measures for institutions that closed. Under the final rule, accrediting agencies will be required to coordinate with institutions to secure teach-out agreements, review teach-out plans and agreements and confirm that students retain access to transcripts and transfer pathways. In addition, if a teach-out agreement includes a program or institution that is accredited by another recognized agency, the accrediting agency must notify the other accrediting agency of its approval.

Burden Calculation

The final rule will remove several overly prescriptive requirements that are not supported in the statutory framework. The removal of these requirements will decrease unnecessary burdens on institutional accrediting agencies and institutions. However, several other consumer protection provisions in § 602.24 will add burden on institutional accrediting agencies.

Requiring a peer or independent site visitor to accompany accrediting agency staff during on-site reviews will require some accrediting agencies to assign additional peer or independent site visitors to be present during site visits. As noted above, most agencies already have such a site visitor present during

on-site reviews, and the Department estimates that codifying this practice in the regulations as a quality assurance criterion for all recognized agencies will only impact several agencies. Recognized accrediting agencies will also be required to request and review documents from institutions and maintain communication with institutions and State agencies, another common practice.

In the NPRM, the Department estimated that this new requirement would take approximately 470 hours for each agency and each institution to initially implement this provision of the final rule. However, the Department found that its analysis in the NPRM was incorrect because it mistakenly included burden for all institutions when the provisions in the final rule will only apply to recognized agencies. The Department also reassessed its estimates in the NPRM for the one-time burden on institutional agencies to implement this provision of the final rule.

To implement these new regulations, institutional accrediting agencies will be required to review and identify the scope of the new regulations (20 hours), amend policies and procedures (40 hours), train volunteers and staff (100 hours). The Department estimates that this will take approximately 160 hours per institutional accrediting agency.

§ 602.26 Notification of Accrediting Decisions

Requirements

The final rule in § 602.26 will make minor modifications to the requirements for accrediting agencies to report accrediting decisions to the Secretary. Recognized accrediting agencies will now be required to maintain a record of all actions taken against institutions or programs accredited by the agency on its website for a period of at least five years.

Burden Calculation

Prior to the final rule, Section 602.26 required recognized agencies to maintain on their website a clear record of all actions taken for each institution or program it accredits or preaccredits for a period of at least five years. The final rule provides additional transparency and consumer protections which adds burden to accrediting agencies. This additional burden includes requiring agencies to expand their monitoring and reporting processes. Agencies will need to review the new requirements and create a process to ensure their website is compliant with this proposed rule. Agencies may also have to update their

systems or train staff to keep their website up to date with actions taken for each institution or program. We estimate this will add 100 burden hours per year.

$$100 \text{ Burden Hours} \times 50 \text{ Accrediting Agencies} = 5,000 \text{ Burden Hours}$$

§ 602.27 Other Information an Agency Must Provide the Department

Requirements

The final rule in § 602.27 will require more frequent updates of an agency's accredited and preaccredited institutions and programs to the Department's website directory. The proposed reporting requirements would require agencies to submit regular and timely updates throughout the year rather than an annual list.

Burden Calculation

Complying with these requirements in the final rule will require recognized accrediting agencies to expand their reporting processes to allow for more frequent reporting submissions to the Department. Agencies are already accustomed to reporting actions taken.

In 2023, the Department estimated that each website update would take an agency 20 minutes to complete. Under the final rule, we estimate that this will take an average of 2 hours per update. More frequent updates will also increase burden for this regulation. Before this final rule, accrediting agencies were required to submit an update to the Department's website directory once per year. Under the final regulation, agencies are required to submit regular and timely updates throughout the year.

If an agency updates the Department's website directory four times per year, this increases burden to 8 additional burden hours per agency per year.

$$50 \text{ Accrediting Agencies} \times 8 \text{ Hours} = 400 \text{ Burden Hours}$$

§ 602.28 Regard for Decisions of States and Other Accrediting Agencies

Requirements

The final rule in § 602.28 requires accrediting agencies to expand the function of reviewing the accreditation or preaccreditation of certain institutions and allow agencies to place institutions on a show cause or equivalent status. This change allows agencies to more precisely specify that programs, not just institutions, are subject to review by an agency when another recognized agency has initiated an adverse action or placed a program on probation or an equivalent status. The final rule will also expand the term "other recognized agencies" to include State and Federal oversight agencies to

provide increased accountability for institutions or programs subject to negative or adverse actions by those entities.

Burden Calculation

Complying with these new regulations will require agencies to expand their institutional review processes. We estimate this would require 30 additional burden hours per year.

$$50 \text{ Accrediting Agencies} \times 30 \text{ Hours} = 1,500 \text{ Burden Hours}$$

§ 602.30 Agency Applications and Reports To Be Submitted to the Department

Requirements

The final rule in § 602.30 will modernize how accrediting agencies submit applications and reports to the Department. The submission timeline and concurrent submission requirements are removed, and there is a new requirement for an accrediting agency to submit a written application to the Secretary if it seeks a contraction of scope. The final rule will also prohibit an accrediting agency from prematurely redacting business and other non-Personally Identifiable Information (PII) in its applications and reports submitted to the Department.

Burden Calculation

Section 602.30 will impose only a nominal amount of burden on recognized accrediting agencies. Prior to this final rule, there has been no requirement for an agency to apply for a contraction of scope. Based on historical trends, we estimate that fewer than 1 accrediting agency per year will apply for a contraction of scope.

In 2019, the Department estimated it would take 20 hours per expansion of scope application. However, since the requirements for contraction of scope are simply a notification and require less explanation and documentation than expansion, we estimate it would take only 1 hour to complete a contraction of scope application. If only 1 agency submits a contraction of scope application every 2 years this adds .5 burden hours per year.

$$.5 \text{ Accrediting Agencies} \times 1 \text{ Hour} = .5 \text{ Total Burden Hours}$$

§ 602.31 Procedures for Submitting Applications for Recognition and Renewal of Recognition

Requirements

The final rule in § 602.31 will change the application process for recognition or renewal of recognition to provide

specific instructions and requirements based on scope of agency activities.

Specifically, under the change in the final rule, if institutions accredited by an agency receive a substantial portion of all Title IV, HEA program funds, institutional accrediting agencies seeking initial or renewed recognition will be required to submit a comprehensive application for recognition. When not designated for review, the institutional accrediting agency would submit an application demonstrating its adherence to the regulatory requirements. When submitting information to the Department, agencies are no longer required to redact certain information prior to submission.

Burden Calculation

The changes in the final rule to § 602.31 will reduce burden on accrediting agencies. In 2019, the Department estimated that accrediting agencies would require 285 additional hours of burden or 5.37 hours per agency. The Department estimates that removing these requirements eliminates 268.5 burden hours (5.37 hours * 50 agencies).

§ 602.32 Procedures for Review of an Expansion of Scope, a Contraction of Scope, Compliance Reports, or Increases in Headcount Enrollment

Requirements

The final rule in § 602.32 will revise procedures for expansions and contractions of scope, compliance reports, and increases in headcount. Specifically, under § 602.32(a)(1) and (2) of the final rule, the Department will consider applications for an expansion or contraction of an accrediting agency's scope only when submitted together with an application for recognition, unless Department staff, at their discretion, elect to review such a request independently.

For compliance reports, Department staff will complete their evaluation and a draft analysis. The draft, along with any materials received by the Department, will be sent to the agency identifying any potential areas of noncompliance. The agency will be invited to submit a written response within at least 45 days.

Under § 602.32(c), reports related to increases in headcount enrollment submitted pursuant to § 602.30(d) will be processed by the Department using the same procedures applicable to compliance reports.

Burden Calculation

The Department estimates there will be 12 agencies invited to respond to a

written compliance report per year. We estimate this response would take an agency 15 hours to outline, draft, complete, and transmit it to the Department.

$$12 \text{ Accrediting Agencies} \times 15 \text{ Hours} = 180 \text{ Burden Hours}$$

§ 602.34 Advisory Committee Meetings Requirements

The final rule in § 602.34 will require the National Advisory Committee on Institutional Quality and Integrity (NACIQI) to review applications for contractions of scope. The Department also now requires that accrediting agencies post public notice of upcoming NACIQI reviews.

Burden Calculation

Under the final rule, agencies will be required to post notices of upcoming reviews to be completed by NACIQI. The Department estimates this will take 2 hours per agency per year to determine if notification is necessary and publish any relevant information.

$$50 \text{ Accrediting Agencies} \times 2 \text{ Hours} = 100 \text{ Burden Hours}$$

§ 668.43 Institutional and Programmatic Information Requirements

The final rule in § 668.43(a)(11) will add an additional requirement to the information that institutions participating in the Federal student aid programs are required to provide to enrolled and prospective students. Specifically, the final rule will add an additional student consumer disclosure that requires institutions to inform students and prospective students of the timeline by which a transcript must be submitted for timely review for transfer of credit. This timeline must conclude prior to the student's enrollment, registration, or making a nonrefundable financial commitment, so that a prospective student will know how many credits that they have earned at other institutions will transfer to a new institution before he or she incurs cost and time at that institution.

Before the final rule, institutions were only required under this section to provide a description of the transfer of credit policies established by the institution, including a statement of the institution's current transfer of credit policies that included: any established criteria the institution uses regarding the transfer of credit earned at another institution and any types of institutions or sources from which the institution will not accept credits; a list of institutions with which the institution has established an articulation

agreement; and written criteria used to evaluate and award credit for prior learning experience including, but not limited to, service in the armed forces, paid or unpaid employment, or other demonstrated competency or learning.

The final rule in § 668.43(c) will also require that if an institution declines to award credit under its transfer of credit policy, the institution must provide a written rationale to the student as to why the transfer credit was not accepted and provide information on each course that did not result in transfer credit.

Burden Calculation

The final rule in § 668.43(a)(11) will require institutions to update their transfer of credit disclosure to include a timeline for submission of transcripts that meets the requirements of the new regulations. The Department notes that all institutions already have policies and procedures for submission of transcripts under their current transfer of credit policy. However, while this is not a new requirement, the Department acknowledges that some institutions may need to revise their timelines to comply with the new requirements. In

calculating administrative burden with the new requirements, the Department assumes institutions will continue their current practices to receive transcripts and send their required disclosures and communications to students electronically.

In the NPRM, the Department estimated that this new requirement would take approximately 470 hours per institution to initially implement. After reviewing its prior analysis in response to the comments, the Department found that its analysis in the NPRM included burden associated with complying with existing requirements in addition to the new requirements in the final rule. The Department has revised its estimates, as explained below.

Institutions will be required to review the requirements and scope of the new regulations (5 hours), identify the scope of the new requirements (10 hours), and amend policies and procedures (25 hours). The Department estimates that this will take approximately 40 hours per institution one time.

The Department also reassessed its estimates for student reporting burden from its estimate in the NPRM. The

analysis in the NPRM improperly identified the regulation as a new reporting requirement. Students seeking transfer of credits already submit transcripts from other institutions to new institutions and the new regulations do not change this practice or impose a new requirement on students. In fact, the new regulations will likely benefit students by ensuring that they do not unwittingly enroll at a new institution under the false presumption that the credits they earned at other institutions will be accepted toward a certificate or degree at that institution.

Estimated Annual Burden and Respondent Costs Table

For institutions, we used the median hourly wage for Education Administrators, Postsecondary (11–9033) from the U.S. Bureau of Labor Statistics. In 2025 this was \$50.29. To account for overhead costs and benefits, the Department has multiplied this amount by two, resulting in hourly costs of \$100.58.

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Information Collection Request

Regulation	OMB Control #	Burden Hours	# of Responses	Costs
\$ 600.11 Special rules regarding institutional accreditation or preaccreditation	1845-NEW	NEW	NEW	NEW
\$ 602.3 What definitions apply to this part?	1840-0788	20 hours per agency burden hours	50 agency responses	1000 burden hours x \$100.58
		5 hours per institution burden hours	5,001 institution responses	=\$100,580 25,005 burden hours x \$100.58
				<u>=\$2,515,003</u>
				=\$2,615,583
\$ 602.12 Accrediting experience.	NA	NA	NA	NA
\$ 602.14 Purpose and organization.	1840-0788	5 hours per agency	34 responses	170 burden hours x \$100.58 = \$17,099
\$ 602.15 Administrative and fiscal responsibilities.	1840-0788	50 accrediting agencies X 30 hours = 1500 burden hours	50 responses	2,400 burden hours x \$100.58 = \$241,392
		50 accrediting agencies X 18 hours = 900 burden hours		
		1500 + 900 = 2,400 burden hours		
\$ 602.17 Application of standards in reaching accreditation decisions.	1840-0788	50 accrediting agencies x 20 hours = 1000 burden hours	50 responses	3,000 burden hours x \$100.58
		50 accrediting agencies x 40		= \$301,740

		hours = 2000 burden hours		
§ 602.18 Ensuring consistency in decision-making.	NA	NA	NA	NA
§ 602.20 Enforcement of standards.	1840-0788	50 accrediting agencies x 30 hours = 1500 burden hours	50 Responses	1,500 burden hours x \$100.58 = \$150,870
§ 602.21 Review of standards.	1840-0788	50 accrediting agencies x -6 hours = -300 burden hours	50 responses	300 burden hours x \$100.58 = -\$30,174
§ 602.22 Substantive changes and other reporting requirements.	1840-0788	34 accrediting agencies x -16 hours of burden = 800 fewer burden hours	3 fewer responses	-800 burden hours x \$100.58 = -\$80,464
§ 602.23 Operating procedures all agencies must have.	1840-0788	50 accrediting agencies x 2 hours = 100 burden hours	50 responses	100 burden hours x \$100.58 = \$10,058
§ 602.24 Additional procedures certain institutional agencies must have.	1840-0788	34 accrediting agencies x 160 burden hours	34 responses	5,440 x \$100.58 = \$547,155
§ 602.26 Notification of accrediting decisions.	1840-0838	50 accrediting agencies x 100 hours = 5,000 burden hours.	50 responses	5,000 burden hours x \$100.58 = \$502,900
§ 602.27 Other information an agency must provide the Department.	1845-0838	50 accrediting agencies x 8 hours = 400 burden hours	50 responses	\$100.58 x 400 burden hours x agencies = \$40,232
§ 602.28 Regard for decisions of States and other accrediting agencies.	1840-0788	50 accrediting agencies x 30 Hours = 1,500 burden hours	50 responses	1500 burden hours x \$100.58 = \$150,870
§ 602.30 Agency applications and	1840-0788	10 accrediting agencies x 20	10 responses	200 burden hours x

reports to be submitted to the Department.		hours = 200 total burden hours		\$100.58 = \$20,116
\$602.31 Procedures for submitting applications for recognition and renewal of recognition.	1840-0788	50 accrediting agencies x -5.37 hours = -268.5 burden hours		-268.5 burden hours x \$100.58 = \$27,006
\$602.32 Procedures for review of an expansion of scope, a contraction of scope, compliance reports, or increases in headcount enrollment.	1840-0788	12 accrediting agencies x 15 hours = 180 burden hours	12 responses	180 burden hours x \$100.58 = \$18,104
\$ 602.34 Advisory Committee meetings.	1840-0788	50 accrediting agencies x 2 hours = 100 burden hours	50 responses	100 burden hours x \$100.58 = \$10,058
\$ 668.43 Institutional and programmatic information.	1845-NEW *after the Department receives OMB approval, we will merge this new collection with 1845- 0022 Student Assistance General Provisions	5,001 institutional responses X 40 institutional hours=200,040 institutional burden hours	5,001 responses	100,020 burden hours X \$100.58 = \$20,120,023
TOTAL		244,667 burden hours		\$ 24,608,557

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4. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), OIRA has determined that this rule does meet the criteria in 5 U.S.C. 804(2).

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that would impose spending costs on State, local, or tribal governments in the aggregate, or on the private sector, in any 1 year of

\$100 million in 1995 dollars, updated annually for inflation. That threshold is currently approximately \$206 million. The Department believes that this rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, in excess of the threshold.

Intergovernmental Review

This program is subject to E.O. 12372 and the regulations in 34 CFR part 79. One of the objectives of the E.O. is to foster an intergovernmental partnership and strengthen Federalism. The E.O. relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Assessment of Education Impact

In accordance with Section 411 of the General Education Provisions Act, 20 U.S.C. 1221e–4, the Secretary requests comments on whether these final regulations would require transmission of information that any other agency or authority of the United States gathers or makes available.

Federalism

E.O. 13132 requires us to provide meaningful and timely input by State and local elected officials in the development of regulatory policies that have Federalism implications.

“Federalism implications” means substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. The regulations do not have Federalism implications.

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List of Subjects

34 CFR Part 600

Colleges and universities, Foreign relations, Grant programs—education, Loan programs—education, Reporting and recordkeeping requirements, Student aid, Vocational education.

34 CFR Part 602

Colleges and universities, Reporting and recordkeeping requirements.

34 CFR Part 668

Administrative practice and procedure, Colleges and universities, Consumer protection, Grant programs—education, Reporting and recordkeeping requirements, Student aid, Vocational education.

Nicholas Kent,

Under Secretary of Education.

For the reasons discussed in the preamble, the Secretary of Education amends parts 600, 602, and 668 of title 34 of the Code of Federal Regulations as follows:

PART 600—INSTITUTIONAL ELIGIBILITY UNDER THE HIGHER EDUCATION ACT OF 1965, AS AMENDED

- 1. The authority citation for part 600 continues to read as follows:

Authority: 20 U.S.C. 1001, 1002, 1003, 1088, 1091, 1094, 1099b, and 1099c, unless otherwise noted.

- 2. Amend § 600.11 by:

- a. Revising paragraphs (a) and (b); and
- b. Removing the parenthetical authority citation at the end of the section.

The revisions read as follows:

§ 600.11 Special rules regarding institutional accreditation or preaccreditation.

(a) *Change of accrediting agencies.* (1) For purposes of §§ 600.4(a)(5)(i), 600.5(a)(6), and 600.6(a)(5)(i), the Secretary does not recognize the accreditation or preaccreditation of an otherwise eligible institution if that institution is in the process of changing its accrediting agency, unless the institution provides the following to the Secretary:

- (i) All materials related to its prior accreditation or preaccreditation.
- (ii) Materials demonstrating reasonable cause for changing its accrediting agency. The Secretary will determine such cause to be reasonable unless the Secretary determines that the

institution is seeking the change in order to—

(A) Evade or circumvent a requirement of Federal law or regulation;

(B) Avoid or delay enforcement or oversight by the Department or an accrediting agency;

(C) Obtain eligibility for title IV, HEA programs through misrepresentation or other unlawful means; or

(D) Otherwise undermine the integrity of the title IV, HEA programs.

(2) The institution must publicly disclose within 10 business days on its website and make reasonable efforts to notify all current students, and recent graduates for whom they have active contact information, of the change of accrediting agency.

(b) *Multiple accreditation.* (1) An institution may obtain accreditation or preaccreditation from more than one accrediting agency recognized by the Secretary if the institution provides the following to the Secretary:

(i) Materials related to its prior accreditation or preaccreditation;

(ii) A written explanation showing reasonable cause for having multiple accreditors. The Secretary will determine such cause to be reasonable unless the Secretary determines that the institution is seeking to be accredited by more than one accrediting agency in order to—

(A) Evade or circumvent a requirement of Federal law or regulation;

(B) Avoid or delay enforcement or oversight by the Department or an accrediting agency;

(C) Obtain eligibility for title IV, HEA programs through misrepresentation or other unlawful means; or

(D) Otherwise undermine the integrity of the title IV, HEA programs.

(2) The Secretary will not determine the cause of having multiple accrediting agencies to be unreasonable due to a withdrawal, revocation, other termination of accreditation, probation or equivalent, show cause order, or suspension order.

* * * * *

PART 602—THE SECRETARY'S RECOGNITION OF ACCREDITING AGENCIES

- 3. The authority citation for part 602 continues to read as follows:

Authority: 20 U.S.C. 1099b, unless otherwise noted.

- 4. Revise § 602.2 to read as follows:

§ 602.2 How do I know which agencies the Secretary recognizes?

(a) Periodically, the Secretary publishes a list of recognized agencies

in the **Federal Register**, together with each agency's scope of recognition. You may obtain a copy of the list from the Department at any time. The list is also available on the Department's website.

(b) If the Secretary denies continued recognition to a previously recognized agency, or if the Secretary limits, suspends, or terminates the agency's recognition before the end of its recognition period, the Secretary publishes an announcement of that action on the Department's website, which includes the reasons for the action and date it was taken, and also publishes such information of the list and scope of recognized agencies published in the **Federal Register** pursuant to paragraph (a) of this section.

■ 5. Revise § 602.3 to read as follows:

§ 602.3 What definitions apply to this part?

(a) The following definitions are contained in 34 CFR part 600:

- (1) Accredited.
- (2) Additional location.
- (3) Branch campus.
- (4) Correspondence course.
- (5) Direct assessment program.
- (6) Distance education.
- (7) Nationally recognized accrediting agency.
- (8) Preaccreditation.
- (9) Religious mission.
- (10) Secretary.
- (11) State.
- (12) Teach-out.
- (13) Teach-out agreement.
- (14) Teach-out plan.

(b) The following additional definitions apply to this part:

Accreditation means the status of public recognition that an accrediting agency grants to an institution or program that meets the agency's standards and requirements.

Accrediting agency or agency means a legal entity, or that part of a legal entity, that conducts accrediting activities through voluntary, non-Federal review, that may include peer review, and makes decisions concerning the accreditation or preaccreditation status of institutions, programs, or both.

Act means the Higher Education Act of 1965, as amended.

Adverse accrediting action or adverse action means the denial, withdrawal, suspension, revocation, or termination of accreditation or preaccreditation, or any comparable accrediting action an agency may take against an institution or program.

Advisory Committee means the National Advisory Committee on Institutional Quality and Integrity.

Compliance report means a written report that the Department requires an agency to file when the agency is found

to be out of compliance to demonstrate that the agency has corrected deficiencies specified in the decision letter from the senior Department official or the Secretary. Compliance reports must be reviewed by Department staff and the Advisory Committee and approved by the senior Department official or, in the event of an appeal, by the Secretary.

Designated Federal Official means the Federal officer designated under 5 U.S.C. 1009(e).

Final accrediting action means a final determination by an accrediting agency regarding the accreditation or preaccreditation status of an institution or program. A final accrediting action is a decision made by the agency, at the conclusion of any appeals process available to the institution or program under the agency's due process policies and procedures.

Institution means an educational institution that meets the requirements of paragraph (1) of the definition of *eligible institution* found in 34 CFR 600.2.

Institutional accrediting agency means an agency that accredits institutions.

Monitoring report means a report that an agency is required to submit to Department staff when it is found to be substantially compliant. The report contains documentation to demonstrate that—

- (i) The agency is implementing its current or corrected policies; or
- (ii) The agency, which is compliant in practice, has updated its policies to align with those compliant practices.

Program means a postsecondary educational program offered by an institution that leads to an academic or professional degree, certificate, or other recognized educational credential.

Programmatic accrediting agency means an agency that accredits specific educational programs, including those that prepare students in specific academic disciplines or for entry into a profession, occupation, or vocation.

Recognition means an unappealed determination by the senior Department official under § 602.36, or a determination by the Secretary on appeal under § 602.37, that an accrediting agency complies with the criteria for recognition listed in subpart B of this part and that the agency is effective in its application of those criteria. A grant of recognition to an agency as a reliable authority regarding the quality of education or training offered by institutions or programs it accredits remains in effect for the term granted except upon a determination made in accordance with subpart C of

this part that the agency no longer complies with the subpart B criteria or that it has become ineffective in its application of those criteria.

Related, associated, or affiliated trade association means an organization that:

- (i) Is generally a membership organization;
- (ii) Is organized to promote a line of commerce, business, industry, or profession;
- (iii) Does not engage in a regular business of a kind ordinarily carried on for profit, and no part of the net earnings of which inures to the benefit of any member; and
- (iv) Is related to a particular accrediting agency in that the agency accredits institutions or programs that prepare students to enter the workforce of the same or substantially the same line of commerce, business, industry, or profession that organization promotes.

Representative of the public means a person who is not—

- (i) An employee, member of the governing board, owner, or shareholder of, or consultant to, an institution or program that either is accredited or preaccredited by the agency or has applied for accreditation or preaccreditation;
- (ii) A member of any trade association or membership organization related to, associated with, or affiliated with the agency; or
- (iii) A spouse, parent, child, or sibling of an individual identified in paragraph (i) or (ii) of this definition.

Scope of recognition or scope means the range of accrediting activities for which the Secretary recognizes an agency. The Secretary may place a limitation on the scope of an agency's recognition for title IV, HEA purposes. The Secretary's designation of scope defines the recognition granted according to—

- (i) Types of degrees and certificates covered;
- (ii) Types of institutions and programs covered;
- (iii) Types of preaccreditation status covered, if any; and
- (iv) Coverage of accrediting activities related to distance education or correspondence courses.

Senior Department official means the official in the U.S. Department of Education designated by the Secretary who has, in the judgment of the Secretary, appropriate seniority and relevant subject matter knowledge to make independent decisions on accrediting agency recognition.

Substantial compliance means the agency demonstrated to the Department that it has the necessary policies, practices, and standards in place and

generally adheres with fidelity to those policies, practices, and standards; or the agency has policies, practices, and standards in place that need minor modifications to reflect its generally compliant practice.

■ 6. Revise § 602.10 to read as follows:

§ 602.10 Link to Federal programs.

(a) If the agency is seeking renewal of recognition and the agency accredits institutions, it must demonstrate that its accreditation is a required element in enabling at least one of those institutions to establish eligibility to participate in the title IV, HEA programs. If, pursuant to 34 CFR 600.11(b), an agency accredits one or more institutions that participate in the title IV, HEA programs and that could designate the agency as its link to the title IV, HEA programs, the agency satisfies this requirement, even if the institution currently designates another institutional accrediting agency as its Federal link; or

(b) If the agency is seeking renewal of recognition and the agency accredits institutions or programs, or both, it must demonstrate that its accreditation is a required element, as stated in a Federal statute, Federal regulation, Federal grant or funding announcement, or other official Federal agency notice establishing eligibility requirements for participation in the program, in enabling at least one of those entities to establish eligibility to participate in non-HEA Federal programs and provide documentation that an institution or program is currently relying on the agency's accreditation as a condition of eligibility to participate in such programs.

(c)(1) If the agency is seeking initial recognition, it must demonstrate that an institution or program it accredits is likely to rely on the agency's accreditation to establish or continue eligibility to participate in an HEA or non-HEA Federal program upon recognition of the agency within two years.

(2) In the event the agency does not have an institution or program that is relying upon the agency's accreditation to establish or continue eligibility to participate in an HEA or non-HEA Federal program when the agency is recognized by the Department, it must report to the Secretary when the first institution or program it accredits begins relying upon its accreditation for such purposes.

(3) If, after two years after initial recognition, there are no institutions or programs that rely on the agency's accreditation to establish or continue eligibility to participate in an HEA or

non-HEA Federal program upon recognition of the agency, then the agency ceases to be recognized by the Department.

■ 7. Revise § 602.11 to read as follows:

§ 602.11 Extent of accrediting activities.

(a) The agency must identify the extent of its accrediting activities and demonstrate that it has the capacity, policies, and procedures necessary to conduct accrediting activities within the identified extent.

(b)(1) An agency may seek recognition to operate in a group of States, or in all States, but the Secretary does not assign, prefer, or limit geographic extent, except as necessary to ensure that the agency has the capacity to carry out its intended accrediting activities.

(2) The Secretary may not assign institutions or programs to accrediting agencies; restrict institutions or programs from seeking accreditation from any agency recognized by the Secretary; directly or indirectly discourage institutions or programs from seeking accreditation from another recognized agency through policy, guidance, communications, or other actions; or otherwise favor one recognized accrediting agency over another.

(3) The Secretary may not delay, condition, or otherwise adversely affect an institution's participation in title IV, HEA programs solely because the institution seeks accreditation from, or changes accreditation to, another agency recognized by the Secretary.

■ 8. Revise § 602.12 to read as follows:

§ 602.12 Accrediting experience.

(a) An agency seeking initial recognition must demonstrate that it has sufficient accreditation experience prior to submitting an application for recognition. An agency will be eligible to submit an application for recognition when it can show the following—

(1) The agency is legally established to operate in the relevant jurisdiction;

(2) The agency has adopted accreditation standards consistent with § 602.16;

(3) The agency has adopted operating procedures consistent with § 602.23; and

(4) The agency has established a process to accept applications for accreditation consistent with § 602.17 and has at least one institution or program which has submitted an application for accreditation.

(b) An agency seeking initial recognition must undergo the Secretary's recognition process, defined in § 602.31, and an evaluation of the agency's compliance with the

Secretary's recognition criteria, defined in this part, for the purpose of determining if the agency is a reliable authority as to the quality of education or training provided by the institutions or programs it accredits before its application for recognition may be considered by the Advisory Committee.

(c) The agency must have granted accreditation to one or more institutions if it is requesting recognition as an institutional accrediting agency and to one or more programs if it is requesting recognition as a programmatic accrediting agency before the agency may be granted recognition.

(d)(1) A recognized agency seeking an expansion or contraction of its scope of recognition must follow the requirements of § 602.32 and demonstrate that it has accreditation or preaccreditation policies in place that meet all the criteria for recognition covering the range of the specific degrees, certificates, institutions, and programs it seeks in its proposed scope. A change to an agency's geographic area of accrediting activities does not constitute an expansion or contraction of the agency's scope of recognition, but the agency must notify the Department of, and publicly disclose on the agency's website, any such change.

(2) An agency that cannot demonstrate experience in making accreditation or preaccreditation decisions under expanded scope at the time of its application or review for an expansion of scope may—

(i) If it is an institutional accrediting agency, be limited in the number of institutions to which it may grant accreditation under the expanded scope for a designated period of time; or

(ii) If it is a programmatic accrediting agency, be limited in the number of programs to which it may grant accreditation under that expanded scope for a certain period of time; and

(iii) Be required to submit a monitoring report regarding accreditation decisions made under the expanded scope.

(e) Experience qualifying under this section is not limited to the accreditation of institutions within a particular geographic area and may include experience obtained on a national, State or group of States, or programmatic basis.

■ 9. Add § 602.13 to read as follows:

§ 602.13 Effect of recognition.

(a) Recognition under this part does not confer immunity or any relief from Federal or State antitrust laws. Accrediting agencies, institutions, and programs remain subject to those laws notwithstanding recognition or

eligibility determinations made by the Department.

(b) Recognition under this part does not authorize collective action among accrediting agencies, institutions, or programs that would otherwise be subject to oversight under Federal or State law.

(c) Recognition under this part does not create a property interest or entitlement to continued recognition.

■ 10. Revise § 602.14 to read as follows:

§ 602.14 Purpose and organization.

(a) The Secretary recognizes only the following four categories of accrediting agencies:

(1) A State agency that—

(i) Has as a principal purpose the accrediting of institutions, programs, or both; and

(ii) Has been listed by the Secretary as a nationally recognized accrediting agency on or before October 1, 1991.

(2) An accrediting agency that—

(i) Has a voluntary membership of institutions;

(ii) Has as a principal purpose the accrediting of institutions and that accreditation is used to provide a link to Federal HEA programs in accordance with § 602.10; and

(iii) Satisfies the “separate and independent” requirements in paragraph (b) of this section.

(3) An accrediting agency that—

(i) Has a voluntary membership; and
(ii) Has as its principal purpose the accrediting of institutions or programs, and the accreditation it offers is used to provide a link to Federal programs in accordance with § 602.10.

(4) An accrediting agency that, for purposes of determining eligibility for title IV programs—

(i)(A) Has a voluntary membership of individuals participating in a profession; or

(B) Has as its principal purpose the accrediting of programs within institutions that are accredited by another nationally recognized accrediting agency; and

(ii) Satisfies the “separate and independent” requirements in paragraph (b) of this section.

(b) For purposes of this section, “separate and independent” means that—

(1) The members of the agency’s decision-making body, who decide the accreditation or preaccreditation status of institutions or programs, establish the agency’s accreditation policies, or both, are not elected or selected by the board or chief executive officer of any related, associated, or affiliated trade association or professional organization and are not staff of the related, associated, or

affiliated trade association or professional organization;

(2) At least one member of an agency’s decision-making body is a representative of the public, and at least one-seventh of the body consists of representatives of the public;

(3) The agency has established and implemented mandatory conflict of interest controls for each member of the decision-making body in accordance with § 602.15(e);

(4) The agency’s dues are paid and held separately from any dues paid to any related, associated, or affiliated trade association or professional organization;

(5) The agency develops and determines its own budget, without review by or in consultation with any other entity or organization, including any related, associated or affiliated trade association or professional organization; and

(6) The authorized representative of the agency submits a signed statement certifying that it has met the requirements to be “separate and independent” within each petition for recognition submitted to the Department, and includes in that statement information regarding any complaints received during the current recognition period that are material.

■ 11. Revise § 602.15 to read as follows:

§ 602.15 Administrative and fiscal responsibilities.

The agency must have the administrative and fiscal capability, including conflict of interest controls, to carry out its accreditation activities in light of its requested scope of recognition. The agency meets this requirement if the agency demonstrates that—

(a) The agency has—

(1) Adequate administrative staff and financial resources to carry out its accrediting responsibilities;

(2) Competent and knowledgeable individuals, qualified by education or experience in their own right, as appropriate for their roles;

(3) Training provided to all agency representatives and staff that includes topics related to best practices in various educational delivery methods, models, and modalities; innovative or lower-cost educational delivery models that may provide high-quality education to students; and avoiding unnecessary costs to institutions in the accreditation process; and

(4) Representatives of the public on all decision-making bodies.

(b) The agency maintains complete and accurate records of—

(1) Its last full accreditation or preaccreditation review of each institution or program, including on-site evaluation team reports, the institution’s or program’s responses to on-site reports, periodic review reports, any reports of special reviews conducted by the agency between regular reviews, and a copy of the institution’s or program’s most recent self-study if applicable; and

(2) All decision letters issued by the agency regarding the accreditation and preaccreditation of any institution or program and any substantive changes.

(c) The agency conducts its accreditation activities in a manner that seeks to avoid unnecessary financial, compliance, and administrative burdens, including by avoiding duplicative reporting, excessive documentation requirements, and unwarranted prescriptive processes.

(d) The agency will cooperate with other recognized agencies and the Department in the development of common templates and forms for institutions or programs to submit when seeking to change accrediting agencies.

(e) The agency has clear and effective controls, including guidelines, to—

(1) Prevent or resolve conflicts of interest, or the appearance of conflicts of interest, by the agency’s—

(i) Officers and directors;

(ii) Employees (including temporary, part-time, and full-time employees);

(iii) Evaluation team members;

(iv) Consultants and contractors;

(v) Volunteers; and

(vi) Other agency representatives.

(2) Ensure that members of the standards-setting body, which may include members of the decision-making body, do not vote as members of the decision-making body on the setting of standards or policies that affect any institution or program of which such a member is an officer, director, or employee;

(3) Determine its dues without review by any related, associated, or affiliated trade association or professional organization;

(4) Disallow shared resources, such as personnel, services, equipment, facilities, or information technology, nor have office space in the same building as any related, associated, or affiliated trade association or professional organization. The requirement in this paragraph (e)(4) for separate office space will take effect July 1, 2028;

(5) Ensure that any officers, directors, employees, or volunteers of the agency do not share or solicit feedback regarding the agency’s policies, standards, or decisions with respect to any institution or program from any

related, associated, or affiliated trade association or professional association;

(6) Prominently disclose on its website all relationships with related, associated, or affiliated trade associations or professional organizations; and

(7)(i) Not act to restrict access to employment in a profession, occupation, or vocation unless the agency provides notice of clear and convincing evidence to the Secretary that:

(A) The restriction is necessary to protect the public interest;

(B) The expected public benefits outweigh the costs to the public from reduced access to the profession, occupation, or vocation; and

(C) No less restrictive alternative would adequately protect the public interest.

(ii) For the purposes of this subsection, restricting access to employment includes:

(A) Taking steps to increase credentialing standards;

(B) Increasing the cost or level of required education or training; or

(C) Decreasing the availability of education or training in a manner that may benefit any related, associated, or affiliated trade association or professional organization.

(f) The agency's accreditation standards, policies, and enforcement practices must not restrict public institutions from fulfilling their obligations under the First Amendment to the Constitution of the United States. These standards similarly also must not restrict any private institutions that, through their institutional policies, guarantee the same or similar protections for students or faculty, unless the institution has a religious mission.

■ 12. Revise § 602.16 to read as follows:

§ 602.16 Accreditation and preaccreditation standards.

(a) The agency must demonstrate that it has standards for accreditation, and preaccreditation, if offered, that are sufficiently rigorous to ensure that the agency is a reliable authority regarding the quality of the education or training provided by the institutions or programs it accredits. The agency meets this requirement if the following conditions are met:

(1) The agency's accreditation standards must establish requirements for the institutions or programs it accredits in the following areas:

(i) Success with respect to student achievement at the institutional and program level in relation to the institution's mission, which may

include different standards for different institutions or programs, as established by the institution, including, as appropriate, consideration of State licensing examinations, course completion, and job placement rates, as described in § 602.17(a)(1).

(ii) Curricula.

(iii) Faculty.

(iv) Facilities, equipment, and supplies.

(v) Fiscal and administrative capacity as appropriate to the specified scale of operations.

(vi) Student support services.

(vii) Recruiting and admissions practices, academic calendars, catalogs, publications, grading, and advertising.

(viii) Measures of program length and the objectives of the degrees or credentials offered.

(ix) Record of student complaints received by, or available to, the agency.

(x) Record of compliance with the institution's program responsibilities under title IV of the Act, based on the most recent student loan default rate data provided by the Secretary, the results of financial or compliance audits, program reviews, and any other information that the Secretary may provide to the agency; and

(2) The agency's preaccreditation standards, if offered, must—

(i) Be appropriately related to the agency's accreditation standards; and

(ii) Not permit the institution or program to hold preaccreditation status for more than five years before a final accrediting action is made.

(b) Agencies are not required to apply the standards described in paragraph (a)(1)(x) of this section to institutions that do not participate in title IV, HEA programs. Under such circumstance, the agency's grant of accreditation or preaccreditation must specify that the grant does not include participation by the institution in title IV, HEA programs.

(c) If the agency only accredits programs and does not serve as an institutional accrediting agency for any of those programs, its accreditation standards must address the areas in paragraph (a)(1) of this section in terms of the type and level of the program rather than in terms of the institution.

(d)(1) If the agency has or seeks to include within its scope of recognition the evaluation of the quality of institutions or programs offering distance education, correspondence courses, or direct assessment education, the agency's standards must effectively address the quality of an institution's distance education, correspondence courses, or direct assessment education

in the areas identified in paragraph (a)(1) of this section.

(2) The agency is not required to have separate standards, procedures, or policies for the evaluation of distance education or correspondence courses.

(e) If none of the institutions an agency accredits participates in any title IV, HEA program, or if the agency only accredits programs within institutions that are accredited by a nationally recognized institutional accrediting agency, the agency is not required to have the accreditation standards described in paragraphs (a)(1)(viii) and (x) of this section.

(f) An agency that has established and applies the standards in paragraph (a) of this section may establish any additional lawful accreditation standards that are consistent with ensuring institutional or programmatic quality and integrity as it deems appropriate.

(g) Nothing in paragraph (a) of this section restricts—

(1) An accrediting agency from setting, with the involvement of its members, and applying accreditation standards for or to institutions or programs that seek review by the agency;

(2) An institution from developing and using institutional standards to show its success with respect to student achievement, which achievement may be considered as part of any accreditation review;

(3) Agencies from having separate standards regarding an institution's or a program's process for approving curriculum to enable programs to more effectively meet the recommendations of—

(i) Industry advisory boards that include employers who hire program graduates;

(ii) Widely recognized industry standards and organizations;

(iii) Credentialing or other occupational registration or licensure; or

(iv) Employers in a given field or occupation, in making hiring decisions; or

(4) Agencies from having separate faculty standards for instructors teaching courses within a dual or concurrent enrollment program, as defined in 20 U.S.C. 7801, or career and technical education courses, as long as the instructors, in the agency's judgment, are qualified by education or work experience for that role.

■ 13. Revise § 602.17 to read as follows:

§ 602.17 Application of standards in reaching accreditation decisions.

(a) The agency must have effective mechanisms for evaluating an

institution's or program's compliance with the agency's standards before reaching a decision to accredit or preaccredit the institution or program. The agency meets this requirement if it demonstrates that when reviewing institutions in accordance with the standards the agency establishes under § 602.16, it—

(1) For the purposes of meeting the standards requirements of § 602.16(a)(1)(i), evaluates whether an institution or program—

(i) Maintains clearly specified educational objectives, which may include credit for prior learning, that are consistent with its mission and appropriate in light of the degrees or certificates awarded that are developed, regularly reviewed, and updated using reliable data (which may include Federal or state data); and

(ii) As appropriate to its own standards, reviews an institution's student success with respect to student achievement at both the institutional and program levels, including minimum expectations, by assessing:

(A) State licensing or certification examination results, where applicable to the program of study;

(B) Program retention, completion, or graduation rates, including as appropriate the extent to which grades meaningfully reflect student learning and support progression through the program of study;

(C) Post-completion or graduation outcomes, including employment and continued education;

(D) Scores on relevant standardized assessments taken for admission to a higher-level degree, during and after the time of enrollment at an institution, as available; and

(E) Educational and economic returns aligned to the program's credential level, length, and occupational context relative to the total cost of attendance. Such returns shall be assessed using the earnings data calculated under 34 CFR part 668, subpart Q, enhanced Unemployment Insurance wage records, or other reliable earnings data available to the agency.

(2) When applying its standards according to § 602.16(a)(1)(iii) on faculty, evaluates whether an institution maintains:

(i) A sufficient number of appropriately qualified faculty and other subject matter instructors who are regularly evaluated on the performance of their instructional, research, or service responsibilities;

(ii) Written faculty performance evaluation policies that include defined performance criteria and are conducted on a periodic basis;

(iii) Academic freedom protections that are clearly articulated and applied consistently to faculty regardless of appointment classification, race or other immutable characteristics, viewpoint, or ideology, unless the institution has a religious mission. If an institution has a religious mission, the agency evaluates whether the institution maintains academic freedom protections that are consistent with the institution's religious mission and applied consistently to faculty regardless of appointment classification, race, or other immutable characteristics;

(iv) Sufficient flexibility in instructional staffing policies and procedures to respond to persistent material changes in student demand, program viability, or financial conditions;

(v) In the case of public institutions, consistently applied policies that protect the First Amendment to the Constitution of the United States. The agency should similarly evaluate any private institutions that, through their institutional policies, guarantee the same or similar protections for students or faculty;

(vi) Policies regarding the integrity of scholarly activity and research and practices designed to prevent, detect, and address fabrication, material misrepresentation or falsification, plagiarism, and other forms of research misconduct as well as mechanisms for timely investigation, corrective actions, and, as appropriate, public disclosure;

(vii) A policy or policies to protect civil rights and, as applicable, First Amendment rights, and whether such policy or policies include:

(A) Academic freedom protections that are clearly articulated and applied consistently to faculty regardless of appointment classification, race or other immutable characteristics, viewpoint, or ideology, unless the institution has a religious mission. If an institution has a religious mission, the agency evaluates whether the institution maintains academic freedom protections that are consistent with the institution's religious mission and applied consistently to faculty regardless of appointment classification, race, or other immutable characteristics;

(B) Academic freedom and freedom of inquiry protections for faculty in teaching, scholarship and research within the subject matter of a course and research within their academic discipline, including conditions under which a range of academic perspectives may be expressed and examined without adverse action based on lawful viewpoints unrelated to professional or

academic competence, unless the

institution has a religious mission; and
(C) In the case of a private institution, policies that if established guarantee the same or similar protections as those described in paragraphs (a)(2)(vii)(A) and (B) of this section; and

(viii) A policy that is designed to support, promote, and appropriately prioritize intellectual diversity and the free exchange of ideas amongst faculty, to include elements that address intellectual inquiry and student learning, and measures student and faculty perceptions on the range of viewpoints and perspectives offered by the institution or program, unless the institution or program has a religious mission. If an institution or program has a religious mission, the policy shall include elements that address intellectual inquiry and student learning that are consistent with the institution's religious mission.

(3) When applying its standards according to § 602.16(a)(1)(iv) and (v), conducts:

(i) A review of any cost/benefit analysis performed by an institution. Cost/benefit analysis means a review by the agency of the institution's budget, resource utilization and allocation, and, if existing, its business/strategic plan, continuous improvement strategic plan, and review of whether the institution considers whether the expected benefits of the institution's activities justify the associated financial, administrative, and opportunity costs and the impact of capital expenditures on future operating expenses;

(ii) A review of an institution's practices and capabilities regarding the administration of student aid programs; and

(iii) A review of the sufficiency and proper maintenance of the institution's facilities and that such facilities comply with applicable safety standards, laws, and regulations.

(4) When applying its standards according to § 602.16(a)(1)(viii), seeks to ensure that program length is appropriate to the objectives of the program and credential awarded at the institution. In applying its standard, the agency must not categorically prohibit or unreasonably restrict the accreditation of a:

(i) Short-term program that is designed to prepare students for employment in recognized occupations eligible for Federal student aid under applicable law; or

(ii) Certificate or degree program offered for a shorter period of time than is traditionally required to obtain that credential, so long as the program results in comparable academic,

professional, and employment outcomes for students who would complete such programs.

(b) When applying and determining an institution's or program's compliance with its standards, the agency must:

(1) Require the institution or program to engage in a comprehensive process, that may include a self-study, that assesses the institution's or program's education quality and success in meeting its mission and objectives, highlights opportunities for improvement, and includes a plan for making those improvements;

(2) Conduct at least one on-site review of the institution or program during which it obtains sufficient information to determine if the institution or program complies with the agency's standards;

(3) Allow the institution or program the opportunity to respond in writing to the report of the on-site review;

(4) Conduct its own analysis of the comprehensive process and supporting documentation furnished by the institution or program, the report of the on-site review, the institution's or program's response to the report, and any other information substantiated by the agency from other sources to determine whether the institution or program complies with the agency's standards; and

(5) Provide the institution or program with a detailed written report that assesses the institution's or program's compliance with the agency's standards, including areas needing improvement, and the institution's or program's performance with respect to student achievement.

(c) When applying its standards, an agency requires institutions to have processes in place through which the institution establishes that a student who registers in any course offered via distance education or correspondence is the same student who academically engages in the course or program.

(d) When applying its standards, an agency seeks to reduce unnecessary barriers which restrict the ability of institutions or programs from adopting instructional, programmatic, or delivery practices that improve student access, accelerate credential or degree completion, or support innovative models of postsecondary education, including program length.

(e) The agency has adopted, implements, and enforces written policies and procedures that seek to ensure the accuracy, completeness, and integrity of all representations made by the agency to:

(1) The Secretary;

(2) The public, including current and prospective students;

(3) State, Tribal, and other governmental authorities; and

(4) Institutions or programs it accredits or preaccredits.

(f) The agency has policies that the agency:

(1) Does not knowingly make false, misleading, or materially incomplete statements regarding:

(i) The accreditation or preaccreditation status of any institution or program; or

(ii) The scope, conditions, or implications of accreditation or preaccreditation; and

(iii) Compliance of an institution or program with applicable Federal or State law;

(2) Maintains procedures for the prompt correction of materially inaccurate public statements or disclosures;

(3) Maintains procedures for investigating credible allegations that the agency or its representatives made materially inaccurate or misleading representations; and

(4) Takes appropriate corrective or disciplinary action when the agency determines that materially inaccurate or misleading representations have occurred.

(g) The agency may not have standards that encourage, direct, or otherwise require institutions or programs to violate Federal or State law, including by having policies that provide any preferences on the basis of race.

(h) Nothing in this section shall be construed to require any action that would conflict with applicable Federal or State law.

■ 14. Revise § 602.18 to read as follows:

§ 602.18 Ensuring consistency in decision-making.

(a) The agency must consistently apply and enforce standards that respect the stated mission of the institution, including religious mission, and that ensure that the education or training offered by an institution or program, including any offered through distance education, correspondence courses, or direct assessment education is of sufficient quality to achieve its stated objective for the duration of any accreditation or preaccreditation period.

(b) The agency meets the requirement in paragraph (a) of this section if the agency—

(1) Has written specification of the requirements for accreditation and preaccreditation that include clear standards for an institution or program to be accredited or preaccredited;

(2) Has effective controls against the inconsistent application of the agency's standards;

(3) Bases decisions regarding accreditation and preaccreditation on the agency's published standards and does not use as a negative factor the institution's religious mission-based policies, decisions, and practices in the areas covered by § 602.16(a)(1)(ii), (iii), (iv), (vi), and (vii) provided, however, that the agency may require that the institution's or program's curricula include all core components required by the agency;

(4) Has adopted and followed procedures to ensure that agency decisions are neutral with respect to viewpoint and ideology that are unrelated to its accrediting policies or standards, except that nothing in this paragraph requires an accrediting agency with a religious mission to be neutral with respect to viewpoints;

(5) Has a reasonable basis for determining that the information the agency relies on for making accrediting decisions is accurate; and

(6) Provides the institution or program with a detailed written report that clearly identifies any deficiencies in the institution's or program's compliance with the agency's standards; and

(7) Publishes any policies for retroactive application of an accreditation decision, which must not provide for an effective date that predates either—

(i) An earlier denial by the agency of accreditation or preaccreditation to the institution or program; or

(ii) The agency's formal approval of the institution or program for consideration in the agency's accreditation or preaccreditation process.

(c) This section does not prohibit an agency from reducing barriers that limit institutions and programs from adopting practices that advance credential and degree completion and that promote new models of education by applying equivalent written standards, policies, and procedures that provide alternative means of satisfying one or more of the requirements set forth in §§ 602.16, 602.17, 602.19, 602.20, 602.22, and 602.24, as compared with written standards, policies, and procedures the agency ordinarily applies, if—

(1) The alternative standards, policies, and procedures, and the selection of institutions or programs to which they will be applied, are approved by the agency's decision-making body and otherwise meet the intent of the agency's expectations and requirements;

(2) The agency sets and applies equivalent goals and metrics for

assessing the performance of institutions or programs;

(3) The agency's process for establishing and applying the alternative standards, policies, and procedures is set forth in its published accreditation manuals; and

(4) The agency requires institutions or programs seeking the application of alternative standards to demonstrate the need for an alternative assessment approach, that students will receive equivalent benefit, and that students will not be harmed through such application.

■ 15. Revise § 602.20 to read as follows:

§ 602.20 Enforcement of standards.

(a) If the agency's review of an institution or program under any standard indicates that the institution or program is not in compliance with that standard, the agency must—

(1) Follow its written policy for notifying the institution or program of the finding of noncompliance;

(2) Provide the institution or program with a written timeline for coming into compliance that is reasonable, as determined by the agency's decision-making body, based on the nature of the finding, the stated mission, and educational objectives of the institution or program. The timeline may include intermediate checkpoints on the way to full compliance and must not exceed the lesser of four years or 150 percent of the—

(i) Length of the program in the case of a programmatic accrediting agency; or

(ii) Length of the longest program at the institution in the case of an institutional accrediting agency;

(3) Follow its written policies and procedures for granting a good cause extension that may exceed the standard timeframe described in paragraph (a)(2) of this section when such an extension is determined by the agency to be warranted; and

(4) Have a written policy to evaluate an institution's or program's progress in resolving the finding of noncompliance.

(b) Notwithstanding paragraph (a) of this section, the agency must have a policy for taking an immediate adverse action, and take such action, when the agency has determined that such action is warranted.

(c) If the institution or program does not bring itself into compliance within the period specified in paragraph (a) of this section, the agency must take adverse action against the institution or program, but may maintain the institution's or program's accreditation or preaccreditation until the institution or program has had reasonable time to complete the activities in its teach-out

plan or to fulfill the obligations of any teach-out agreement to assist students in transferring or completing their programs.

(d) An agency that accredits institutions may limit the adverse or other action to particular programs that are offered by the institution or to particular additional locations of an institution, without necessarily taking action against the entire institution and all of its programs, provided the noncompliance was limited to that particular program or location.

(e) All adverse actions taken under this subpart are subject to the arbitration requirements in 20 U.S.C. 1099b(e). Any agency arbitration standard or policy must be nonbinding, except that both parties may agree to binding arbitration after a dispute arises on a case-by-case basis. If an agency has an arbitration policy or standard, it must:

(1) Apply to all final adverse actions; however, an agency may require the institution or program to first exhaust the agency's appeal process;

(2) Ensure that the arbitration process is fair and impartial; and

(3) Provide for a transparent and reasonable period of time for resolution of disputes.

(f) An agency is not responsible for enforcing requirements in 34 CFR 668.14, 668.15, 668.16, 668.41, or 668.46, but if, in the course of an agency's work, it identifies instances or potential instances of noncompliance with any of these requirements, it must notify the Department.

(g) The Secretary may not require an agency to take action against an institution or program that does not participate in any title IV, HEA or other Federal program as a result of a requirement specified in this part.

(h) The agency must have a policy for restoring accreditation (including retroactive restoration) in circumstances that the agency determines are appropriate, including if required by an applicable judicial decision.

(i) Nothing in this part prohibits an agency from permitting the institution or program to be out of compliance with one or more of its standards, policies, and procedures adopted in satisfaction of §§ 602.16, 602.17, 602.19, 602.22, and 602.24 for a period of time, as determined by the agency annually, not to exceed three years unless the agency determines there is good cause to extend the period of time and if—

(1) The agency and the institution or program can show that the circumstances requiring the period of noncompliance are beyond the institution's or program's control, such as—

(i) A natural disaster or other catastrophic event significantly impacting an institution's or program's operations;

(ii) Accepting students from another institution that is implementing a teach-out or closing;

(iii) Significant and documented local or national economic changes, such as an economic recession or closure of a large local employer;

(iv) Changes in State licensure requirements; and

(v) Instructors who do not meet the agency's typical faculty standards but who are otherwise qualified by education or work experience to teach courses within a dual or concurrent enrollment program, as defined in 20 U.S.C. 7801, or career and technical education courses;

(2) The grant of the period of noncompliance is approved by the agency's decision-making body;

(3) The agency projects that the institution or program has the resources necessary to achieve compliance with the standard, policy, or procedure within the time allotted; and

(4) The institution or program demonstrates to the satisfaction of the agency that the period of noncompliance will not—

(i) Increase the cost of the program to the student without the student's consent;

(ii) Create any undue hardship on, or harm to, students; or

(iii) Compromise the program's academic quality.

(5) The agency timeline must include the enforcement of intermediate checkpoints that allow the agency to ensure the institution will be in full compliance by the end of the timeline.

(6) An extension under this paragraph (i) can only be granted by the agency if the special circumstances constitute a new and independent cause for the non-compliance.

■ 16. Revise § 602.21 to read as follows:

§ 602.21 Review of standards.

The agency must maintain a comprehensive systematic program of review that occurs at regular intervals, involves all relevant constituencies (including students), and that demonstrates that its standards are adequate to evaluate the quality of the education or training provided by the institutions and programs it accredits and relevant to the educational or training needs of students.

■ 17. Revise § 602.22 to read as follows:

§ 602.22 Substantive changes and other reporting requirements.

(a)(1) If the agency accredits institutions, it must maintain adequate

substantive change policies that ensure that any substantive change, as defined in this section, after the agency has accredited or preaccredited the institution does not adversely affect the capacity of the institution to continue to meet the agency's standards. The agency meets this requirement if—

(i) The agency requires the institution to obtain the agency's approval of substantive change defined in paragraph (a)(1)(ii) of this section before the agency includes the change in the scope of accreditation or preaccreditation it previously granted to the institution; and

(ii) The agency's definition of substantive change covers at least the following:

(A) Any substantial change in the established mission or objectives of the institution or its programs.

(B) Any change in the legal status, form of control, or ownership of the institution that results in a change of control.

(C) The addition of programs that represent a significant departure from the existing offerings or educational programs, or method of delivery, from those that were offered or used when the agency last evaluated the institution.

(D) The addition of graduate programs by an institution that previously offered only undergraduate programs or certificates.

(E) An increase in the level of credential awarded for successful completion of one or more programs.

(F) The acquisition of any other institution or any program or location of another institution not otherwise reviewed as part of a change of control transaction or the process for the addition of a location.

(G) The addition of a permanent location at a site at which the institution is conducting a teach-out for students of another institution that has ceased operating before all students have completed their program of study.

(H) The addition of a new location or branch campus, except as provided in paragraph (c) of this section. The institution must document its fiscal and administrative capability to operate the location or branch campus, including verification of the following:

(1) Academic control by the institution.

(2) The institution has adequate faculty, facilities, resources, and academic and student support systems in place.

(3) The institution is financially stable.

(4) The institution had appropriate planning for the addition.

(I) Entering into a written arrangement under 34 CFR 668.5 under which an institution or organization not certified to participate in the title IV, HEA programs offers more than 25 percent but less than 50 percent of one or more of the accredited institution's educational programs.

(J) Addition of each direct assessment program.

(K) Addition of the first prison education program at the first two additional locations and the first additional prison education program offered by a new method of delivery.

(2)(i) For substantive changes under only paragraph (a)(1)(ii)(C), (E), (G), or (I) of this section, the agency's decision-making body may designate agency senior staff to approve or disapprove the request in a timely, fair, and equitable manner; and

(ii) In the case of a request under paragraph (a)(1)(ii)(I) of this section, the agency must make a final decision within 90 days of receipt of a materially complete request, unless the agency or its staff determine significant circumstances related to the substantive change require a review by the agency's decision-making body to occur within 180 days.

(b) Institutions that have been placed on probation or equivalent status, have been subject to negative action by the agency over the prior three academic years, or are under a provisional certification, as provided in 34 CFR 668.13, must receive prior approval for the following additional changes (all other institutions must report these changes within 30 days to their accrediting agency or as directed by their accrediting agency):

(1) A change in the way an institution measures student progress, including whether the institution measures progress in clock hours or credit hours, semesters, trimesters, or quarters, or uses time-based or non-time-based methods.

(2) A substantial increase in the number of clock hours or credit hours awarded.

(3) Entering into a written arrangement under 34 CFR 668.5 under which an institution or organization not certified to participate in the title IV, HEA programs offers up to 25 percent of one or more of the accredited institution's educational programs.

(c) Institutions that have successfully completed at least one cycle of accreditation and have received agency approval for the addition of at least two additional locations as provided in paragraph (a)(1)(ii)(H) of this section, and that have not been placed on probation or equivalent status or been

subject to a negative action by the agency over the prior three academic years, and that are not under a provisional certification, as provided in 34 CFR 668.13, need not apply for agency approval of subsequent additions of locations, and must report these changes to the accrediting agency within 30 days, if the institution has met criteria established by the agency indicating sufficient capacity to add additional locations without individual prior approvals, including, at a minimum, satisfactory evidence of a system to ensure quality across a distributed enterprise.

(d) The agency may determine the procedures it uses to grant prior approval of the substantive change. However, these procedures must specify an effective date on which the change is included in the program's or institution's grant of accreditation or preaccreditation. The date of prior approval must not pre-date either an earlier agency denial of the substantive change, or the agency's formal acceptance of the application for the substantive change for inclusion in the program's or institution's grant of accreditation or preaccreditation. An agency may designate the date of a change in ownership as the effective date of its approval of that substantive change if the accreditation decision is made within 30 days of the change in ownership.

(e) The agency's substantive change policy must define when the changes made or proposed by an institution are or would be sufficiently extensive to require the agency to conduct a new comprehensive evaluation of that institution.

■ 18. Amend § 602.23 by:

■ a. Revising paragraphs (c) through (g);

■ b. Adding paragraphs (h) through (l); and

■ c. Removing the parenthetical authority citation at the end of the section.

The revisions and additions read as follows:

§ 602.23 Operating procedures all agencies must have.

* * * * *

(c) The accrediting agency must—

(1) Review in a timely, fair, and equitable manner any complaint it receives against an accredited or preaccredited institution or program that is related to the agency's standards or procedures. The agency may not complete its review and make a decision regarding a complaint unless, in accordance with published procedures, it ensures that the institution or program

has sufficient opportunity to provide a response to the complaint;

(2) Take follow-up action, as necessary, including enforcement action, if necessary, based on the results of its review; and

(3) Review in a timely, fair, and equitable manner, and apply unbiased judgment to, any complaints against itself, to include conflict of interest violations, and take follow-up action, as appropriate, based on the results of its review, and document such complaints and actions.

(d) The agency must require its accredited institutions or programs to publicly disclose any action by the agency that begins the enforcement timeline in § 602.20(a) or (b). When an institution or program makes such a disclosure or elects to make a public disclosure of its accreditation or preaccreditation status, the agency must ensure that the institution or program discloses that status accurately, including the specific academic or instructional programs covered by that status, the reason(s) for the action, and the name and contact information for the agency.

(e) The accrediting agency must provide for the public correction of incorrect or misleading information an accredited or preaccredited institution or program releases about—

(1) The accreditation or preaccreditation status of the institution or program;

(2) The contents of reports of on-site reviews; and

(3) The agency's accrediting or preaccrediting actions with respect to the institution or program.

(f) All credits and credentials earned and issued by an institution or program holding preaccreditation from a nationally recognized agency are considered by the Secretary to be from an accredited institution or program.

(g) The agency may establish any additional operating procedures it deems appropriate. At the agency's discretion, these may include unannounced inspections.

(h) The agency must not have policies that require institutions or programs to violate any Federal or State law, including title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq.*, and title IX of the Education Amendments Act of 1972, 20 U.S.C. 1681 *et seq.* (title IX), which means, among other things, that agencies must not have policies that require institutions or programs to provide unlawful preferences to students, faculty, staff, contractors, or any employees based upon their race, color, national origin, or sex, including

in admissions, hiring, and the selection of contracts.

(i) The agency must have internal controls to ensure compliance with antitrust laws, including by ensuring that the agency does not directly or indirectly facilitate coordination or collusive activities that are anticompetitive among institutions or programs or unnecessarily restrict access to employment in an occupation.

(j) The agency must refrain from reviewing aspects of institutional governance of public institutions that are established by State law, including the appointment of institutional directors or officers by elected or appointed State officials.

(k) The agency may have a timely procedure to accelerate the comprehensive accreditation process for an institution or program seeking initial accreditation. An institution or program would be eligible to access this process if, at a minimum, it—

(1) Holds current accreditation from another nationally recognized accrediting agency; and

(2)(i) Meets the requirements of 34 CFR 600.11; or

(ii) Is impacted by a decision by the senior Department official or Secretary to terminate an agency's recognition.

(l) The agency must establish and maintain at least one structured mechanism through which currently enrolled students, employed staff, and employed faculty of accredited or preaccredited institutions or programs may communicate directly with the agency concerns related to the agency's accreditation standards or the institution's or program's compliance therewith. Such mechanism(s) must be designed to ensure that information received is substantive and manageable in volume. Permissible mechanisms include, but are not limited to, any one or more of the following:

(1) A registration process through which students, staff, or faculty may sign up to participate in structured meetings with agency representatives during scheduled site visits or virtual visits, subject to reasonable limits on the number of participants and appointment availability;

(2) Randomized panels of students, staff, or faculty selected by the accrediting agency or its authorized representatives to participate in confidential interviews or focus groups during site visits, conducted in a manner that ensures a representative cross-section of the institutional community; or

(3) Student, faculty, staff surveys independently administered by the agency as part of an initial or renewal

of accreditation process which minimally address the standards areas required by § 602.16(a).

* * * * *

■ 19. Revise and republish § 602.24 to read as follows:

§ 602.24 Additional procedures certain institutional agencies must have.

(a) *Branch campus.* The agency must require the institution to notify the agency if it plans to establish a branch campus and to submit a business plan for the branch campus that describes—

(1) The educational program to be offered at the branch campus; and

(2) The projected revenues and expenditures and cash flow at the branch campus.

(b) *Site visits.* The agency must undertake a site visit that cannot be conducted solely by agency staff to a new branch campus or following a change of ownership or control as soon as practicable, but no later than six months, after the establishment of that campus or the change of ownership or control.

(c) *Teach-out plans and agreements.* (1) The agency must require an institution it accredits to submit a teach-out plan as defined in 34 CFR 600.2 within 30 days to the agency for approval upon the occurrence of any of the following events:

(i) For a nonprofit or proprietary institution, the Secretary notifies the agency of a determination by the institution's independent auditor expressing doubt about the institution's ability to operate as a going concern or indicating an adverse opinion or a finding of material weakness related to financial stability.

(ii) The agency acts to place the institution on probation or equivalent status.

(iii) The Secretary notifies the agency that the institution's participation in title IV, HEA programs has changed from full to provisional certification.

(2) The agency must require an institution it accredits or preaccredits to submit a teach-out agreement (as defined in 34 CFR 600.2) to the agency for approval upon the occurrence of any of the following events:

(i) The Secretary notifies the agency that it has placed the institution on the reimbursement payment method under 34 CFR 668.162(c) or the heightened cash monitoring payment method requiring the Secretary's review of the institution's supporting documentation under 34 CFR 668.162(d)(2).

(ii) The Secretary notifies the agency that the Secretary has initiated an emergency action against an institution, in accordance with section 487(c)(1)(G)

of the HEA, or an action to limit, suspend, or terminate an institution participating in any title IV, HEA program, in accordance with section 487(c)(1)(F) of the HEA.

(iii) The agency acts to withdraw, terminate, or suspend the accreditation or preaccreditation of the institution.

(iv) The institution notifies the agency that it intends to cease operations entirely or close a location that provides one hundred percent of at least one program, including if the location is being moved and is considered by the Secretary to be a closed school, unless the institution is completing its own teach-out.

(v) A State licensing or authorizing agency notifies the agency that an institution's license or legal authorization to provide an educational program has been or will be revoked.

(3) If an institution is unable to secure a teach-out agreement within 30 days with another institution as required under paragraph (c)(2) of this section—

(i) The institution must provide documentation to the agency and the State detailing why a teach-out agreement cannot be secured; and

(ii) The institution must notify the Department that a teach-out agreement cannot be secured and if this is the case, the Department may require the institution to provide financial protection.

(4) The agency must evaluate the teach-out plan to ensure it includes a list of currently enrolled students, academic programs offered by the institution, a plan to maintain and provide access to transcripts in the event of closure, and the names of other institutions that offer similar programs and that could potentially enter into a teach-out agreement with the institution.

(5) If the agency approves a teach-out plan or a teach-out agreement that includes a program or institution that is accredited by another recognized accrediting agency, it must notify that accrediting agency of its approval.

(6) The agency may require an institution it accredits or preaccredits to enter into a teach-out agreement as part of its teach-out plan.

(7) The agency must require an institution to include in its teach-out agreement—

(i) A complete list of students currently enrolled in each program at the institution and the program requirements each student has completed;

(ii) A plan to provide all potentially eligible students with information about how to obtain a closed school discharge

and, if applicable, information on State refund policies;

(iii) A record retention plan to be provided to all enrolled students that delineates the final disposition of teach-out records (e.g., student transcripts, billing, financial aid records);

(iv) Information on the number and types of credits the teach-out institution is willing to accept prior to the student's enrollment; and

(v) A clear statement to students of the tuition and fees of the educational program and the number and types of credits that will be accepted by the teach-out institution.

(8) The agency must require an institution it accredits or preaccredits that enters into a teach-out agreement, either on its own or at the request of the agency, to submit that teach-out agreement for approval. The agency may approve the teach-out agreement only if the agreement meets the requirements of 34 CFR 600.2 and this section, is consistent with applicable standards and regulations, and provides for the equitable treatment of students being served.

(9) Irrespective of any teach-out plan or signed teach-out agreement, the agency must not permit an institution to serve as a teach-out institution under the following conditions:

(i) The institution is subject to the conditions in paragraph (c)(1) or (2) of this section.

(ii) The institution is under investigation, subject to an action, or being prosecuted for an issue related to academic quality, misrepresentation, fraud, or other severe matters by a law enforcement agency.

(10) The agency is permitted to waive requirements regarding the percentage of credits that must be earned by a student at the institution awarding the educational credential if the student is completing his or her program through a written teach-out agreement or transfer.

(d) *Closed institution.* If an institution the agency accredits or preaccredits closes without a teach-out plan, the agency must work with the Department and the appropriate State agency, to the extent feasible, to assist students in finding reasonable opportunities to complete their education without additional charges, including by—

(1) Working with institutions to secure teach-out agreements;

(2) Where a teach-out agreement cannot be arranged, working with institutions to secure transfer options;

(3) Making teach-out or transfer options, the terms of such options, and information on obtaining transcripts, loan discharges, and reimbursement

publicly available on the agency's website; and

(4) Sharing such information with appropriate State agencies and, as applicable, with other recognized accrediting agencies.

(e) *Transfer of credit policies.* The accrediting agency must confirm, as part of its review for initial accreditation or preaccreditation, or renewal of accreditation, that the institution has transfer of credit policies which include provisions that—

(1) Are publicly disclosed in accordance with 34 CFR 668.43(a)(11) and include general policies for specific academic standards, time limits, and curricular requirements for acceptance of credits;

(2) Include a comprehensive statement of all transfer of credit criteria established by the institution, which must consider the comparability and applicability of coursework completed or credit earned at another institution accredited by an agency recognized by the Secretary;

(3) Do not deny the transfer of credit based on the institution at which the student completed the coursework or the agency that accredits that institution, so long as the agency is recognized by the Secretary;

(4) Award transfer credit for undergraduate programs for coursework that has been successfully completed at another institution that is accredited by an agency recognized by the Secretary and is comparable in content and learning outcomes to the institution's own course offerings, unless the institution provides a written basis for denial under 34 CFR 668.43(c)(4) in accordance with its academic standards or curricular requirements; and

(5) Provide the student an opportunity to appeal the decision within 15 calendar days of receipt of the institution's written notification if an institution declines to award transfer credit under paragraph (e)(4) of this section.

(f) *Agency designations.* In its accrediting practice, the agency must—

(1) Adopt and apply the definitions of "branch campus" and "additional location" in 34 CFR 600.2;

(2) On the Secretary's request, conform its designations of an institution's branch campuses and additional locations with the Secretary's if it learns its designations diverge; and

(3) Ensure that it does not accredit or preaccredit an institution comprising fewer than all of the programs, branch campuses, and locations of an institution as certified for title IV participation by the Secretary, except

with notice to and permission from the Secretary.

■ 20. Revise § 602.25 to read as follows:

§ 602.25 Due process.

The agency must demonstrate that the procedures it uses throughout the accrediting process satisfy due process. The agency meets this requirement if the agency does the following:

(a) Provides adequate written specification of its requirements, including clear standards, for an institution or program to be accredited or preaccredited.

(b) Uses procedures that afford an institution or program a reasonable period of time to comply with the agency's requests for information and documents.

(c) Provides written specification of any deficiencies identified at the institution or program examined.

(d) Provides sufficient opportunity for a written response by an institution or program regarding any deficiencies identified by the agency, to be considered by the agency within a timeframe determined by the agency, and before any adverse action is taken.

(e) Notifies the institution or program in writing of any adverse accrediting action or an action to place the institution or program on probation or show cause. The notice describes the basis for the action.

(f) Provides an opportunity, upon written request of an institution or program, for the institution or program to appeal any adverse action prior to the action becoming final.

(1) The appeal must take place at a hearing before an appeals panel that—

(i) May not include current members of the agency's decision-making body that took the initial adverse action; and

(ii) Is subject to a conflict of interest policy.

(2) The agency must recognize the right of the institution or program to employ counsel to represent the institution or program during its appeal, including to make any presentation that the agency permits the institution or program to make on its own during the appeal.

(g) The agency notifies the institution or program in writing of the result of its appeal and the basis for that result.

(h)(1) The agency must provide for a process, in accordance with written procedures, through which an institution or program may, before the agency reaches a final adverse action decision, seek review of new financial information if all of the following conditions are met:

(i) The financial information was unavailable to the institution or program

until after the decision subject to appeal was made.

(ii) The financial information is significant and bears materially on the financial deficiencies identified by the agency. The criteria of significance and materiality are determined by the agency.

(iii) The only remaining deficiency cited by the agency in support of a final adverse action decision is the institution's or program's failure to meet an agency standard pertaining to finances.

(2) An institution or program may seek the review of new financial information described in paragraph (h)(1) of this section only once and any determination by the agency made with respect to that review does not provide a basis for an appeal.

■ 21. Revise § 602.26 to read as follows:

§ 602.26 Notification of accrediting decisions.

The agency must demonstrate that it has established and follows written procedures requiring it to provide written notice of its accrediting decisions to the Secretary, the appropriate State licensing or authorizing agency, the appropriate accrediting agencies, and the public. The agency meets this requirement if the agency, following its written procedures—

(a) Provides to the Secretary written notice of the following types of decisions, the appropriate State licensing or authorizing agency, the appropriate accrediting agencies, and the public no later than 30 days after it makes the decision:

(1) A decision to award initial accreditation or preaccreditation to an institution or program.

(2) A decision to renew an institution's or program's accreditation or preaccreditation.

(b) Provides the decision letter or clear explanation in writing of the reasons for a final decision of a probation or equivalent status or an initiated adverse action to the Secretary, the appropriate State licensing or authorizing agency, and the appropriate accrediting agencies at the same time it notifies the institution or program of the decision and requires the institution or program to disclose such an action within seven business days of receipt to all current and prospective students.

(c) Provides the decision letter or clear explanation in writing of the following types of decisions to the Secretary, the appropriate State licensing or authorizing agency, and the appropriate accrediting agencies at the same time it notifies the institution or

program of the decision, but no later than 30 days after it reaches the decision:

(1) A final decision to deny, withdraw, suspend, revoke, or terminate the accreditation or preaccreditation of an institution or program.

(2) A final decision to take any other adverse action, as defined by the agency, not listed in paragraph (c)(1) of this section.

(d) For the decisions listed in paragraphs (b) and (c) of this section, the agency must update its website directory of accredited institutions or programs to note the decision within one business day of its notice to the institution or program.

(e) For any decision listed in paragraph (c) of this section, requires the institution or program to disclose the decision to current and prospective students within seven business days of receipt and makes available to the Secretary, the appropriate State licensing or authorizing agency, and the public, no later than 60 days after the decision, the agency's decision letter or clear explanation of the reasons for the agency's decision and the official comments that the affected institution or program may wish to make with regard to that decision, or evidence that the affected institution has been offered the opportunity to provide official comment.

(f) The agency must maintain on its website a clear record of all actions taken for each institution or program it accredits or preaccredits for a period of at least five years, including in the agency's decision letter required pursuant to paragraphs (b), (c), and (e) of this section.

(g) Notifies the Secretary, the appropriate State licensing or authorizing agency, the appropriate accrediting agencies, and, upon request, the public if an accredited or preaccredited institution or program—

(1) Decides to withdraw voluntarily from accreditation or preaccreditation, within 10 business days of receiving notification from the institution or program that it is withdrawing voluntarily from accreditation or preaccreditation; or

(2) Lets its accreditation or preaccreditation lapse, within 10 business days of the date on which accreditation or preaccreditation lapses.

(h) If the agency issues a final decision to withdraw, suspend, revoke, or terminate the accreditation or preaccreditation of the institution, and the institution challenges this final decision, the Department may continue to provide access to title IV, HEA programs to an institution until both

arbitration and judicial review (if applicable) has concluded or until relief is denied, whichever occurs first, if failure to do so would result in immediate, irreparable harm to the institution. This provision does not authorize the Department to nullify agency decisions that are made in a manner consistent with the agency's standards, even if the Department disagrees with said decision.

■ 22. Amend § 602.27 by revising paragraph (a)(1) to read as follows:

§ 602.27 Other information an agency must provide the Department.

(a) * * *

(1) Regular and timely updates, occurring throughout the year, of its accredited and preaccredited institutions and programs on the Department's website directory;

* * * * *

■ 23. Amend § 602.28 by:

■ a. Revising paragraph (d); and

■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

§ 602.28 Regard for decisions of States and other accrediting agencies.

* * * * *

(d) If the agency learns that an institution it accredits or preaccredits, an institution that offers a program it accredits or preaccredits, or a program it accredits or preaccredits, is the subject of an adverse action or has been placed on probation or an equivalent status by another recognized agency, or has been the subject of a similar action or status by a State agency or Federal agency, the agency must promptly review its accreditation or preaccreditation of the institution or program to determine if it should also take adverse action or place the institution or program on probation or an equivalent status.

* * * * *

§§ 602.31 and 602.32 [Redesignated as §§ 602.30 and 602.31]

■ 24. Redesignate §§ 602.31 and 602.32 as §§ 602.30 and 602.31.

■ 25. Revise newly redesignated §§ 602.30 and 602.31 to read as follows:

§ 602.30 Agency applications and reports to be submitted to the Department.

(a) *Applications for recognition or renewal of recognition.* An accrediting agency seeking initial or continued recognition must submit a written application to the Secretary. Each accrediting agency must submit an application for continued recognition at least once every five years, or within a

shorter time period specified in the final recognition decision. The application must consist of—

(1) A statement of the agency's requested scope of recognition;

(2) Documentation that the agency complies with the criteria for recognition listed in subpart B of this part, including a copy of its policies and procedures manual and its accreditation standards; and

(3) Documentation of how an agency that includes or seeks to include distance education, correspondence courses, or direct assessment education in its scope of recognition applies its standards in evaluating programs and institutions it accredits that offer distance education or correspondence courses.

(b) *Applications for expansions or contractions of scope.* An agency seeking an expansion or contraction of scope by application must submit a written application to the Secretary. The application must—

(1) Specify the scope requested;

(2) Provide copies of any relevant standards, policies, or procedures developed and applied by the agency for its use in accrediting activities conducted within an expansion of scope proposed and documentation of the application of these standards, policies, or procedures; and

(3) Provide the materials required by § 602.32(a).

(c) *Compliance or monitoring reports.* If an agency is required to submit a compliance or monitoring report, it must do so within 30 days following the end of the period for achieving compliance as specified in the decision of the senior Department official or Secretary, as applicable.

(d) *Review following an increase in headcount enrollment.* If an agency that has notified the Secretary in writing of its change in scope to include distance education or correspondence courses in accordance with § 602.27(a)(4) reports an increase in headcount enrollment in accordance with § 602.19(e) for an institution it accredits, or if the Department notifies the agency of such an increase at one of the agency's accredited institutions, the agency must, within 45 days of reporting the increase or receiving notice of the increase from the Department, as applicable, submit a report explaining—

(1) How the agency evaluates the capacity of the institutions or programs it accredits to accommodate significant growth in enrollment and to maintain education quality;

(2) The specific circumstances regarding the growth at the institution or program that triggered the review and

the results of any evaluation conducted by the agency; and

(3) Any other information that the agency deems appropriate to demonstrate the effective application of the criteria for recognition or that the Department may require.

(e) *Consent to sharing of information.* By submitting an application for recognition, the agency authorizes Department staff throughout the application process and during any period of recognition—

(1) To observe its site visits to one or more of the institutions or programs it accredits or preaccredits, on an announced or unannounced basis;

(2) To visit locations where agency activities such as training, review and evaluation panel meetings, and decision meetings take place, on an announced or unannounced basis;

(3) To obtain copies of all documents the staff deems necessary to complete its review of the agency; and

(4) To gain access to agency records, personnel, and facilities.

(f) *Public availability of agency records obtained by the Department.* (1) The Secretary's processing and decision-making on requests for public disclosure of agency materials reviewed under this part are governed by the Freedom of Information Act, 5 U.S.C. 552; the Trade Secrets Act, 18 U.S.C. 1905; the Privacy Act of 1974, as amended, 5 U.S.C. 552a; 5 U.S.C. chapter 10 (Federal Advisory Committees); and all other applicable laws. In recognition proceedings, agencies must, before submission to the Department—

(i) Redact the names and any other personally identifiable information about individual students and any other individuals who are not agents of the agency or of an institution or program the agency is reviewing;

(ii) Redact the personal addresses, personal telephone numbers, personal email addresses, Social Security numbers, and any other personally identifiable information regarding individuals who are acting as agents of the agency or of an institution or program under review;

(iii) Designate, but not redact, all business information within agency submissions that the agency believes would be exempt from disclosure under exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. 552(b)(4). A blanket designation of all information contained within a submission, or of a category of documents, as meeting this exemption will not be considered a good faith effort and will be disregarded; and

(iv) Ensure documents submitted are only those required for Department review or as requested by Department officials.

(2) The agency may identify any other material the agency believes would be exempt from public disclosure under FOIA, the factual basis for the request, and any legal basis the agency has identified for withholding the document from public disclosure.

(3) The Secretary processes FOIA requests in accordance with 34 CFR part 5 and makes all documents provided to the Advisory Committee available to the public.

(4) Upon request by Department staff, the agency must disclose to Department staff any specific material the agency has redacted that Department staff believes is needed to conduct the staff review. Department staff will make any arrangements needed to ensure that the materials are not made public if prohibited by law.

(g) *Length of submissions.* The Secretary may publish reasonable, uniform limits on the length of submissions described in this section.

§ 602.31 Procedures for submitting applications for recognition and renewal of recognition.

(a) An agency must submit an application for initial or renewal of recognition and meet the submission deadline set by the Department. The type of application that must be submitted and the scope and priority of the Department's review are determined by the Department as follows:

(1) If the total title IV, HEA program funds received by the institutions accredited by an accrediting agency constitute a substantial portion, as determined by the Secretary, of the total funds awarded for the title IV, HEA programs, the agency must submit a comprehensive application that addresses the agency's compliance with all criteria in subpart B of this part.

(2) If an institutional accrediting agency is not identified for review under paragraph (a)(1) of this section, the agency must submit an application that addresses the agency's compliance with §§ 602.15, 602.16, 602.17, 602.19, and 602.20 and any other criteria as directed by Department staff. The agency must also attest that since its last comprehensive review the agency's policies and practices have remained in compliance with all criteria in subpart B of this part not addressed in its application.

(3) If the Secretary determines that an agency or its officers or directors have been the subject of legal actions, complaints, or other compliance issues

that individually or in the aggregate raise substantial concerns regarding the agency's compliance with this part, the agency must submit a comprehensive application that addresses the agency's compliance with all criteria in subpart B of this part.

(4) If an agency is exclusively a programmatic accrediting agency and is not identified for review under paragraph (a)(3) of this section, the agency must submit an application that addresses the agency's compliance with the criteria in §§ 602.10, 602.16, 602.17, 602.19, and 602.20 and any other criteria as directed by Department staff. The agency must also attest that since its last comprehensive review the agency's policies and practices have remained in compliance with all criteria in subpart B of this part not addressed in its application.

(5) An agency described in paragraph (a)(2) or (4) of this section must submit a comprehensive application that addresses the agency's compliance with all criteria in subpart B of this part at least once every third cycle of review.

(6) The Department may also consider factors that include but are not limited to—

(i) Whether any of its accredited institutions closed without an approved teach-out agreement in place when such an agreement was required in accordance with § 602.24(c);

(ii) Whether the Department has received serious or a high proportion of complaints about the institutions or programs the agency accredits;

(iii) Whether the agency has significantly increased the number of institutions or programs it accredits; and

(iv) The number and severity of noncompliant findings identified in the senior Department official's or Secretary's decision letter for the agency's application for renewal of recognition.

(7) An agency submitting an application for initial recognition must submit a comprehensive application that addresses the agency's compliance with all criteria in subpart B of this part.

(b)(1) After receipt of an agency's application for initial or renewal of recognition, Department staff publishes a notice in the **Federal Register** stating that the agency submitted an application and inviting the public to provide information concerning the performance of the agency to assist the Department in determining whether the agency meets the criteria for recognition and establishing a deadline for receipt of information from the public.

(2) Within 10 business days after publication of the notice described in paragraph (b)(1) of this section, the

agency must publish the request for information on the agency's website to include instructions on how the public can submit information in response to the request.

(c) The Department staff analyzes the agency's application for initial or renewal of recognition, to determine whether the agency satisfies the criteria for recognition, taking into account all available relevant information concerning the compliance of the agency with those criteria and the agency's consistency in applying the criteria. The analysis of an application will include—

(1) A site visit, which may be conducted as an in-person visit at the agency, including an on-site file review of agency documents, or through a virtual file review of agency documents. The site visit may also include, as appropriate, an in-person visit to the agency's member institutions or programs, an on-site or virtual observation of a meeting of the agency's decision-making body, or an on-site or virtual observation of other agency activity. During the site visit, Department staff may retain copies of documents needed for inclusion in the administrative record;

(2) Review of the public information Department staff receives by the established deadline, the agency's responses to the third-party information, as appropriate, and any other information Department staff obtains for purposes of evaluating the agency under this part; and

(3) Review of complaints or legal actions involving the agency; and

(4) Review of complaints or legal actions against an institution or program accredited or preaccredited by the agency, which may be considered but are not necessarily determinative of compliance.

(d) The Department may view as a negative factor when considering an application for initial recognition as proposed by an agency anticompetitive conduct that is violative of the antitrust laws, such as collusion between accrediting agencies and any related, associated, or affiliated trade association, professional organization, standard setting organization, State certification organization, or membership organization to unnecessarily inflate the qualifications necessary for a student to sit for a licensure or certification examination or otherwise be eligible for entry into a profession, occupation, or vocation due to an increase in related education or training requirements.

(e) Department staff's evaluation of an agency may also include a review of

information directly related to institutions or programs accredited or preaccredited by the agency relative to their compliance with the agency's standards, the effectiveness of the standards, and the agency's application of those standards, but must make all materials relied upon in the evaluation available to the agency for review and comment.

(f) If, at any point in its evaluation of an agency seeking initial recognition, Department staff determines that the agency fails to demonstrate compliance with the basic eligibility requirements in §§ 602.10 through 602.15, the staff—

(1) Returns the agency's application and provides the agency with an explanation of the deficiencies that caused staff to take that action; and

(2) Requires that the agency withdraw its application and instructs the agency that it may reapply when the agency is able to demonstrate compliance.

(g) Except with respect to an application that has been returned and is withdrawn under paragraph (f) of this section, when Department staff completes its evaluation of the agency, the staff will—

(1) Within 120 days of the submission deadline set by the Department, prepare a written draft analysis of the agency's application;

(2) Send to the agency the draft analysis including any identified areas of potential noncompliance and all third-party information and complaints, if applicable, and any other materials the Department received by the established deadline or is including in its review;

(3) Invite the agency to provide a written response to the draft analysis and third-party comments or other material included in the review, specifying a deadline that provides at least 90 days for the agency's response;

(4) Review the response to the draft analysis the agency submits, if any, and prepares the written final analysis—

(i) Indicating that the agency is in full compliance, substantial compliance, or noncompliance with each of the criteria for recognition; and

(ii) Recommending that the senior Department official approve, continue recognition with a compliance report-to be submitted to the Department within 12 months, continue recognition with a compliance report to be submitted to the Department with a deadline in excess of 12 months based on a finding of good cause and extraordinary circumstances, approve with monitoring or other reporting requirements, or deny, limit, suspend, or terminate recognition; and

(5) Provide to the agency, no later than 30 days before the Advisory

Committee meeting, the final staff analysis and any other available information provided to the Advisory Committee under § 602.34(c).

(h) The agency may request that the Advisory Committee defer acting on an application at that Advisory Committee meeting if Department staff fails to provide the agency with the materials described, and within the timeframes provided, in paragraphs (g)(3) and (5) of this section. If the Department staff's failure to send the materials in accordance with the timeframe described in paragraph (g)(3) or (5) of this section is due to the agency's failure to timely submit reports or other information requested by the Secretary, submit its response to the draft analysis, or to comply with the requirements of § 602.30(e), the Department will not grant the agency any requests to defer consideration of its application.

(i) If Department staff does not conclude its review of the application for recognition before the expiration of an agency's recognition period, the recognition period automatically extends for a period of time that expires when a recognition decision is made and Department staff will limit the length of the recognition recommendation to not exceed five years from the expiration.

■ 26. Add a new § 602.32 to read as follows:

§ 602.32 Procedures for review of an expansion of scope, a contraction of scope, compliance reports, or increase in headcount enrollment.

(a) For an expansion or contraction of scope—

(1) The Department will only accept such applications in conjunction with an application for recognition, except as provided in paragraph (a)(2) of this section; and

(2) At the discretion of Department staff and on a case-by-case basis, Department staff may review an application for an expansion or contraction of scope independent of a renewal application.

(3) The Department may view as a negative factor, when considering an expansion or contraction of scope as proposed by an agency, anticompetitive conduct that is violative of the antitrust laws, such as collusion between accrediting agencies and any related, associated, or affiliated trade association, professional organization, standard setting organization, State certification organization, or membership organization to unnecessarily inflate the qualifications necessary for a student to sit for a licensure or certification examination or

otherwise be eligible for entry into a profession, occupation, or vocation due to an increase in related education or training requirements.

(b) For the review of a compliance report, Department staff—

(1) Completes its evaluation of the agency's compliance report;

(2) Within 90 days of the submission deadline set by the SDO or Secretary decision letter for the compliance report, prepares a written draft analysis of the agency's compliance report;

(3) Sends to the agency the draft analysis, including any identified areas of potential noncompliance and any other materials the Department received by the established deadline or that is included in its review;

(4) Invites the agency to provide a written response to the draft analysis and other material included in the review, specifying a deadline that provides at least 45 days for the agency's response;

(5) Reviews any response to the draft analysis the agency submits and prepares the written final analysis—

(i) Indicating that the agency is in full compliance, substantial compliance, or noncompliance with each of the criteria for recognition under review; and

(ii) Including a recognition recommendation to the senior Department official, including, but not limited to, a recommendation that the senior Department official approve, continue recognition with compliance reporting requirements based on a finding of good cause and extraordinary circumstances, approve with monitoring or other reporting requirements, or deny, limit, suspend, or terminate recognition; and

(6) Provides to the agency, no later than 30 days before the Advisory Committee meeting, the final staff analysis and any other available information provided to the Advisory Committee under § 602.34(c).

(c) For the review of a report related to an increase in headcount enrollment, the agency will provide the report required by § 602.30(d); and the Department will process the report in accordance with the procedures described in paragraph (b) of this section for a compliance report.

■ 27. Revise § 602.33 to read as follows:

§ 602.33 Procedures for review of agencies during the period of recognition, including the review of monitoring reports.

(a) Department staff may review the compliance of a recognized agency with the criteria for recognition at any time—

(1) Based on the submission of a monitoring report as directed by a decision by the senior Department official or Secretary; or

(2) Based on any information that, as determined by Department staff, appears credible and raises concerns relevant to the criteria for recognition.

(b) The review may include, but need not be limited to, any of the activities described in § 602.31(c) and (e).

(c) If the inquiry was initiated under paragraph (a)(2) of this section, Department staff will provide the agency with documentation concerning the inquiry and an opportunity to respond within a reasonable time.

(d) If, in the course of the review, Department staff determines that the agency is in compliance with the criteria for recognition, the Department will conclude the review and notify the agency.

(e) If, in the course of the review, Department staff notes that one or more deficiencies may exist in the agency's compliance with the criteria for recognition or in the agency's effective application of those criteria, Department staff—

(1) Prepares a written draft analysis of the agency's compliance with the criteria of concern;

(2) Sends to the agency the draft analysis including any identified areas of noncompliance and all supporting documentation not previously provided;

(3) Invites the agency to provide a written response to the draft analysis within 45 days; and

(4) Reviews any response provided by the agency, and either—

(i) Determines the agency is in compliance with the criteria and concludes the review;

(ii) Continues monitoring of the agency's areas of deficiencies; or

(iii)(A) Notifies the agency, in the event that the agency's response or monitoring report does not satisfy the staff, that the draft analysis will be finalized for presentation to the Advisory Committee;

(B) Finalizes the staff analysis as necessary to reflect its review of any agency response and any public comment received;

(C) Provides to the agency, no later than 30 days before the Advisory Committee meeting, the final staff analysis and a recognition recommendation and any other information provided to the Advisory Committee under § 602.34(c); and

(D) Submits the matter for review by the Advisory Committee in accordance with § 602.34.

■ 28. Revise § 602.34 to read as follows:

§ 602.34 Advisory Committee meetings.

(a) Department staff submits a proposed schedule to the Chairperson of the Advisory Committee based on anticipated completion of staff analyses.

(b) The Chairperson of the Advisory Committee establishes an agenda for the next meeting and, in accordance with the Federal Advisory Committee Act, presents it to the Designated Federal Official for approval.

(c) Before the Advisory Committee meeting, Department staff provides the Advisory Committee with—

(1) As applicable, the agency's application for recognition, renewal of recognition, or the agency's application for expansion or contraction of scope when Advisory Committee review is required, or the agency's compliance report, and supporting documentation submitted by the agency;

(2) The final Department staff analysis of the agency developed in accordance with § 602.31, § 602.32, or § 602.33, and any supporting documentation;

(3) The agency's response to the draft analysis;

(4) Any written third-party information the Department received about the agency on or before the established deadline;

(5) Any agency response to third-party information; and

(6) Any other information Department staff relied upon in developing its analysis.

(d)(1) At least 30 days before the Advisory Committee meeting, the Department publishes a notice of the meeting in the **Federal Register** inviting interested parties to make oral presentations before the Advisory Committee.

(2) Within 10 business days after publication of the notice described in paragraph (d)(1) of this section, the agency must publish the meeting notice on the agency's website to include instructions on how the public can participate.

(e) The Advisory Committee considers the materials provided under paragraph (c) of this section in a public meeting and invites Department staff, the agency, and other interested parties to make oral presentations during the meeting. A transcript is made of all Advisory Committee meetings.

(f) The written motion adopted by the Advisory Committee regarding each agency's recognition will be made available during the Advisory Committee meeting. The Department will provide each agency, upon request, with a copy of the motion on recognition at the meeting. Each agency that was reviewed will be sent an electronic copy of the motion relative to that agency as soon as practicable after the meeting.

(g) After each meeting of the Advisory Committee, the Advisory Committee forwards to the senior Department

official its recommendation with respect to each agency, which may include, but is not limited to—

(1)(i) For an agency that is fully compliant, approve initial or renewed recognition; or

(ii) In the case of non-compliance—

(A) Continue recognition with a required compliance report to be submitted to the Department within 12 months from the decision of the senior Department official;

(B) In conjunction with a finding of exceptional circumstances and good cause, continue recognition for a specified period in excess of 12 months pending submission of a compliance report; or

(C) Deny, limit, suspend, or terminate recognition.

(iii) In the case of substantial compliance, grant initial recognition or renewed recognition and recommend a monitoring report with a set deadline to be reviewed by Department staff to ensure that corrective action is taken, and full compliance is achieved or maintained (or recommend for action by staff under § 602.33 if it is not); or

(iv) Grant or deny a request for expansion or contraction of scope; or

(v) Revise or affirm the scope of the agency.

(2) [Reserved]

■ 29. Amend § 602.35 by:

■ a. Revising paragraphs (a) and (c)(2); and

■ b. Removing the parenthetical authority citation at the end of the section.

The revisions read as follows:

§ 602.35 Responding to the Advisory Committee's recommendation.

(a) Within 10 business days following the publication of transcripts of the Advisory Committee meeting, the agency and Department staff may submit written comments to the senior Department official on the Advisory Committee's recommendation. The agency must simultaneously submit a copy of its written comments, if any, to Department staff. Department staff must simultaneously submit a copy of its written comments, if any, to the agency.

* * * * *

(c) * * *

(2) Within 10 business days of receipt by the Department staff of an agency's comments or new evidence, if applicable, or of receipt by the agency of the Department staff's comments, Department staff, the agency, or both, as applicable, may submit a response to the senior Department official. Simultaneously with submission, the agency must provide a copy of any response to the Department staff.

Simultaneously with submission, Department staff must provide a copy of any response to the agency. No additional comments or new documentation may be submitted after the responses described in this paragraph (c)(2) are submitted.

■ 30. Amend § 602.36 by:

■ a. Revising paragraphs (a), (b), (d), (e), (h), and (i); and

■ b. Removing the parenthetical authority citation at the end of the section.

The revisions read as follows:

§ 602.36 Senior Department official's decision.

(a) The senior Department official makes a decision regarding recognition of an agency based on the record compiled under §§ 602.31, 602.32, 602.33, 602.34, and 602.35 including, as applicable, the following:

(1) The materials provided to the Advisory Committee under § 602.34(c).

(2) The transcript of the Advisory Committee meeting.

(3) The recommendation of the Advisory Committee.

(4) Written comments and responses submitted under § 602.35.

(5) New documentation submitted in accordance with § 602.35(c)(1).

(6) A communication from the Secretary referring an issue to the senior Department official's consideration under § 602.37(e).

(b) In the event that statutory authority or appropriations for the Advisory Committee ends, or there are fewer duly appointed Advisory Committee members than needed to constitute a quorum, and under extraordinary circumstances when there are serious concerns about an agency's compliance with subpart B of this part that require prompt attention, the senior Department official may make a decision on an application for renewal of recognition or compliance report on the record compiled under § 602.31 or § 602.32 after providing the agency with an opportunity to respond to the final staff analysis. Any decision made by the senior Department official under this paragraph (b) from the Advisory Committee may be appealed to the Secretary as provided in § 602.37.

(d) Except with respect to decisions made under paragraph (f) or (g) of this section and matters referred to the senior Department official under § 602.37(e) or (f), the senior Department official notifies the agency in writing of the senior Department official's decision regarding the agency's recognition within 90 days following the publication of transcripts of the

Advisory Committee meeting or conclusion of the review under paragraph (b) of this section.

(e) The senior Department official's decision may include, but is not limited to, approving for recognition; approving with a monitoring report; denying, limiting, suspending, or terminating recognition following the procedures in paragraph (g) of this section; granting or denying an application for an expansion of scope; granting or denying an application for a contraction of scope; revising or affirming the scope of the agency; or continuing recognition pending submission and review of a compliance report under §§ 602.32 and 602.34 and review of the report by the senior Department official under this section.

(1)(i) The senior Department official approves recognition if the agency has demonstrated compliance or substantial compliance with the criteria for recognition listed in subpart B of this part. The senior Department official may determine that the agency has demonstrated compliance or substantial compliance with the criteria for recognition if the agency has a compliant policy or procedure in place but has not had the opportunity to apply such policy or procedure.

(ii) If the senior Department official approves recognition, the recognition decision defines the scope of recognition and the recognition period. The recognition period does not exceed five years, including any time during which recognition was continued to permit submission and review of a compliance report.

(iii) If the scope of recognition is less than that requested by the agency, the senior Department official explains the reasons for continuing or approving a lesser scope.

(2)(i) Except as provided in paragraph (e)(3) of this section, if the agency fails to comply with the criteria for recognition listed in subpart B of this part, the senior Department official denies, limits, suspends, or terminates recognition.

(ii) If the senior Department official denies, limits, suspends, or terminates recognition, the senior Department official specifies the reasons for this decision, including all criteria the agency fails to meet and all criteria the agency has failed to apply effectively.

(3)(i) If the senior Department official concludes an agency is noncompliant, the senior Department official may continue the agency's recognition, pending submission of a compliance report that will be subject to review in the recognition process, provided that—

(A) The senior Department official concludes that the agency will demonstrate compliance with, and effective application of, the criteria for recognition within 12 months from the date of the senior Department official's decision; or

(B) The senior Department official identifies a deadline more than 12 months from the date of the decision by which the senior Department official concludes the agency will demonstrate full compliance with, and effective application of, the criteria for recognition, and also identifies exceptional circumstances and good cause for allowing the agency more than 12 months to achieve compliance and effective application.

(ii) In the case of a compliance report ordered under paragraph (e)(3)(i) of this section, the senior Department official specifies the criteria the compliance report must address, and the time period for achieving compliance and effective application of the criteria. The compliance report documenting compliance and effective application of criteria is due not later than 30 days after the end of the period specified in the senior Department official's decision.

(iii) If the record includes a compliance report required under paragraph (e)(3)(i) of this section, and the senior Department official determines that an agency has not complied with the criteria for recognition, or has not effectively applied those criteria, during the time period specified by the senior Department official in accordance with paragraph (e)(3)(i) of this section, the senior Department official denies, limits, suspends, or terminates recognition, except, in extraordinary circumstances, upon a showing of good cause for an extension of time as determined by the senior Department official and detailed in the senior Department official's decision. If the senior Department official determines good cause for an extension has been shown, the senior Department official specifies the length of the extension and what the agency must do during it to merit a renewal of recognition.

(h) If relevant and material information pertaining to an agency's compliance with recognition criteria, but not contained in the record, comes to the senior Department official's attention while a decision regarding the agency's recognition is pending before the senior Department official, and if the senior Department official concludes the recognition decision should not be

made without consideration of the information, the senior Department official either—

(1)(i) Does not make a decision regarding recognition of the agency; and

(ii) Refers the matter to Department staff for review and analysis under § 602.31, § 602.32, or § 602.33, as appropriate, and consideration by the Advisory Committee under § 602.34; or

(2)(i) Provides the information to the agency and Department staff;

(ii) Permits the agency to respond to the senior Department official and the Department staff in writing, and to include additional documentation relevant to the issue, and specifies a deadline;

(iii) Provides Department staff with an opportunity to respond in writing to the agency's submission under paragraph (h)(2)(ii) of this section, specifying a deadline; and

(iv) Issues a recognition decision based on the record described in paragraph (a) of this section, as supplemented by the information provided under this paragraph (h).

(i) No agency may submit information to the senior Department official, or ask others to submit information on its behalf, for purposes of invoking paragraph (h) of this section. Before invoking paragraph (h) of this section, the senior Department official will take into account whether the information, if submitted by a third party, could have been submitted in accordance with § 602.31, § 602.32, or § 602.33.

* * * * *

■ 31. Amend § 602.37 by:

■ a. Revising paragraphs (g) and (h); and

■ b. Removing the parenthetical authority citation at the end of the section.

The revisions read as follows:

§ 602.37 Appealing the senior Department official's decision to the Secretary.

* * * * *

(g) If relevant and material information pertaining to an agency's compliance with recognition criteria, but not contained in the record, comes to the Secretary's attention while a decision regarding the agency's recognition is pending before the Secretary, and if the Secretary concludes the recognition decision should not be made without consideration of the information, the Secretary either—

(1)(i) Does not make a decision regarding recognition of the agency; and

(ii) Refers the matter to Department staff for review and analysis under § 602.31, § 602.32, or § 602.33, as appropriate; review by the Advisory Committee under § 602.34; and

consideration by the senior Department official under § 602.36; or

(2)(i) Provides the information to the agency and the senior Department official;

(ii) Permits the agency to respond to the Secretary and the senior Department official in writing, and to include additional documentation relevant to the issue, and specifies a deadline;

(iii) Provides the senior Department official with an opportunity to respond in writing to the agency's submission under paragraph (g)(2)(ii) of this section, specifying a deadline; and

(iv) Issues a recognition decision based on all the materials described in paragraphs (e) and (g) of this section.

(h) No agency may submit information to the Secretary, or ask others to submit information on its behalf, for purposes of invoking paragraph (g) of this section. Before invoking paragraph (g) of this section, the Secretary will take into account whether the information, if submitted by a third party, could have been submitted in accordance with § 602.31, § 602.32, or § 602.33.

* * * * *

PART 668—STUDENT ASSISTANCE GENERAL PROVISIONS

■ 32. The general authority citation for part 668 continues to read as follows:

Authority: 20 U.S.C. 1001–1003, 1070g, 1085, 1088, 1091, 1092, 1094, 1099c, 1099c–1, 1221e–3, and 1231a, unless otherwise noted.

* * * * *

■ 33. Amend § 668.43 by revising paragraph (a)(11), (c), and (d)(3) to read as follows:

§ 668.43 Institutional and programmatic information.

(a) * * *

(11) A description of the transfer of credit policies established by the institution, which must include a statement of the institution's current transfer of credit policies that includes, at a minimum—

(i) The timeline by which a transcript must be submitted for timely review so that a prospective student can make an informed decision prior to making a nonrefundable financial commitment, enrollment, or registration;

(ii) Any established criteria the institution uses regarding the transfer of credit earned at another institution and any types of institutions or sources from which the institution will not accept credits;

(iii) A list of institutions with which the institution has established an articulation agreement; and

(iv) Written criteria used to evaluate and award credit for prior learning experience including, but not limited to, service in the armed forces, paid or unpaid employment, or other demonstrated competency or learning; and

(v) A statement regarding whether the institution considers credit earned in a non-degree program, or hours completed in a non-credit program, for transfer or articulation to a degree program;

* * * * *

(c)(1) If the institution has made a determination under paragraph (a)(5)(v) of this section that the program's curriculum does not meet the State educational requirements for licensure or certification in the State in which a prospective student is located, or if the institution has not made a determination regarding whether the program's curriculum meets the State educational requirements for licensure or certification, the institution must provide notice to that effect to the student prior to the student's enrollment in the institution in accordance with § 668.14(b)(32).

(2) If the institution makes a determination under paragraph (a)(5)(v) of this section that a program's curriculum does not meet the State educational requirements for licensure or certification in a State in which a student who is currently enrolled in such program is located, the institution must provide notice to that effect to the student within 14 calendar days of making such determination.

(3) If a student timely provides a transcript to an institution during the period described in paragraph (a)(11)(i) of this section, the institution must—

(i) Inform the student of the credit that will be awarded for courses on that transcript;

(ii) Inform the student of the credit that the institution declines to award for courses on that transcript; and

(iii) Disclose the estimated time and, when applicable, courses that would be needed to replace the courses for which the institution declined to award credit under paragraph (c)(3)(ii) of this section.

(4) If the institution declines to award credit to a student pursuant to its transfer of credit policy under 34 CFR 602.24(e)(4), the institution must provide to the student a written rationale specific to each course that does not result in transfer credit.

(5)(i) Disclosures under paragraphs (c)(1) through (4) of this section must be made directly to the student in writing, which may include through email or other electronic communication.

(ii) Disclosures under paragraph (c)(3) of this section must be provided to the student by the earlier of the date that the student—

- (A) Signs an enrollment agreement;
- (B) Completes registration; or
- (C) Makes a nonrefundable financial commitment to the institution.

(iii)(A) For purposes of paragraphs (c)(1) and (2) of this section, an institution must make a determination regarding the State in which a student is located in accordance with the institution’s policies or procedures, which must be applied consistently to all students.

(B) The institution must, upon request, provide the Secretary with

written documentation of its determination of a student’s location under paragraph (c)(5)(iii)(A) of this section, including the basis for such determination.

(C) An institution must make a determination regarding the State in which a student is located at the time of the student’s initial enrollment in an educational program and, if applicable, upon formal receipt of information from the student, in accordance with the institution’s procedures under paragraph (c)(5)(iii)(A) of this section, that the student’s location has changed to another State.

* * * * *

(d) * * *

(3) *Distribution to prospective students.* The institution must provide the relevant information to access the website maintained by the Secretary to any prospective student, or a third party acting on behalf of the prospective student, before the prospective student signs an enrollment agreement, completes registration, or makes a nonrefundable financial commitment to the institution.

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 413

Medicare Program; CY 2027 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Acute Kidney Injury (AKI) Dialysis Payment, and ESRD Quality Incentive Program

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS–1846–F]

RIN 0938–AV81

Medicare Program; CY 2027 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Acute Kidney Injury (AKI) Dialysis Payment, and ESRD Quality Incentive Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule updates and revises the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2027. This rule also includes updates to the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, this rule updates the requirements for the ESRD Quality Incentive Program.

DATES: These regulations are effective on January 1, 2027.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov or Abigail Ryan at (410) 786–4343, for issues related to the ESRD Prospective Payment System (PPS) and coverage and payment for renal dialysis services furnished to individuals with acute kidney injury (AKI).

ESRDApplications@cms.hhs.gov, for issues related to applications for the Transitional Drug Add-on Payment Adjustment (TDAPA) or Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

QNETSUPPORT-ESRD@cms.hhs.gov, for issues related to the ESRD Quality Incentive Program (QIP).

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose

This rule finalizes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), and the ESRD Quality Incentive Program (QIP).

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted,

bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule updates the ESRD PPS for CY 2027, including a routine rebasing and revising of the ESRD Bundled (ESRDB) market basket. This rule also modifies the ESRD PPS base rate to reflect the incorporation of phosphate binders¹ into the ESRD PPS base rate, makes budget neutral changes to certain ESRD PPS payment adjustments, and makes modifications to the transitional drug add-on payment adjustment (TDAPA) and post-TDAPA add-on payment adjustment. The payment adjustments changed budget neutrally include the low-volume payment adjustment (LVPA), the case mix adjusters for pediatric ESRD patients, and the home and self-dialysis add-on payment adjustment.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid

¹ We note that all currently available phosphate binders are oral. Throughout this rule, we use the term “oral phosphate binders” when specifically discussing these drugs in certain contexts, such as the TDAPA or historical payment policies. The CY 2027 ESRD PPS base rate increase will encompass all current and future phosphate binders, including a hypothetical future injectable phosphate binder or other form of administration.

under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This rule updates the AKI dialysis payment rate for CY 2027. The AKI dialysis payment rate update will be indirectly affected by the rebasing and revising of the ESRDB market basket under the ESRD PPS because the AKI dialysis payment rate is the ESRD PPS base rate, which is annually updated by the ESRDB market basket percentage increase factor minus a productivity adjustment, adjusted by the wage index. The change to the ESRD PPS case mix adjusters for pediatric ESRD patients, the expansion of the LVPA, and the technical changes to the TDAPA and post-TDAPA add-on payment adjustment that we are finalizing in this rule will not directly affect the CY 2027 AKI dialysis payment rate update.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The ESRD QIP is authorized by section 1881(h) of the Act. The Program establishes incentives for facilities to achieve high quality performance on measures with the goal of improving outcomes for ESRD beneficiaries. This final rule includes the following changes to the ESRD QIP measure set beginning with PY 2029: replace the Hypercalcemia reporting measure with the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients (Hyperphosphatemia) clinical measure, update the National Healthcare Safety Network Bloodstream Infection (NHSN BSI) clinical measure, remove the Medication Reconciliation (MedRec) reporting measure, and remove the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) reporting measure. Finally, this final rule discusses feedback received on the inclusion of the Dialysis Facility Discussion of Patient Life Goals (D-PaLS) Patient-Reported Outcome Performance Measure (PRO–PM) in the ESRD QIP.

B. Summary of the Major Provisions

1. ESRD PPS

- *Rebasing and revising of the End-Stage Renal Disease Bundled (ESRDB) market basket for CY 2027:* We are rebasing and revising the ESRDB market basket to a 2024 base year, reflecting the most recent and complete set of Medicare cost report data as well as other publicly available data. In addition, we are updating the labor-related share of the ESRD PPS base rate to reflect the 2024 base year labor-related cost share weights designated in the ESRDB market basket.

• *Update to the ESRD PPS base rate for CY 2027:* The CY 2027 ESRD PPS base rate is \$297.52, an increase from the CY 2026 ESRD PPS base rate of \$281.71. This amount reflects the application of the wage index budget neutrality adjustment factor (1.00260), the addition to the base rate of \$12.85 to include phosphate binders, the budget neutrality factor for the budget neutral changes to several payment adjustments² (0.98864), and an ESRDB market basket update of 1.9 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $\$297.52 (((\$281.71 + \$12.85) \times 1.00260 \times 0.98864) \times 1.019 = \$297.52)$.

• *Annual update to the wage index:* We adjust the ESRD PPS wage index on an annual basis using the most current mean hourly wage data for occupations related to the furnishing of renal dialysis services from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) program and occupational mix data from the most recent full CY of freestanding ESRD facility Medicare cost reports. This wage index uses the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. This final rule updates the wage index based on this methodology and the latest available data.

• *Annual update to the outlier policy:* We are updating the outlier policy based on the most current data and established methodology. Accordingly, we are updating the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2027 using the latest available CY 2025 claims data. We are updating the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2025 claims data and updating the FDL amount for adult patients using the latest available claims data from CY 2023, CY 2024, and CY 2025. For pediatric beneficiaries, the FDL amount will increase from \$162.43 to \$229.49, and the MAP amount will increase from \$50.19 to \$63.27, as compared to CY 2026 values. For adult beneficiaries, the FDL amount will increase from \$14.80 to \$90.60, and the MAP amount will increase from \$23.68 to \$41.83, as compared to CY 2026 values. The 1.0 percent target for outlier payments was not achieved in CY 2025, as outlier payments represented approximately 0.9 percent of total

Medicare payments. Our current estimates indicate outlier payments will be above the 1.0 percent target for CY 2026, which also reflects the underlying utilization and cost trends that are contributing to increases in the MAP and FDL amounts.

• *Update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2027:* The CY 2027 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is \$10.63. This offset amount reflects the application of the final ESRDB market basket update of 1.9 percent ($\$10.43 \times 1.019 = \10.63). There are no capital-related assets set to receive the TPNIES in CY 2027 for which this offset will apply.

• *Update to the post-TDAPA add-on payment adjustment amounts:* We calculated the post-TDAPA add-on payment adjustment in accordance with 42 CFR 413.234(g). The final first quarter (Q1) post-TDAPA add-on payment adjustment amount for Korsuva® is \$0.0793 per treatment, which will be included in the calculation of the total post-TDAPA add-on payment adjustment for only the first quarter of CY 2027. The final Q1 post-TDAPA add-on payment adjustment amount for DefenCath® is \$8.3220 per treatment. The post-TDAPA add-on payment adjustment amount for DefenCath® will be included in the calculation for each quarter of CY 2027. The final Q1 post-TDAPA add-on payment adjustment amount for Vafseo® is \$0.9970 per treatment. The post-TDAPA add-on payment adjustment amount for Vafseo® will be included in the calculation for each quarter of CY 2027. We are finalizing the proposal to update the post-TDAPA add-on payment adjustment amounts quarterly. As such, we are only finalizing the post-TDAPA add-on payment adjustment amount for the first quarter of CY 2027 in this final rule and will publish the amounts for the other quarters in CRs published after this final rule, conditional on the continued receipt of Average Sales Price (ASP) data. The final post-TDAPA add-on payment adjustment amount for a given quarter will be added to ESRD PPS payments for all renal dialysis treatments furnished during that quarter and will be adjusted by applicable patient level adjustment factors.

• *Incorporation of phosphate binders into the base rate:* We are incorporating phosphate binders into the ESRD PPS base rate at the end of the TDAPA period for the drugs, for CY 2027 and beyond. The final increase to the ESRD

PPS base rate for phosphate binders is \$12.85. This final amount includes an increase to account for operational costs, as outlined in section II.B.7. of this final rule.

• *Expansion of the LVPA:* We are expanding the LVPA to ESRD facilities which furnish up to 8,000 treatments per year. We are finalizing our proposal to make payments based on 6 tiers of volume. This change will be budget neutral with a budget neutrality factor of 0.98901.

• *Modifications to certain adjustments for pediatric ESRD patients:* We are modifying the case mix adjusters for pediatric ESRD patients. Additionally, we are allowing ESRD facilities to receive the LVPA for pediatric ESRD patients. These changes coincide with the end of the Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA) as of December 31, 2026. We are finalizing these permanent policies to address payment for pediatric ESRD patients after the temporary increase through TPEAPA is no longer available.

• *Modifications to the home and self-dialysis training add-on:* We are increasing the home and self-dialysis training add-on payment adjustment to \$138.00 from the current amount of \$95.60. We also will allow training sessions during the onset period (the first 120 days of ESRD dialysis). To reduce the potential for duplicative payments during the onset period, we are reducing the onset adjustment factor from 1.327 to 1.311. For the reasons discussed in section II.B.10. of this final rule this change is budget neutral with a budget neutrality factor of 0.99964.

• *Modifications to the TDAPA and post-TDAPA add-on payment adjustment:* We are finalizing that, when ASP data is not usable because ASP is zero or negative, we will use the most recent usable quarter of ASP data, if available, as the basis for the TDAPA and the post-TDAPA add-on payment adjustment.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

• *Updates to the dialysis payment rate for individuals with AKI:* We are updating the AKI dialysis payment rate for CY 2027. The final CY 2027 payment rate is \$297.52, which is the same as the final CY 2027 ESRD PPS base rate.

3. ESRD QIP

We are replacing the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure beginning with PY 2029. Beginning with PY 2029, we are updating the NHSN BSI clinical measure to use the most

² This budget neutrality factor accounts for the budget neutral changes to the LVPA (0.98901), the changes to payment for pediatric ESRD patients (0.99999), and the changes to the home and self-dialysis add-on payment adjustment (0.99964).

recently available national baseline data and to update the risk adjustment methodology. We are removing the MedRec reporting measure and the COVID–19 Vaccination Coverage Among HCP reporting measure from the ESRD QIP measure set beginning with

PY 2029. This final rule also includes public comments received in response to an RFI on the potential inclusion of the Dialysis Facility Discussion of Patient Life Goals Patient-Reported Outcome Performance measure (D-PaLS PRO–PM) in the ESRD QIP.

C. Summary of Costs and Transfers

In section VII.C.5. of this final rule, we set forth a detailed analysis of the impacts that the changes will have on affected entities and beneficiaries. Table 1 summarizes the impacts of each final change in this final rule.

TABLE 1: Summary of Economic Costs and Transfers, By Provision

Changes	Estimated total costs/transfers
CY 2027 ESRD PPS update	The overall economic impact of this final rule is an estimated increase of approximately \$240 million in aggregate Medicare payments to ESRD facilities in CY 2027.
CY 2027 AKI dialysis payment rate update	We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the final CY 2027 ESRD PPS base rate, will increase by approximately \$5 million.
PY 2029 ESRD QIP updates	We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are finalizing, the overall economic impact of the PY 2029 ESRD QIP will be approximately \$133.2 million, which includes \$114.5 million in costs associated with the collection of information requirements and approximately \$18.7 million in payment reductions across all facilities.

1. Impacts of the Updates to the ESRD PPS

The impact table in section VII.C.5.a. of this final rule displays the estimated change in Medicare payments to ESRD facilities in CY 2027 compared to estimated Medicare payments in CY 2026. The overall impact of the CY 2027 payment changes is projected to be a 2.7 percent increase in Medicare payments. Hospital-based ESRD and freestanding ESRD facilities will both have an estimated 2.7 percent increase in Medicare payments. We estimate that the aggregate Medicare program payments under the ESRD PPS will increase by approximately \$190 million in CY 2027 compared to CY 2026 because of the payment policies in this rule. Because of the projected 2.7 percent overall payment increase, we estimate there will be an increase in beneficiary coinsurance payments of 2.7 percent in CY 2027, which translates to approximately \$50 million (20 percent of the overall \$240 million estimated payment increase). This overall \$240 million estimated increase, or 2.7 percent, includes the estimated impact of the final ESRD PPS market basket update of 1.9 percent (\$170 million), as well as the estimated changes in payments associated with several changes that are expected between CY 2026 and 2027. First, as outlined in section II.B.3.b. of this final rule, we estimate that outlier payments in CY 2026 will be approximately 2.6 percent

of total ESRD PPS payments. Accordingly, the increases to the FDL and MAP amounts for CY 2027 are projected to reduce ESRD PPS payments by approximately 1.6 percent (\$140 million). At the same time, we estimate that approximately \$410 million will be paid through the TDAPA for DefenCath®, Vafseo®, and phosphate binders in CY 2026. The end of the TDAPA periods for these drugs is projected to result in a corresponding decrease to CY 2027 payments of (4.6 percent), which is offset by the final 4.4 percent increase to the ESRD PPS base rate for phosphate binders for a net decrease of \$40 million, and further offset by the estimated 2.9 percent increase in payments under the post-TDAPA add-on payment adjustment in CY 2027 (\$260 million). The net difference between estimated CY 2026 TDAPA payments and estimated CY 2027 payments under the post-TDAPA add-on payment adjustment and the ESRD PPS base rate, including the final incorporation of phosphate binders, is therefore a 2.5 percent increase in payments to ESRD facilities ($1.044 \times 1.029 \times 0.954 = 1.025$) which equals approximately \$220 million (\$260 million – \$40 million = \$220 million). For CY 2027, we estimate total payments associated with the post-TDAPA add-on payment adjustment will be approximately \$290 million. Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment

adjustments as the Secretary determines appropriate. Under this authority, CMS implemented § 413.234(c) to establish the TDAPA, a transitional drug add-on payment adjustment for certain new renal dialysis drugs and biological products; § 413.236 to establish the TPNIES, a transitional add-on payment adjustment for certain new and innovative equipment and supplies; and § 413.234(g) to establish the post-TDAPA add-on payment adjustment. The TDAPA, the TPNIES, and the post-TDAPA add-on payment adjustment are not budget neutral. As discussed in section II.D. of this final rule, there are no new or continuing TPNIES payments for CY 2027. As discussed in section II.E. of this final rule, there are no continuing TDAPA payments in CY 2027.

2. Impacts of the Final Payment Rate for Renal Dialysis Services Furnished to Individuals With AKI

The impact table in section VII.C.5.c. of this final rule displays the estimated change in Medicare payments to ESRD facilities for renal dialysis services furnished to individuals with AKI for CY 2027 compared to estimated Medicare payments for such services in CY 2026. The overall impact of the CY 2027 changes is projected to be a 5.4 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities will have an estimated 5.2 percent increase in Medicare payments compared with

freestanding ESRD facilities that would have an estimated 5.4 percent increase. The overall impact reflects the effects of the final Medicare ESRD PPS payment rate update and the final CY 2027 ESRD PPS wage index and final labor related share of 63.5 percent. We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the final CY 2027 ESRD PPS base rate, will increase by approximately \$5 million in CY 2027 compared to CY 2026.

3. Impacts of the PY 2029 ESRD QIP

We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are finalizing in this final rule, the overall economic impact of the PY 2029 ESRD QIP will be approximately \$133.2 million. The \$133.2 million estimate for PY 2029 includes \$114.5 million in costs associated with the collection of information requirements and approximately \$18.7 million in payment reductions across all facilities.

II. Calendar Year (CY) 2027 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148), established that beginning with CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014, to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and

biologicals³ (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule, we finalized \$29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. Section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket percentage increase should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis drugs and biological

products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025. Effective January 1, 2025, all oral-only renal dialysis drugs and biological products are paid for under the ESRD PPS.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to an individual for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies.

The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 13, or age 13 to 17) and two dialysis modalities (that is, peritoneal dialysis (PD) or hemodialysis (HD) (§ 413.235(a) and (b)(1)).

The ESRD PPS provides four facility-level adjustments. The first payment adjustment reflects differences in area wage levels developed from core-based statistical areas (CBSAs) (§ 413.231). The second payment adjustment, the low volume payment adjustment (LVPA), accounts for ESRD facilities furnishing a low volume of dialysis treatments, with two tiers such that smaller low-volume facilities receive a higher payment adjustment (§ 413.232). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233(a)). The fourth payment adjustment, the non-contiguous areas payment adjustment (NAPA), accounts for non-labor costs for ESRD facilities in certain non-contiguous areas of the U.S. (§ 413.233(b)).

There are six additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3)

³ As discussed in the CY 2019 ESRD PPS final rule (83 FR 56922), we began using the term “biological products” instead of “biologicals” under the ESRD PPS to be consistent with FDA nomenclature. We use the term “biological products” in this final rule except when referencing specific language in the Act or regulations.

a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); (4) a TPNIES for certain new and innovative renal dialysis equipment and supplies (§ 413.236(d)); (5) a transitional pediatric ESRD add-on payment adjustment (TPEAPA) of 30 percent of the per-treatment payment amount for renal dialysis services furnished to pediatric ESRD patients for CYs 2024 through 2026 (§ 413.235(b)(2));⁴ and (6) a post-TDAPA add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA period (§ 413.234(g)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule appeared in the August 12, 2010, issue of the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

Most recently, in a final rule that appeared in the November 24, 2025, issue of the **Federal Register**, titled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model” (90 FR 53068 through 53142), referred to herein as the “CY 2026 ESRD PPS final rule,” we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2026. This rule also finalized modifications to the eligibility timeframe for the TDAPA and established a new payment adjustment for ESRD facilities in certain non-contiguous areas, the NAPA. For further detailed information regarding the CY 2026 updates and policy changes, see 90 FR 53068.

B. Summary of the Provisions of the Proposed Rule, Public Comments, and Responses on the CY 2027 ESRD PPS Update

The proposed rule, titled “Medicare Program; CY 2027 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Acute Kidney Injury

Dialysis (AKI) Payment, and ESRD Quality Incentive Program” (91 FR 38784–38875), referred to as the “CY 2027 ESRD PPS proposed rule,” appeared in the June 26, 2026, issue of the **Federal Register**, with a comment period that ended on August 24, 2026. In that proposed rule, we proposed to make several annual updates for CY 2027 including a routine proposal to rebase and revise the ESRD Bundled (ESRDB) market basket. This rule also proposed to modify the ESRD PPS base rate to reflect the incorporation of phosphate binders into the ESRD PPS bundled payment and to make budget neutral changes to certain ESRD PPS payment adjustments, including proposed changes to the case mix adjusters for pediatric ESRD patients, changes to the LVPA, and modifications to the TDAPA and post-TDAPA add-on payment adjustment. The proposed rule also included several requests for information to advance alternative dialysis care, in accordance with E.O. 13879, which were related to payment policy under the ESRD PPS (91 FR 38847 through 38855). The requests for information focused on advancing home dialysis, palliative care to ESRD beneficiaries nationwide, and potential changes to support alternative dialysis schedules.

We received 228 public comments on our proposals, 171 of which were unique comments. These included comments from patients, caregivers, health care providers, ESRD facilities, large dialysis organizations (LDOs), regional chain dialysis organizations, small dialysis organizations, non-profit healthcare organizations, professional organizations, advocacy groups, drug manufacturers, device manufacturers, and two coalitions of kidney care providers. We also received comments from interested parties and health care providers in the skilled nursing facility (SNF) and hospice industries.

We received several comments about ESRD PPS policies for which we did not propose any changes for CY 2027. These comments are briefly summarized in the following paragraphs; however, we are not addressing these comments in this final rule because they are not within the scope for the CY 2027 ESRD PPS proposed rule or final rule. We received approximately 54 timely pieces of correspondence from unique submitters which advocated for the removal of oral drugs which lower serum phosphate from the ESRD PPS bundled payment.

We also received comments that offered suggestions broadly related to improving quality of care for ESRD patients. Two professional organizations and an advocacy group encouraged CMS

to address ESRD facility staffing concerns. One urged CMS to invest in nursing education and raised safety concerns for home dialysis nurses. Similarly, two others called for CMS to address dietitian-to-patient staffing ratios, pointing to high rates of malnutrition among dialysis patients. Several patients and caregivers urged CMS to prioritize patient choice, shared decision-making, and outcomes that matter to patients, like fatigue, recovery time, and ability to work or travel. One professional organization added that therapy interventions improve daily function and quality of life for patients with chronic kidney disease. Industry commenters focused on payment mechanics requesting new payment categories or lengthening the TDAPA payment period with continued coverage for specific products. Comments from trade groups highlighted unique barriers facing rural patients or those in non-contiguous areas of the United States, requesting formal CMS review and payment adjustments to reflect higher operational costs for rural areas or the NAPA. One advocacy group raised concerns about limited transparency in Medicare Advantage (MA) plans covering ESRD beneficiaries, asking CMS to improve data collection on contracting, payment, and home dialysis/transplant referral rates. We also received comments which discussed the impact of ESRD PPS payment policies on MA payment rates. One professional organization requested CMS use “Physician Assistant/Physician Associate” dual terminology in regulatory language to reflect the profession’s evolving title, while another professional organization urged CMS to recognize the professional standard of care that can be provided by physician extenders in policy and regulation.

As we previously stated, we are not providing detailed responses to these comments as they are not within the scope of the CY 2027 ESRD PPS proposed rule or final rule. Nevertheless, we thank the commenters for their input and will consider their recommendations to potentially inform future rulemaking.

1. Rebasing and Revising of the ESRD Bundled (ESRDB) Market Basket; and CY 2027 Market Basket Percentage Increase, Productivity Adjustment, and Labor-Related Share (LRS)

a. Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable

⁴ As the TPEAPA only applies for CYs 2024, 2025, and 2026, it will not apply for the CY 2027 payment year or future years.

Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. Section 1881(b)(14)(F)(i) of the Act also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index using CY 2008 as the base year effective for CY 2012 (75 FR 49151 through 49162). We subsequently rebased and revised the ESRDB input price index to a base year of CY 2012 in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136), and to a base year of CY 2016 in the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964). In the CY 2023 ESRD PPS final rule (87 FR 67141 through 67157), we finalized a rebased ESRDB input price index to reflect a CY 2020 base year. Effective for CY 2027, we proposed to rebase and revise the ESRDB market basket to a 2024 base year.

Although “market basket” technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term “ESRDB market basket,” as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index itself is constructed in three steps. First, a base period is selected (in the proposed rule, we proposed to use 2024 as the base period) and total base period costs are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage

variable, referred to as a “price proxy.” In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the cost weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the cost weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to provide renal dialysis services. The effects on total costs resulting from changes in the mix of goods and services purchased after the base period are not measured. For example, an ESRD facility hiring more staff to accommodate the needs of patients would increase the volume of goods and services purchased by the ESRD facility but would not be factored into the price change measured by a fixed-weight ESRDB market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect changes between base periods in the mix of goods and services that ESRD facilities purchase to furnish ESRD treatment.

We last rebased the ESRDB market basket cost weights effective for CY 2023 (87 FR 67141 through 67157), with 2020 data used as the base period for the construction of the market basket cost weights. In the CY 2027 ESRD PPS proposed rule, we proposed to rebase the ESRDB market basket to reflect the 2024 cost structure for ESRD facilities and to revise applicable cost categories and price proxies used to determine the ESRDB market basket.

We refer to the market basket as a CY market basket because the base period for all price proxies and weights is set to CY 2024 (that is, the average index level for CY 2024 is equal to 100). The major source data for the ESRDB market basket is the 2024 Medicare cost reports (Form CMS-265–11, OMB No. 0938–0236), supplemented with 2022 data from the United States (U.S.) Census Bureau’s Services Annual Survey (SAS)

inflated to 2024 levels and the Bureau of Economic Analysis’s (BEA) 2017 Benchmark Input-Output (I–O) data, inflated to 2024. The 2022 SAS data and 2017 Benchmark I–O data are the most recent year of detailed cost data published by the Census Bureau and the BEA for North American Industry Classification System (NAICS) Code 6214: Outpatient Care Centers, which is the 4-digit industry code that Kidney Dialysis Centers are classified within. We also proposed to use the May 2024 OEWS data from BLS for NAICS 6214 to further disaggregate the Wages and Salaries and Employee Benefits cost weights into occupational categories. We provide more detail on our methodology in section II.B.1.b. of this final rule.

In the following section, we provide an overview of the ESRDB market basket, describe the methodologies for developing the cost weights, and provide information on the price proxies. Then, we present the proposed CY 2027 market basket update and labor-related share based on the 2024-based ESRDB market basket.

b. Rebasing and Revising of the ESRDB Market Basket

The terms “rebasing” and “revising,” while often used interchangeably, denote different activities. “Rebasing” means moving the base year for the structure of costs of an input price index (for example, in the proposed rule, we proposed to shift the base year cost structure from 2020 to 2024). “Revising” means changing data sources or price proxies used in the input price index. For CY 2027, we proposed to rebase the ESRDB market basket to reflect the 2024 cost structure of ESRD facilities and to revise the index, that is, make changes to cost categories or price proxies used in the index.

(1) Development of Cost Categories and Weights

(a) Use of Medicare Cost Report Data

The major source of cost data for developing the rebased and revised ESRDB market basket cost weights is the 2024 Medicare cost reports. The 2024 Medicare cost reports are for those freestanding ESRD facilities whose cost reporting period began on or after October 1, 2023, and before October 1, 2024 (approximately 95 percent of freestanding ESRD facilities had a begin date on January 1, 2024, approximately 4 percent had a begin date prior to January 1, 2024, and approximately 1 percent had a begin date after January 1, 2024). Using this methodology allowed our sample to include ESRD facilities

with varying cost report years including, but not limited to, the federal fiscal year (FY) or CY. We proposed to use 2024 as the base year because we believe that the 2024 Medicare cost reports represent the most recent, complete set of Medicare cost report data available to develop cost weights for ESRD facilities at the time of rulemaking. We proposed to maintain our policy of using data from freestanding ESRD facilities (which account for over 95 percent of total ESRD facilities in CY 2024) because freestanding ESRD facility data reflects only the cost structure faced by the ESRD facility itself. In contrast, cost data for hospital-based ESRD facilities reflect the allocation of overhead from the entire institution.

The current set of instructions and associated forms for the Medicare cost reports for ESRD facilities (Form 265–11, OMB No. 0938–0236) can be found in Chapter 42 of the Provider Reimbursement Manual at the following website (<https://www.cms.gov/regulations-and-guidance/guidance/manuals/paper-based-manuals-items/cms021935>). We reviewed cost data from freestanding ESRD Medicare cost reports (CMS Form 265–11, OMB No. 0938–0236) for 2024 for each ESRD facility that reported costs and payments.

The major types of costs underlying the 2024-based ESRDB market basket are derived from the Medicare cost reports (Form 265–11, OMB No. 0938–0236). Specifically, we proposed to use the Medicare cost reports for eleven specific types of costs: Wages and Salaries; Employee Benefits; Pharmaceuticals (both Erythropoiesis Stimulating Agents (ESAs) and All Other Drugs in the ESRD PPS bundled payment); Supplies; Laboratories; Housekeeping; Operations & Maintenance; Capital-related: Buildings and Fixtures; Capital-related: Moveable Equipment; Professional Liability Insurance; and Administrative & Other. Total Costs are defined as the sum of the eleven cost categories and associated costs identified previously.

To create a market basket that is representative of ESRD facilities and to help ensure the major cost weights accurately reflect the percentage of total costs for furnishing ESRD treatment, we proposed to apply edits to remove reporting errors and outliers. Specifically, edits were applied to include only Medicare cost reports that had total costs greater than zero. Total costs as reported on the Medicare cost report include those costs reimbursable under the ESRD PPS. For example, we excluded costs related to vaccines from total expenditures since these are not

paid for under the ESRD PPS. Next, to reduce potential distortions from outliers in the calculation of the individual cost weights for the major expenditure categories for each cost category, values less than the 5th percentile or greater than the 95th percentile were excluded from the major cost weight computations. The resulting 2024 data set, after removing cost reports with total costs equal to or less than zero and excluding outliers, included information from approximately 6,514 independent ESRD facilities' cost reports from an available pool of 7,297 cost reports (roughly 89 percent of the universe). This sample of ESRD facilities is representative of the national universe of facilities by ownership-type (proprietary, nonprofit, and government) and by urban/rural status.

Since each cost weight is determined independently, that is, the 5 percent trim is applied to each cost category, the resulting weights may not sum to 100.0. We proposed normalizing the results proportionally so that the sum of each of the cost category weights will equal 100.0. A similar methodology was used to derive the major cost weights in the 2020-based ESRDB market basket.

We note that for the 2024 Medicare cost reports, a discrepancy was found with most Medicare cost reports submitted by a major large dialysis organization (LDO) where Medicare cost report field designating the ESRD facility as a chain was completed incorrectly. Worksheet S, Part II, column 1, line 19 states "Are you part of a chain organization? Enter 'Y' for yes or 'N' for no. If yes, complete lines 20 through 22." Many of these ESRD facilities entered "N"; however, they provided the location of the chain organization in lines Worksheet S, Part II, lines 20 through 22, indicating that the correct response to line 19 should have been "Y". (We note that these ESRD facilities had also indicated being part of a chain organization in their prior year's cost report.) This led to reporting of Administrative & Other net expenses that was inconsistent with the chain designation. Worksheet A–3 provides for the computation of any needed adjustments to costs applicable to services, facilities, and supplies furnished to the ESRD facility by a related organization (by common ownership or control). This worksheet is potentially completed when an ESRD facility answers 'Y' to Worksheet S, Part II. These adjustments to costs are transferred to Worksheet A, column 7 (to be reflected in Worksheet A, column 8) and, therefore, would then be

reflected in the Administrative & Other net expenses.

To correct this misreporting, we first checked if the value reported on Worksheet A–3, Part B, column 1, line 1 was missing or 0, and whether the value reported on Worksheet A–3, Part B, column 6, line 1 was greater than zero. If these conditions were satisfied, we added the dollar (\$) value of the related organization adjustment (Worksheet A–3, Part B, column 6, line 1) to the Administrative & Other cost center net expenses reported on Worksheet B, column 9, line 8.01. For any ESRD facility that didn't have a discrepancy, no adjustment was required to the Administrative & Other net expenses.

(i) Wages and Salaries Costs

We proposed to determine Wages and Salaries costs as the sum of (1) direct patient care wages and salaries costs and (2) non-direct patient care wages and salaries costs. Direct patient care wages and salaries for 2024 are equal to the sum of costs from Worksheet B, column 4.01 (salaries for dialysis equipment technicians) and column 5 (direct patient care salaries), lines 8.01 through 17.03 (reimbursable cost centers) of the Medicare cost reports. Non-direct patient care wages and salaries are equal to the sum of all other wages and salaries costs for non-health workers, which we proposed to derive using the following steps:

Step 1: To capture the salary costs associated with non-direct patient care cost centers, we calculated salary percentages for non-direct patient care from Worksheet A of the Medicare cost reports. The estimated ratios were calculated as the ratio of salary costs (Worksheet A, columns 1 and 2) to total costs (Worksheet A, column 4). The salary percentages were calculated for seven distinct groups of cost centers: 'Operations & Maintenance of Plant' combined with 'Capital Related Costs—Renal Dialysis Equipment' (line 3 and 6), Housekeeping (line 4), Employee Health and Wellness (EH&W) Benefits for Direct Patient Care (line 8), Supplies (line 9 and 9.01), Laboratory (line 10), Administrative & General (line 11), and Drugs (line 12).

Step 2: We then multiplied the salary percentages computed in step 1 by the total net costs for each corresponding reimbursable cost center as reported on Worksheet B. The Worksheet B totals are based on the sum of reimbursable costs reported on lines 8.01 through 17.03. For example, the salary percentage for Supplies (as measured by line 9 and 9.01 on Worksheet A) was applied to the total net costs for the

Supplies cost center (the sum of costs reported on Worksheet B, column 7, lines 8.01 through 17.03). We complete this calculation for each of the seven groups of cost centers listed in step 1.

Step 3: The estimated wages and salaries for each of the non-direct patient cost centers in step 2 were summed and then added to the direct patient care wages and salaries costs to calculate total Wages and Salaries costs.

(ii) Employee Benefits Costs

We proposed to determine the Employee Benefits costs as the sum of direct patient care EH&W benefits (which we will refer to as direct patient care employee benefit costs) and estimated non-direct patient care employee benefit costs. Direct patient care employee benefit costs are reported on Worksheet B, column 6, lines 8.01 through 17.03 of the Medicare cost reports. Non-direct patient care employee benefit costs are not reported separately but are included in Worksheet A, column 3 (“Other”). We proposed to derive the non-direct patient care benefit costs using the following steps:

Step 1: We calculate the ratio of direct patient care employee benefit costs to direct patient care salaries for each ESRD facility. This ratio is calculated as direct patient care employee benefit costs (Worksheet B, column 6, lines 8.01 through 17.03) divided by the direct patient care wages and salaries costs (Worksheet B, columns 4.01 and 5, lines 8.01 through 17.03).

Step 2: We estimate total salaries for all non-direct patient care cost centers except Administrative & Other. This would be the sum of direct patient care salaries plus estimated salaries for the non-direct patient care cost centers: EH&W benefits, pharmaceuticals, supplies, laboratory, housekeeping, and operation and maintenance of plant and equipment.

Step 3: To determine estimated non-direct patient care employee benefit costs for all cost centers other than Administrative & Other we multiply the costs from step 2 by the ratio determined in step 1.

Step 4: To calculate the employee benefit costs for Administrative & Other cost centers, we first estimate adjusted Administrative & Other costs by subtracting Professional Liability Insurance costs, estimated employee benefits costs for all workers except those associated with the Administrative & Other cost center (as derived in step 3), and Administrative & Other costs associated with Non-ESRD related costs or costs that are paid outside the ESRD PPS bundled payment

(Worksheet B, column 9, lines 5 through 7).

Step 5: We estimate the adjusted Administrative & Other salary costs by multiplying the salary percentage for Administrative & Other cost centers (calculated in step 1 of the wages and salaries section) by the adjusted Administrative & Other costs calculated in step 4 of this section.

Step 6: Total salaries are calculated by summing up the salary costs associated with the non-direct patient care cost centers (derived in step 2) and the adjusted Administrative & Other salary costs (derived in step 5).

Step 7: To determine employee benefits costs for all employees, we multiply the total salaries (calculated in step 6) by the ratio of direct patient care benefits to direct patient care salaries (calculated in step 1).

We note that the proposed methodology for deriving total employee benefits costs from the Medicare cost report differs from the methodology we have used in prior ESRDB market baskets. Previously, we derived the Employee Benefits cost weight from Medicare cost report data for direct patient care employee benefits and supplemented with data from the 2012 U.S. Census Bureau’s Services Annual Survey (SAS) for NAICS 621492, Kidney Dialysis Centers, which were inflated to the applicable base year (for example 2020) to account for non-direct patient care employee benefits. The U.S. Census Bureau discontinued publication of the SAS data for NAICS 621492 beginning in 2012 and discontinued publication of the SAS effective after the 2022 data release. For years between 2012 and 2022, the SAS data was only available at the four-digit NAICS level of detail, and we therefore continued to rely on the inflated 2012 data. We believe the proposed methodology is a technical improvement to the prior methodology used to derive the non-direct patient care employee benefits because it relies on more recent Medicare cost report data that are specific to ESRD facilities.

(iii) Pharmaceuticals Costs

The 2024-based ESRDB market basket includes expenditures for all drugs, including formerly separately billable drugs and all other renal dialysis drugs that were covered under Medicare Part D before the ESRD PPS was implemented. We proposed to determine the pharmaceuticals costs using data reported on Worksheet B; specifically, the sum of lines 8.01 through 17.03, for the following columns: column 11, “Drugs Included in Composite Rate,” column 12,

“Erythropoiesis stimulating agents (ESAs)” and column 13, “ESRD-Related and AKI-Related Drugs.” We did not include the drug costs for Non-ESRD Related Drugs, Supplies, and Labs as reported on line 5, column 10 or the AKI Non-Renal Related Drugs, Supplies, & Lab as reported on line 5.01 column 10 as these costs are not included in the ESRD PPS bundled payment amount. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, COVID-19, and hepatitis B vaccines described in paragraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of average wholesale price (AWP) of the vaccine. Since these vaccines are not paid for under the ESRD PPS, we did not include costs reported on Worksheet B, column 9, line 7 in the 2024-based ESRDB market basket. Finally, to avoid double-counting, the pharmaceuticals costs are reduced by the estimated share of non-direct patient care wages and salaries associated with the applicable drug cost centers referenced previously. This results in a 2024-based ESRDB market basket cost weight for Pharmaceuticals of 5.3 percent, with ESA costs accounting for 3.0 percentage points and All Other Drugs accounting for the remaining 2.3 percentage points.

(iv) Supplies Costs

We calculate the Supplies costs using the costs reported in the Supplies cost center (Worksheet B, column 7, lines 8.01 through 17.03) of the Medicare cost report. To avoid double-counting, the Supplies costs are reduced to exclude the estimated share of non-direct patient care wages and salaries associated with this cost center.

(v) Laboratory Costs

We calculate the Laboratory costs using the costs reported in the Laboratory cost center (Worksheet B, column 8, lines 8.01 through 17.03) of the Medicare cost report. To avoid double-counting, the Laboratory costs are reduced to exclude the estimated share of non-direct patient care wages and salaries associated with this cost center.

The Medicare cost report data include reported costs for Housekeeping, Operations & Maintenance, Capital-related: Buildings and Fixtures, and Capital-related: Moveable Equipment in a single cost center. We estimated the net costs for each of these four categories using the following steps.

Step 1: We calculate the total net costs for Housekeeping, Operations & Maintenance, and Capital-related as the sum of costs reported on Worksheet B, column 3, lines 8.01 through 17.03).

Step 2: For each of the four subcategories, we estimate the share of the total costs of each subcategory as follows:

- The Housekeeping share is determined based on the total costs for Housekeeping reported on Worksheet A, column 4, line 4 divided by the total costs for all four subcategories reported on Worksheet A, column 4, line 5.
- The Operations & Maintenance share is determined based on the total costs for Operations & Maintenance costs reported on Worksheet A, column 4, line 3 divided by the total costs for all four subcategories reported on Worksheet A, column 4, line 5.
- *The Capital-related: Buildings and Fixtures* share is determined based on the total costs for Capital-related buildings and fixtures reported on Worksheet A, column 4, line 1 divided by the total costs for all four subcategories reported on Worksheet A, column 4, line 5.
- *The Capital-related: Moveable Equipment* share is determined based on the total costs for Capital-related moveable equipment reported on Worksheet A, column 4, line 2 divided by the total costs for all four subcategories reported on Worksheet A, column 4, line 5.

(vi) Housekeeping Costs

The Housekeeping costs are estimated by multiplying the housekeeping share determined in step 2 by the total net costs calculated in step 1. To avoid double-counting, the costs for the Housekeeping category are reduced to exclude the estimated share of non-direct patient care wages and salaries associated with this cost center.

(vii) Operations & Maintenance Costs

The Operations & Maintenance costs are estimated by multiplying the operations & maintenance share determined in step 2 by the total net costs calculated in step 1. The operations & maintenance costs include the direct costs incurred in the operation and maintenance of the plant and equipment such as heat, light, water (excluding water treatment for dialysis purposes), air conditioning, and air treatment; the maintenance and repair of buildings, parking facilities, and equipment; painting; elevator maintenance; performance of minor renovation of buildings and equipment; and protecting employees, visitors, and facility property. To avoid double counting, the costs for the Operations & Maintenance category are reduced to exclude the estimated share of non-direct patient care wages and salaries associated with this cost center.

(viii) Capital-Related: Buildings and Fixtures Costs

The Capital-related: Buildings and Fixtures costs are estimated by multiplying the capital-related buildings and fixtures share from step 2 by the total net costs calculated in step 1. The capital-related buildings and fixtures costs include depreciation and lease costs for buildings and fixtures, property taxes, insurance costs, and capital improvements.

(ix) Capital-Related: Moveable Equipment Costs

The Capital-related: Moveable Equipment costs are estimated by multiplying the capital-related moveable equipment share from step 2 by the total net costs calculated in step 1. The capital-related moveable equipment costs include depreciation and lease costs for moveable equipment, property taxes, insurance costs, and capital improvements. Next, we sum the costs for capital-related moveable equipment to the Capital-related Renal Dialysis Equipment costs (Worksheet B, column 4, lines 8.01 through 17.03). We believe this delineation was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with buildings and fixtures could move differently than those associated with moveable equipment, we continue to believe that two capital-related cost categories are appropriate.

(x) Professional Liability Insurance Costs

We proposed for the 2024-based ESRDB market basket to have a separate category for professional liability insurance (PLI) costs (often referred to as malpractice costs). The PLI costs are equal to the sum of premiums, paid losses, and self-insurance costs reported on Worksheet S, Part II, column 1, lines 15 through 17. For the 2020-based ESRDB market basket we did not create a separate cost category and the PLI costs were included with the Administrative & Other costs.

(xi) Administrative & Other Costs

We proposed to compute the proportion of total Administrative & Other costs using the Administrative & Other cost center data from Worksheet B, the sum of column 9, lines 8.01 through 17.03, less PLI costs and other costs reported in this cost center but paid separately from the ESRDB PPS, which include Non-ESRD Related Drugs, Supplies, & Lab (line 5); AKI Non-renal Related Drugs, Supplies, & Labs (line 5.01); Whole Blood and Packed Red Blood cells (line 6); and

Vaccines (line 7). To avoid double-counting, the costs for the Administrative & Other category are also reduced to exclude the estimated share of non-direct patient care wages and salaries associated with this cost center and the estimated non-direct patient care employee benefits costs.

(b) Final Major Cost Category Computation

After deriving the costs for the major cost categories for each ESRD facility using the Medicare cost report data as previously described, we proposed to address data outliers using the following steps.

First, for each of the major cost weights, we proposed to trim the data to remove outliers (a standard statistical process) by: (step 1) requiring that major costs (such as Wages and Salaries costs) and total costs be greater than zero; (step 2) dividing the costs for each of the eleven categories (calculated as previously described in this section) by total costs to obtain cost weights for each ESRD facility; and (step 3) excluding the top and bottom five percent of the major cost weight (for example, Wages and Salaries costs as a percent of total costs). We note that missing values are assumed to be zero consistent with the methodology for how missing values were treated in the 2020-based ESRDB market basket.

After the outliers are removed, we sum the costs for each category across all remaining ESRD facilities. We then divide this by the sum of total costs across all remaining ESRD facilities to obtain a cost weight for the 2024-based ESRDB market basket for the given category. This is the same methodology used for the 2020-based ESRDB market basket.

The trimming process is done individually for each cost category so that ESRD facilities excluded from one cost weight calculation are not automatically excluded from another cost weight calculation. We note that these trimming methods are the same types of edits performed for the 2020-based ESRDB market basket, as well as other PPS market baskets (including but not limited to Inpatient Prospective Payment System (IPPS) operating market basket, Skilled Nursing Facility (SNF) market basket, and home health market basket). We note that for each of the cost weights, we evaluate the distribution of facilities and costs by ownership-type, and by urban/rural status. For all cost weights, the trimmed sample is nationally representative.

Table 2 presents the 2024-based ESRDB market basket major cost weights as derived directly from the

Medicare cost report data compared to the 2020-based ESRDB market basket

major costs weights derived directly from the Medicare cost report data.

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TABLE 2: ESRDB Market Basket Major Cost Weights Derived from the Medicare Cost Report Data

	2024	2020	Difference between 2024 weight and 2020 weight
Wages and Salaries	37.4	34.5	2.9
Employee Benefits*	11.3	7.7	3.6
Pharmaceuticals	5.3	10.1	-4.8
ESAs	3.0	6.0	-3.0
All Other Drugs	2.3	4.1	-1.8
Supplies	10.4	11.0	-0.6
Laboratories	1.3	1.3	0.0
Housekeeping	0.5	0.5	0.0
Operations & Maintenance	4.2	3.7	0.5
Capital-related: Buildings and Fixtures	9.0	9.4	-0.4
Capital-related: Moveable Equipment	3.4	4.4	-1.0
Professional Liability Insurance	0.4	n/a	n/a
Administrative & Other	16.8	17.5	-0.7
	100.0	100.0	0.0

Note: Totals may not sum to 100.0 due to rounding.

*The 2020 employee benefits weight, based only on Medicare cost report data, reflects direct-patient care employee benefits costs only while the 2024 employee benefits weight reflects all employee benefits costs.

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From 2020 to 2024, the Wages and Salaries and Employee Benefits cost weights increased by 2.9 percentage points and 3.6 percentage points, respectively. The increase in the 2024-based Wages and Salaries and Employee Benefits cost weights is the result of faster growth in labor costs compared to costs associated with the other market basket cost weights (such as Pharmaceutical costs). This faster growth is consistent with comments received during prior ESRD PPS rulemaking. The Pharmaceuticals cost weight as calculated directly from the Medicare cost reports decreased by 4.8 percentage points, which continues the downward trend in the Pharmaceuticals cost weight observed since the

implementation of the ESRD PPS in 2011. We believe this falling Pharmaceuticals cost weight is attributable to three main inter-related factors: (1) reduced utilization per treatment of certain high-cost drug classes (such as ESAs), (2) a shift to more price-competitive products, including generic drugs or biosimilars, and (3) facility-level cost management and efficiency.

(c) Derivation of the Detailed Cost Weights

There are three instances where the ESRDB market basket costs weights are further adjusted using secondary data sources. The first adjustment is to estimate contract labor costs, which would be reflected in the

Administrative & Other cost weight of 16.8 percent shown in Table 2 derived from the Medicare cost report data. We proposed to estimate the contract labor share of costs and reallocate those from Administrative & Other to Wages and Salaries and Employee Benefits. The second adjustment further disaggregates the Wages and Salaries and Employee Benefits weight, inclusive of contract labor costs, into occupational subcategories. The third adjustment is to further disaggregate the remaining Administrative & Other cost weight (less the contract labor cost weight) into further detail using data from the BEA Benchmark I-O data.

(i) Contract Labor Costs

Contract labor costs are reported in the Medicare cost report; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disaggregated. We proposed the following methodology to derive the contract labor cost weight. Similar to the methodology used in the 2020-based ESRDB market basket, we proposed to use data from the U.S. Census Bureau’s Services Annual Survey (SAS) to estimate these costs for the 2024-based ESRDB market basket. We proposed to use data from the 2022 SAS for NAICS 6214, Outpatient Care Centers, inflated to 2024 to estimate the contract labor weight for the 2024-based ESRDB market basket. Previously, we used the 2012 SAS data for NAICS 621492, Kidney Dialysis Centers inflated to the applicable base year. Since 2012 the SAS data is no longer available from the Census Bureau at the 6-digit NAICS level of detail, we believe our proposal to use the data for NAICS 6214 is a technically appropriate alternative as

ESRD facilities would be included within this NAICS category and the data reflects the more recent experience of this industry’s contract labor usage. We proposed to use the share of the total costs for NAICS 6214 expenses for Temporary staff and leased employee expense from the 2022 SAS. Using this data, the 2024-based ESRDB Contract Labor cost weight is 2.1 percent. To avoid double counting these costs, we proposed to remove the 2.1 percent Contract Labor cost weight from the Administrative & Other cost weight (where we believe most contract labor costs would be reported). The resulting Administrative & Other Residual Cost weight is 14.7 percent, which reflects the 16.8 percent Administrative & Other cost weight from Medicare cost reports less the 2.1 percent Contract Labor cost weight. As we did for the 2020-based ESRDB market basket (87 FR 67143), we proposed to allocate contract labor costs to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions for employed labor under the assumption that contract

labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. Using the 2024 Medicare cost report data, this percentage is 77 percent. Therefore, we proposed to allocate 77 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 23 percent to the Employee Benefits cost weight. The 2020-based ESRDB market basket allocated 80 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 20 percent to the Employee Benefits cost weight. Table 3 shows the Wages and Salaries and Employee Benefits cost weights after contract labor allocation for the 2020-based ESRDB market basket and the 2024-based ESRDB market basket. In aggregate, the Compensation cost weight (calculated using more detailed decimal places) increased from 45.9 percent to 50.9 percent, or 5.0 percentage points.

TABLE 3: Wages and Salaries and Employee Benefits Cost Weights after Contract Labor Allocation

Major Cost Categories	2024-Based ESRDB Market Basket	2020-Based ESRDB Market Basket
Total Compensation	50.9	45.9
Wages and Salaries	39.0	36.5
Employee Benefits	11.9	9.5

Note: Detail may not add to total due to rounding.

(ii) Disaggregation of Compensation Costs Into Occupational Categories

To further disaggregate the “Wages and Salaries” and “Employee Benefits” cost weights into four occupational subgroups (Health-Related, Management, Administrative, and Service), we proposed to use the number of full time equivalents (FTEs) reported on Worksheet S–1, column 3, lines 22 through 35 of the Medicare cost reports and annual mean wages for the occupations within each group from the May 2024 BLS OEWS for NAICS 6214, Outpatient Care Centers.⁵

The ESRD Medicare cost report FTE categories assigned to the Health-Related subgroup include “Physicians,” “Registered Nurses,” “Licensed Practical Nurses,” “Nurses Aides,” “Technicians,” and “Dieticians”; assigned to the Management subgroup is “Management”; assigned to the Administrative subgroup is “Administrative”; and assigned to the Services subgroup are “Social Workers” and “Other”. For each FTE category, we estimate the mean annual wage from the May 2024 BLS OEWS data. We multiply the number of ESRD FTEs in each subgroup by the estimated mean annual

wage. Table 4 shows the share of each FTE group’s compensation (number of FTEs multiplied by the mean annual wage) to total compensation for the 2024-based ESRD market basket and the 2020-based ESRDB market basket. Table 5 shows the Wages and Salaries and Employee Benefits occupational mix for the 2024-based ESRDB market basket compared to the 2020-based occupational mix. The 2024 occupational distribution shows a shift to more health-related FTEs and fewer Management and Administrative Support Occupation FTEs.

⁵ <https://www.bls.gov/oes/>.

TABLE 4: Share of ESRD Compensation by Occupation

Subgroup	Occupation	2024	2020
Health-Related	Physicians and Surgeons	1.5%	3.9%
Health-Related	Registered Nurses	37.9%	36.3%
Health-Related	Licensed Practical and Licensed Vocational Nurses	2.2%	3.2%
Health-Related	Nursing Assistants	1.8%	1.1%
Health-Related	Health Technologists and Technicians, All Other	34.6%	30.9%
Services	Healthcare Social Workers	4.3%	4.0%
Health-Related	Dietitians and Nutritionists	4.4%	4.0%
Administrative	Office and Administrative Support Occupations	4.8%	5.3%
Management	Medical and Health Services Managers	6.1%	9.0%
Services	Healthcare Support Workers, All Other	2.4%	2.3%

TABLE 5: Wages and Salaries and Employee Benefits Occupational Mix (%)

	2024	2020
Health-Related	82.4	79.4
Management	6.1	9.0
Administrative	4.8	5.3
Services	6.7	6.3

We proposed to multiply the occupational mix weights by the Wages and Salaries cost weight and the Employee Benefits cost weight (both inclusive of contract labor) to determine the occupational subgroups' weights for Wages and Salaries and Employee Benefits as shown in Table 6. This is similar to the methodology used in the 2020-based ESRDB market basket to derive these occupational subgroup weights.

(iii) Disaggregation of Administrative & Other Residual Cost Weight

To further divide the “Administrative & Other” residual cost weight estimated from the 2024 Medicare cost report data into more detailed cost categories, we proposed to use the 2017 Benchmark I–O “The Use of Commodities by Industries, Before Redefinitions (Producers' Prices)—Detail” for NAICS 621400, Outpatient care Centers,

published by the BEA.⁶ The BEA Benchmark I–O data are generally scheduled for publication every 5 years on a lagged basis, with the most recent data available for 2017. The 2017 Benchmark I–O data are derived from the 2017 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is

⁶ Source: 2017 Benchmark Input-Output “Use of Commodities by Industries, Before Redefinitions (Producers' Prices)—Detail,” NAICS 621400 (Outpatient Care Centers), published by the U.S. Bureau of Economic Analysis (BEA). Available at https://apps.bea.gov/iTable/?reqid=1602&step=2&Categories=Core&isURI=1&gl=1*4ozlmu*ga*MTczMzgWnZcyNC4xNzYxNTk4OTIx*_ga_J4698JNNFT*cze3OTIwMDY0NzMkbzI0JGcxJHQxNzkyMDA3MTkwJGo1MiRsMCRoMA..#eyJhcHBpZCI6MTYwMiwic3RlcHMlOlsxLDIsM10sImRhGEiOltbImNhdGVnb3p3pZXMlLCJDb3JlI0sWYjUYWJsZV9MaXNOIiwVXNlQlJQcm8iXV19.

produced and distributed.⁷ BEA also produces Annual I–O estimates; however, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we proposed to inflate the detailed 2017 Benchmark I–O data forward to 2024 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2017 Benchmark I–O data and calculate the cost shares that each cost category represents using the inflated data. These resulting 2024 cost shares from this I–O based approach are applied to the “Administrative & Other” cost weight to obtain the detailed cost weights for the 2024-based ESRDB market basket. For example, the cost for

⁷ http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.

Paper & Printing represents 3.9 percent of the sum of the residual “All Other” 2017 Benchmark I–O Outpatient Care Center expenditures inflated to 2024. Therefore, the Paper & Printing cost weight represents 3.9 percent of the 2024-based ESRDB market basket’s “Administrative & Other” cost category (14.7 percent), yielding a Paper & Printing cost weight of 0.6 percent in the 2024-based ESRDB market basket ($3.9 \text{ percent} \times 14.7 \text{ percent} = 0.6 \text{ percent}$). For the 2020-based ESRDB market basket (87 FR 67145), we used a different data source to disaggregate the Administrative & Other residual cost weight. The prior method used data from the 2012 U.S. Census Bureau’s SAS for NAICS 621492, inflated to the 2020 base year of the ESRDB market basket. As mentioned previously, this data is no longer produced or published by the Census Bureau and, therefore we proposed to use an alternative data source.

Using this methodology, we proposed to derive 12 detailed cost categories from the 2024-based ESRDB market basket Administrative & Other cost

weight of 14.7 percent. These categories are: (1) Electricity; (2) Natural Gas; (3) Rubber & Plastics; (4) Paper & Printing; (5) Miscellaneous Products; (6) Telephone and Internet Service; (7) Administrative Services; (8) Financial Services; (9) Professional Fees: Labor-related; (10) Professional Fees: Nonlabor-related; (11) All Other Services: Labor-related; (12) All Other Services: Nonlabor-related.

We noted that the cost category for Professional Fees: Labor-related reflects the proportion of ESRD facilities’ professional fees expenses that we believe vary with local labor market. We conducted a survey of ESRD facilities in 2008 to better understand the proportion of contracted professional services that ESRD facilities typically purchase outside of their local labor market. These purchased professional services include functions such as accounting and auditing, management consulting, engineering, and legal services. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms, and 13 percent are

purchased from businesses located outside of the ESRD’s local labor market. Thus, to derive the Professional Fees: Labor-related weight we proposed to allocate 87 percent of the expenses for Professional Fees for these selected services as labor-related; we note that 87 percent is the same percentage as used in prior years.

This methodology allows for seven additional detailed cost categories than used in the 2020-based ESRDB market basket because the Benchmark I–O data is more comprehensive than the SAS data. The 2020-based ESRDB market basket included categories for Electricity, Natural Gas, Telephone, Professional Fees, and All Other Goods and Services.

Table 6 sets forth the 2024-based ESRDB market basket, including the cost categories and their respective cost weights. For comparison purposes, the corresponding 2020-based ESRDB market basket cost weights also are listed.

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TABLE 6: Comparison of the 2024-based and the 2020-based ESRDB Market Basket Cost Categories and Weights (%)

Cost Category	2024-based ESRDB Market Basket Cost Weight	2020-based ESRDB Market Basket Cost Weight
Total - ESRDB	100.0	100.0
Compensation	50.9	45.9
Wages and Salaries ¹	39.0	36.5
Health-Related Wages and Salaries	32.1	28.9
Management Wages and Salaries	2.4	3.3
Administrative Wages and Salaries	1.9	1.9
Service Wages and Salaries	2.6	2.3
Employee Benefits ¹	11.9	9.5
Health-Related Benefits	9.8	7.5
Management Benefits	0.7	0.9
Administrative Benefits	0.6	0.5
Service Benefits	0.8	0.6
Utilities	1.1	1.4
Electricity	1.0	1.2
Natural Gas	0.1	0.1
Medical Materials and Supplies	16.9	22.4
Pharmaceuticals	5.3	10.1
ESAs	3.0	6.0
All Other Drugs	2.3	4.1
Supplies	10.4	11.0
Laboratories	1.3	1.3
All Other Goods	1.4	n/a
Paper & Printing	0.6	n/a
Rubber & Plastics	0.4	n/a
Miscellaneous Products	0.4	n/a
All Other Services	17.3	16.6
Telephone and Internet Service	0.9	0.5
Housekeeping	0.5	0.5
Operations & Maintenance	4.2	3.7
Administrative Services	0.3	n/a

Cost Category	2024-based ESRDB Market Basket Cost Weight	2020-based ESRDB Market Basket Cost Weight
Financial Services	1.2	n/a
Professional Fees: Labor-related	2.7	0.8
Professional Fees: Nonlabor-related	0.4	n/a
All Other Services: Labor-related	0.7	n/a
All Other Services: Nonlabor-related	6.0	11.1
Professional Liability Insurance	0.4	n/a
Capital Costs	12.4	13.8
Capital-related: Buildings and Fixtures	9.0	9.4
Capital-related: Moveable Equipment	3.4	4.4

Note: The cost weights are calculated using 3 decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detail may not add to the total due to rounding.

¹ Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

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We received public comments on the proposed methodology for deriving the cost weights of the 2024-based ESRDB market basket. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported CMS's proposal to rebase and revise the ESRDB market basket from a 2020 base year to a 2024 base year, describing this as a routine and methodologically sound update that will better reflect current labor and input costs. However, several commenters noted concerns with the timing of this rebasing relative to the addition of oral-only phosphate binders to the ESRD PPS bundled payment, which they noted did not occur until CY 2025. A few commenters stated that because the 2024 cost report data pre-dates this bundling change, that the resulting cost weights do not reflect the current cost structure created by the phosphate-binder addition in 2027, which would have an impact on the resulting market basket cost weights, and ultimately the labor-related share. The commenters stated that the lack of inclusion of the phosphate binder drug costs results in a lower drug cost weight and higher weights for other cost categories, particularly categories that feed into the labor-related share. A couple of commenters requested the market basket rebasing to be delayed, while another commenter suggested conducting a supplemental revaluation using 2025 data once available. A

commenter disagreed with a delay, arguing that more current data would not be sufficiently complete or validated in time for the CY 2027 final rule.

Response: We appreciate the commenters' support of rebasing and revising the ESRDB market basket to a 2024 base year, consistent with our longstanding practice of periodically rebasing CMS market baskets as more current and complete cost report data become available. We recognize commenters' concern that the 2024 cost report data predate the CY 2025 inclusion of oral-only phosphate binders in the ESRD PPS bundled payment, and that there could be factors that have impacted costs in subsequent years. However, rebasing on a cyclical schedule using the most recently available complete data (which at the time of this rulemaking was CY 2024) is necessary to ensure the market basket is more reflective of ESRD cost structures than the 2020-based ESRDB market basket. We will continue to monitor the cost share weights for potential effects from the incorporation of phosphate binders into the ESRD PPS bundled payment and, if technically appropriate, consider updating the ESRD market basket weights at such time.

Final Rule Action: After consideration of the public comments we received, we are finalizing the methodology for deriving the cost weights of the 2024-based ESRDB market basket as proposed without modification.

(2) Price Proxies for the 2024-Based ESRDB Market Basket

After computing the 2024-based cost weights for the ESRDB market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. Except for the proxy for professional liability insurance (PLI), all price proxies are based on BLS data and are grouped into one of the following BLS categories:

- **Producer Price Indexes—**Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (<https://www.bls.gov/ppi/>).

- **Consumer Price Indexes—**Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (<https://www.bls.gov/cpi/>). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

- **Employment Cost Indexes—**Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly

Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- **Reliability.** Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)

- **Timeliness.** Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market basket levels are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

- **Availability.** Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this would help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

- **Relevance.** Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

We believe the PPIs, CPIs, and ECIs selected meet these criteria. Therefore, we believe that they continue to be the best proxy of price changes for the cost categories to which they would be applied.

In the CY 2027 ESRD PPS proposed rule, we presented a detailed explanation of the price proxies that we proposed for each cost category weight.

(a) Health-Related Wages and Salaries

We proposed to use the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code #CIU1026220000000I) as the price proxy for health-related occupations. Of the two health-related ECIs that we considered (Hospitals and Health Care and Social Assistance), the wage distribution within the Hospital NAICS sector (622) is more closely related to the wage distribution of ESRD facilities than it is to the wage distribution of the Health Care and Social Assistance NAICS sector (62). This is the same price proxy used in the 2020-based ESRDB market basket.

(b) Management Wages and Salaries

We proposed to use the ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU202000110000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of management personnel at ESRD facilities. This is the same price proxy used in the 2020-based ESRDB market basket.

(c) Administrative Wages and Salaries

We proposed to use the ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support (BLS series code #CIU202000220000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of administrative support personnel at ESRD facilities. This is the same price proxy used in the 2020-based ESRDB market basket.

(d) Services Wages and Salaries

We proposed to use the ECI for Wages and Salaries for Private Industry Workers in Service Occupations (BLS series code #CIU202000300000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of all other non-health related, non-management, and non-administrative service support personnel at ESRD facilities.

BLS does not publish ECI for Benefits price proxies for each wages and salaries ECI; however, where these series are not published, they can be derived by using the ECI for Total Compensation and the relative importance of wages and salaries with total compensation as published by BLS for each detailed ECI occupational index. Therefore, we proposed to use these derived ECI benefit price proxies for each of the respective occupational benefit cost categories.

(e) Health-Related Benefits

We proposed to use the ECI for Benefits for All Civilian Workers in Hospitals to measure price growth of this subcategory. This is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code #CIU1016220000000I) and the relative importance of Wages and Salaries within Total Compensation as published by BLS. We believe this constructed ECI series is technically appropriate for the reasons stated in the Wages and Salaries price proxy section. This is the same price proxy used in the 2020-based ESRDB market basket.

(f) Management Benefits

We proposed to use the ECI for Benefits for Private Industry Workers in Management, Business, and Financial to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2010000110000I) and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reasons stated in the Wages and Salaries price proxy section. This is the same price proxy used in the 2020-based ESRDB market basket.

(g) Administrative Benefits

We proposed to use the ECI for Benefits for Private Industry Workers in Office and Administrative Support to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2010000220000I) and the relative importance of Wages and Salaries within Total Compensation. We believe this constructed ECI series is technically appropriate for the reasons stated in the wages and salaries price proxy section. This is the same price proxy used in the 2020-based ESRDB market basket.

(h) Services Benefits

We proposed to use the ECI for Total Benefits for Private Industry Workers in Service Occupations (BLS series code #CIU2030000300000I) to measure price growth of this subcategory. We believe this ECI series is technically appropriate for the reasons stated in the Wages and Salaries price proxy section. This is the same price proxy used in the 2020-based ESRDB market basket.

(i) Electricity

We proposed to use the PPI Commodity for Commercial Electric Power (BLS series code #WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

(j) Natural Gas

We proposed to use the PPI Commodity for Commercial Natural Gas (BLS series code #WPU0552) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

(k) ESAs

We proposed to use the PPI Commodity for Biological Products, Excluding Diagnostic, for Human Use (which we will abbreviate as PPI-BPHU) (BLS series code #WPU063719) as the price proxy for the ESA drugs in the market basket. The PPI-BPHU measures the price change of prescription biological products, and ESAs would be captured within this index, if they are included in the PPI sample. Since the PPI relies on confidentiality with respect to the companies and drugs and biological products included in the sample, we do not know if these drugs are indeed reflected in this price index. However, we believe the PPI-BPHU is an appropriate proxy to use because although ESAs may be a small part of the fuller category of biological products, we can examine whether the price increases for the ESA drugs are similar to the drugs included in the PPI-BPHU. We did this by comparing the historical price changes in the PPI-BPHU and the average sales price (ASP) for ESAs and found the cumulative growth to be consistent over the 2020 to 2024 timeframe. We will continue to monitor the trends in the prices for ESA drugs as measured by other price data sources to ensure that the PPI-BPHU is still an appropriate price proxy.

(l) All Other Drugs:

For all other drugs included in the ESRD PPS bundled payment other than ESAs, we proposed to use a blend of 47 percent of the PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations (which we will abbreviate as PPI-VNHP) (BLS series code #WPU063807), and 53 percent of the PPI Commodity for Pharmaceuticals for Human Use, Prescription (which we will abbreviate as PPI-Pharmaceuticals) (BLS series code #WPUSI07003). We continue to believe that the PPI-VNHP is an appropriate price proxy for the iron supplements commonly used in the

treatment of ESRD, and an analysis of claims data indicate that iron supplement costs and Vitamin D analogs account for about 47 percent of the All Other Drugs costs. For the remaining drugs represented in the All Other Drugs category we proposed to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription, which captures the inflationary price pressures for all types of prescription drugs rather than a single therapeutic category of drugs. Though this PPI measure includes a wide variety of prescription drugs, we believe it is technically appropriate to use a broad indicator of prescription drug price trends for three key reasons: (1) the more detailed PPI measure where we believe these types of non-ESA drugs would be captured would more likely reflect price trends not faced by ESRD facilities, such as cancer drugs, (2) there have been notable changes to the types and mix of drugs paid for under the ESRD PPS bundled payment since 2016, such as the inclusion of formerly oral-only drugs and the addition of AKI-related drugs, and (3) the potential for future changes to the types and mix of drugs that may be paid for under the ESRD PPS bundled payment. For these reasons, we believe that a broader drug index representing a larger mix of prescription drugs is technically appropriate to the price proxy for this cost category. We will continue to monitor the relative share of costs for iron supplements and other types of drugs for this cost category to determine if the 47/53 PPI blend warrants an adjustment, and if so, we would propose such an adjustment in future rulemaking. This is similar to the price proxy used in the 2020-based ESRDB market basket, but the composite weight was 50/50.

(m) Supplies

We proposed to use the PPI Commodity for Surgical and Medical Instruments (BLS series code #WPU1562) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

We believe this is a technically appropriate price proxy for this cost category. The Medicare cost report form instructions state that Supplies include the direct cost of total dialysis supplies used in furnishing dialysis services—for example, crit-lines, low volume lines and dialyzers, catheter kits, fistula needles and tape, saline flushes, bandages, chlorhexidine, tego caps for catheters, biopatch for catheter dressing, oxygen, suction, emergency supplies, monitors for vitals, and blood pressure

cuffs. We requested comments on other price indexes that could be applicable to the costs reported in this category, as the instructions may not contain the exhaustive list of supply costs that ESRD facilities include in this category. Examples of potential other price proxies would include, but are not limited to, the PPI Commodity for Medical and surgical appliances and supplies (BLS series code WPU1563) and the PPI Commodity for Miscellaneous products, Personal safety equipment and clothing (BLS series code WPU1571).

(n) Laboratories

We proposed to use the PPI Industry for Medical and Diagnostic Laboratories (BLS series code #PCU62156215) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

(o) Paper & Printing

We proposed to use a 25/75 blend of the PPI Commodity for Publications Printed Matter and Printing Material (BLS Series Code WPU094) and the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to proxy the price growth of this cost category. The 2017 Benchmark I-O data shows that 25 percent of paper and printing costs are for Printing (NAICS 323110) and the remaining costs are for Paper manufacturing (NAICS 322). The 2020-based ESRDB market basket did not have a separate cost category for paper and printing. These costs would have been included in the All Other Goods and Services cost category and proxied by the PPI—Final demand—Finished goods less foods and energy.

(p) Rubber & Plastics

We proposed to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to proxy the price growth of this cost category. The 2020-based ESRDB market basket did not have a separate cost category for Rubber & Plastics. These costs would have been included in the All Other Goods and Services cost category and proxied by the PPI—Final demand—Finished goods less foods and energy.

(q) Miscellaneous Products

We proposed to use the PPI Commodity for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to proxy the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket as these costs

were included in the All Other Goods and Services cost category.

(r) Telephone and Internet Service

We proposed to use the CPI U.S. city average for Telephone Services (BLS series code #CUUR0000SEED) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

(s) Housekeeping

We proposed to use the PPI Commodity for Cleaning and Building Maintenance Services (BLS series code #WPU49) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

(t) Operations & Maintenance

We proposed to use the ECI for Total compensation for All Civilian workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

(u) Administrative Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to proxy the price growth of this category. The 2020-based ESRDB market basket did not have a separate cost category for Administrative Services. These costs would have been included in the All Other Goods and Services cost category and proxied by the PPI—Final demand—Finished goods less foods and energy.

(v) Financial Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A000000I) to proxy the price growth of this cost category. The 2020-based ESRDB market basket did not have a separate cost category for Financial Services. These costs would have been included in the All Other Goods and Services cost category and proxied by the PPI—Final demand—Finished goods less foods and energy.

(w) Professional Fees: Labor-Related

We proposed to use the ECI for Total Compensation for Private Industry

Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket; however, the 2012 SAS data did not provide enough detailed information to split the Professional Fees category between labor-related and nonlabor-related services.

(x) Professional Fees: Nonlabor-Related

We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket; however, the 2012 SAS data did not provide enough detailed information to split the professional fees category between labor-related and nonlabor-related services.

(y) All Other Services: Labor-Related

We proposed to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to proxy the price growth of this cost category. The 2020-based ESRDB market basket did not have a separate cost category for All Other Services: Labor-related. These costs would have been included in the All Other Goods and Services cost category and proxied by the PPI—Final demand—Finished goods less food and energy.

(z) All Other Services: Nonlabor-Related

We proposed to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to proxy the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices as they are not included in the ESRD PPS (food) or are already captured elsewhere in the market basket (energy). This is the same price proxy used in other CMS market baskets, such as the IPPS, SNF, Long-term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), and Inpatient Psychiatric Facility (IPF), to proxy the growth in the remaining “All Other Services” cost category. The 2020-based ESRDB market basket did not have a separate cost category for All Other Services: Nonlabor-related, these costs would have been included in the All Other Goods and Services cost category and

proxied by the PPI—Final demand—Finished goods less food and energy.

(aa) Professional Liability Insurance

Unlike the other price proxies that are based on publicly available price indexes from BLS and other public sources, the proxy for PLI is based on data collected directly by CMS from a sample of commercial insurance carriers. We proposed to use the CMS Physician PLI index to measure the price growth of this cost category in the 2024-based ESRDB market basket. This is the same proxy used in the Medicare Economic Index (MEI) and the Home Health market basket. As detailed in the CY 2014 Physician Fee Schedule (PFS) final rule (78 FR 74271), a 2012 MEI Technical Panel expressed that the current index appropriately reflects the price changes in premiums throughout the industry.

(ab) Capital-Related: Buildings and Fixtures

We proposed to use the PPI for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category in the 2024-based ESRDB market basket. This is the same proxy used in the 2020-based ESRDB market basket.

(ac) Capital-Related: Moveable Equipment

We proposed to use the PPI Commodity for Electrical Machinery and Equipment (BLS series code #WPU117) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

Table 7 shows all the price proxies for the 2024-based ESRDB Market Basket as well as whether the price proxy was used in the 2020-based ESRDB market basket. As outlined in section II.B.1.b.(1)(b)(iii) of the proposed rule, for the 2024-based ESRDB market basket we proposed additional cost categories compared to the 2020-based ESRDB market basket. Therefore, in Table 7, the cost category expenses listed as n/a were included in the All Other Goods and Services cost category of the 2020-based ESRDB market basket and were proxied by the PPI Final demand—Finished goods less foods and energy.

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TABLE 7: Price Proxies for the 2024-based ESRDB Market Basket

<u>Cost Category</u>	<u>2024 Price Proxy</u>	<u>2020 Price Proxy</u>
Total - ESRDB24		
Compensation		
Wages and Salaries		
Health-Related Wages and Salaries	ECI - Wages and salaries for All Civilian workers in Hospitals	same
Management Wages and Salaries	ECI - Wages and Salaries for Private Industry workers in Management, Business, and Financial	same
Administrative Wages and Salaries	ECI - Wages and Salaries for Private Industry workers in Office and Administrative Support	same
Service Wages and Salaries	ECI - Wages and Salaries for Private Industry workers in Service Occupations	same
Employee Benefits		
Health-Related Benefits	ECI - Total Benefits for All Civilian workers in Hospitals	same
Management Benefits	ECI - Total Benefits for Private Industry workers in Management, Business, and Financial	same
Administrative Benefits	ECI - Total Benefits for Private Industry workers in Office and Administrative Support	same
Service Benefits	ECI - Total Benefits for Private Industry workers in Service Occupations	same
Utilities		
Electricity	PPI - Commodity - Commercial electric power	same
Natural Gas	PPI - Commodity - Commercial natural gas	same
Medical Materials and Supplies		
Pharmaceuticals		
ESAs	PPI - Commodity - Biological products for human use	same
All Other Drugs	Composite: PPI - Commodity - Vitamin, nutrient, and hematinic preparations (47%) and PPI - Commodity - Special Index - Pharmaceuticals for human use, prescription (53%)	same but 50/50 not 47/53
Supplies	PPI - Commodity - Surgical and medical instruments	same
Laboratories	PPI - Industry - Medical and Diagnostic Laboratories	same
All Other Goods		
Paper & Printing	Composite PPI - PPI Commodity for Publications Printed Matter and Printing Material (25%) and PPI - Commodity - Converted paper and paperboard products (75%)	n/a
Rubber & Plastics	PPI - Commodity - Rubber and plastic products	n/a
Miscellaneous Products	PPI - Final demand - Finished goods less foods and energy	same
All Other Services		
Telephone and Internet Service	CPI - Telephone Services	same
Housekeeping	PPI - Commodity - Cleaning and Building Maintenance Services	same
Operations & Maintenance	ECI - Total Compensation for All Civilian workers in Installation, Maintenance, and Repair	same
Administrative Services	ECI Total Compensation Private Industry workers in Office and Administrative Support	n/a
Financial Services	ECI - Total Compensation for Financial Services	n/a
Professional Fees: Labor-related	ECI - Total Compensation for Private industry workers in Professional and related	same

<u>Cost Category</u>	<u>2024 Price Proxy</u>	<u>2020 Price Proxy</u>
Professional Fees: Nonlabor-related	ECI - Total Compensation for Private industry workers in Professional and related	same
All Other Services: Labor-related	ECI - Total Compensation Private Industry workers in Service Occupations	n/a
All Other Services: Nonlabor-related	CPI - All Items less Food and Energy	n/a
Professional Liability Insurance	CMS: Physicians PLI index	n/a
Capital Costs		
Capital-related: Buildings and Fixtures	PPI - Industry - Lessors of nonresidential buildings	same
Capital-related: Moveable Equipment	PPI - Commodity - Electrical machinery and equipment	same

*The cost category expenses listed as n/a for 2020 were included in the All Other Goods and Services cost category and was proxied by the PPI Final demand - Finished goods less foods and energy.

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We invited public comments on our proposed price proxies for the 2024-based ESRDB market basket.

Final Rule Action: We did not receive any comments on the price proxies we proposed to use in the 2024-based ESRD market basket; therefore, we are finalizing the price proxies used in the 2024-based ESRD market basket as proposed.

(3) 2024-Based ESRDB Market Basket Percentage Increase Results

As discussed in the CY 2027 ESRD PPS proposed rule (91 FR 38802), we compared the yearly increase factors from CY 2021 through CY 2030 for the 2020-based ESRDB market basket and the 2024-based ESRDB market basket. At the time of the proposed rule, based on IGI's first quarter 2026 forecast, this comparison showed that the annual increase factors for individual years sometimes differed between the two indexes; however, on average the two indexes produced identical results across every period we examined: an identical projected CY 2027 update of 2.6 percent, an identical average annual growth of 3.7 percent for CY 2021 through CY 2025, and an identical average annual growth of 2.6 percent for CY 2026 through CY 2030. We did not receive any comments on this

comparison of the proposed 2024-based and 2020-based ESRDB market basket results.

For this final rule, we updated this comparison using IGI's third quarter 2026 forecast, which reflects more recent historical data and a revised economic outlook. Using this updated forecast, the trend identified in the proposed rule no longer holds for CY 2027: the 2024-based ESRDB market basket is now projected to increase 2.9 percent for CY 2027, which is 0.1 percentage point higher than the projected CY 2027 increase under the 2020-based ESRDB market basket of 2.8 percent. For the forecast period CY 2026 through CY 2030, the 2024-based ESRDB market basket percentage is also on average, 0.1 percentage point higher than the 5-year average projected increase of the 2020-based ESRDB market basket. The higher projected increase for the 2024-based market basket is attributable to a relatively higher compensation cost weight compared to the 2020-based market basket, as well as the disaggregation of the All Other Goods and Services cost category into more detailed cost categories in the 2024-based ESRD market basket. This increase is partially offset by the lower pharmaceutical cost weight in the 2024-based ESRD market

basket relative to the 2020-based ESRD market basket.

c. Labor-Related Share for ESRD PPS

We define the labor-related share (LRS) as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market.

We proposed to use the 2024-based ESRDB market basket cost weights to determine the labor-related share for ESRD facilities. Therefore, effective for CY 2027, we proposed a labor-related share of 63.5 percent, compared to the current 55.2 percent that was based on the 2020-based ESRDB market basket cost weights, as shown in Table 8. These figures represent the sum of Wages and Salaries, Employee Benefits, Housekeeping, Operations & Maintenance, Administrative Services, Professional Fees: Labor-related, All Other Services: Labor-related and 46 percent of the weight for Capital-related: Buildings and Fixtures (details discussed later in this section). We used a similar methodology to calculate the 2020-based ESRDB market basket labor-related share.

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TABLE 8: Labor-related Share for CY 2027 and CY 2026, based on ESRDB Market Basket Weights

	Labor-Related Share for CY 2027	Labor-Related Share for CY 2026	Difference
Wages and Salaries	39.0	36.5	2.5
Employee Benefits	11.9	9.5	2.4
Housekeeping	0.5	0.5	0.0
Operations & Maintenance	4.2	3.7	0.5
Administrative Services	0.3	n/a	0.3
Professional Fees: Labor-related	2.7	0.7	2.0
All Other Services: Labor-related	0.7	n/a	0.7
Capital-related: Buildings and Fixtures	9.0	9.4	-0.4
Capital-related: Buildings and Fixtures * 0.46	4.2	4.3	-0.1
Total	63.5	55.2	8.3

*Totals may not sum due to rounding

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The labor-related share for capital-related expenses reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local labor market wages (46 percent of ESRD facilities' Capital-related: Buildings and Fixtures expenses). Capital-related expenses are affected in some proportion by variations in local labor market costs (such as construction worker wages) that are reflected in the price of the capital asset. However, many other inputs that determine capital costs are not related to local labor market costs, such as interest rates. The 46-percent figure is based on regressions run for the inpatient hospital capital PPS in 1991 (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care hospitals, and skilled nursing facilities (66 FR 39585).

We invited public comments on our proposed labor-related share based on the 2024-based ESRDB cost weights. We received public comments on the calculation of the proposed labor-related share based on the 2024-based ESRDB market basket cost weights. The following is a summary of the comments we received and our responses.

Comment: Commenters offered mixed views on the proposed increase to the labor-related share from 55.2 percent to 63.5 percent. Many commenters supported the increase as a more accurate reflection of ESRD facilities'

increasing labor costs and as helpful to staffing and retention efforts. Despite this, some commenters recommended that CMS phase-in the increase in the labor-related share to minimize the impact of this change on ESRD facilities in low-wage index areas. A commenter opposed finalizing the labor-related share as proposed, arguing that it does not reflect the current cost structure faced by ESRD facilities, particularly the impact of the inclusion of the phosphate binder costs. Another commenter noted that they were unable to reach a consensus on the proposed labor-related share given the distributional impacts to their members.

Response: The labor-related share represents the portion of the ESRD PPS base payment rate that is adjusted by the wage index to reflect geographic variation in area wage levels and is derived from the cost weights in the ESRDB market basket that are labor-intensive and vary with, or are influenced by, the local labor market. These categories include Wages and Salaries, Employee Benefits, Housekeeping, Operations & Maintenance, a portion of Professional Fees, and a portion of Capital-Related Building and Fixtures expenses, consistent with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154). We recognize commenters' concern that the 2024 cost report data used to derive the 63.5 percent labor-related share predate the CY 2025 addition of oral-only phosphate binders to the ESRD PPS

bundled payment. However, we believe it is technically appropriate to rebase and revise the labor-related share to 63.5 percent to reflect the most recently available cost report data at the time of CY 2027 rulemaking. We note that in the CY 2026 ESRD PPS final rule (90 FR 53075), several commenters expressed concern regarding the labor-related share of 55.2 percent stating it was outdated.⁸ We will continue to monitor the cost report data and the market basket cost weights and, if appropriate, we will propose changes to the labor-related share during future rulemaking.

We recognize that the increase to the LRS from 55.2 percent to 63.5 percent would reduce relative payments to low-wage index areas in a budget neutral manner and we acknowledge the requests for a policy to phase-in the updated LRS. As noted previously, the updated LRS of 63.5 percent is derived from the updated ESRDB market basket based on CY 2024 cost report data. This updated LRS is based on more recent data, and we believe it is appropriate to use for CY 2027. We note that the LRS is increasing by 8.3 percentage points for CY 2027. For an ESRD facility with the lowest possible wage index value, which is the 0.600 wage index floor, the increase in LRS would result in a decrease in payment of 4.3 percent. So, for the lowest wage index facilities the payment impact of the increase to the LRS is less than 5 percent overall and the impact for most facilities (with

⁸ <https://www.govinfo.gov/content/pkg/FR-2025-11-24/pdf/2025-20681.pdf>.

higher wage index values) would be less. We believe that an across-the-board phase-in of this policy would inappropriately impact other ESRD facilities for which the higher LRS would better align payments with actual costs. As such, we do not believe a phase-in policy would be appropriate at this time.

Final Rule Action: After consideration of public comments received, we are finalizing a labor-related share of 63.5 percent effective for CY 2027, as proposed.

d. CY 2027 ESRD Market Basket Update

Under section 1881(b)(14)(F)(i) of the Act, beginning in CY 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. We proposed to use the 2024-based ESRDB market basket as described in section II.B.1.b. of the proposed rule to compute the CY 2027 ESRDB market basket percentage increase based on the best available data. Consistent with historical practice, we proposed to estimate the ESRDB market basket percentage increase based on IHS Global Inc.'s (IGI) forecast using the most recently available data at the time of rulemaking. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. As outlined in section II.B.1.d.(3) of the proposed rule, we calculated the proposed ESRDB market basket update for CY 2027 based on the 2024-based ESRDB market basket percentage increase and the proposed productivity adjustment, following our longstanding methodology.

(1) CY 2027 ESRDB Market Basket Percentage Increase

Using this methodology and IGI's first quarter of 2026 forecast of the 2024-based ESRDB market basket (with historical data through the fourth quarter of 2025), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2027 ESRDB market basket increase factor was projected to be 2.6 percent. We also proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase), we would use such data to determine the CY 2027 ESRDB market basket percentage increase in the final rule, provided such data is appropriate

(meaning methodologically consistent with the proposed approach, sufficiently complete, and available in time to be reasonably evaluated for the final rule). Based on the more recent data available for this CY 2027 ESRD PPS final rule (that is, IGI's third quarter 2026 forecast of the 2024-based ESRDB market basket with historical data through the second quarter of 2026), the CY 2027 ESRDB market basket percentage increase is 2.9 percent.

We invited public comment on the proposed CY 2027 ESRDB market basket percentage increase. The following is a summary of the comments we received and our responses. Several comments discussing the ESRDB market basket percentage increase also discussed the overall ESRD PPS payment level, the ESRD PPS base rate, budget neutrality adjustments, or payment adequacy under the ESRD PPS. These comments are summarized and responded to in section II.B.4. of this final rule.

Comment: Several commenters acknowledged the proposed ESRDB productivity-adjusted market basket increase of 1.6 percent; however, most expressed that this update is insufficient to address the current inflationary environment and workforce shortages. A few commenters pointed to their own experience or broader trends in labor costs as an indication that the update is insufficient. Several commenters noted that most of the \$17.84 proposed increase to the ESRD PPS base rate (to \$299.55) is attributable to the \$15.96 added to account for phosphate-binders, leaving an effective increase of only about \$1.88, or roughly 0.7 to 1.1 percent, once the phosphate binder amount is excluded. Some commenters underscored the importance of accurate payments to ensure ESRD facilities can hire and retain essential clinical staff, mitigate high rates of staff turnover to higher-paying settings, which has had a negative impact on patient experience. A commenter claimed that the proposed ESRDB market basket percentage increase is lower than economy-wide measures of inflation like the CPI and PPI. A couple of commenters noted that the ESRD PPS update has consistently been lower than updates under other Medicare facility-based PPS systems.

Response: We appreciate commenters' concerns regarding the CY 2027 productivity-adjusted market basket update. Section 1881(b)(14)(F)(i)(I) of the Act requires that the ESRD PPS payment rate be increased by the ESRD bundled (ESRDB) market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. We note that the phosphate binder

payment amount is a separate, distinct modification to the base rate and is not part of the ESRDB market basket update itself; we clarified that they do not offset one another. Additionally, we note that the application of several budget neutrality factors is decreasing the CY 2027 ESRD PPS base rate. We discuss these budget neutrality factors in greater detail in section II.B.4. of this final rule, however, we want to emphasize that these factors maintain estimated payment at the same amount and do not offset the overall payment impact of the ESRDB market basket update.

The 2024-based ESRDB market basket percent change is equal to the weighted price change of the individual price proxies and their respective cost weights. The cost weights are primarily derived using the freestanding ESRD Medicare cost reports and reflect relative shares of input costs needed to provide medical services to ESRD beneficiaries. Similarly, the other CMS PPS market baskets, such as the 2022-based SNF market basket and 2023-based IPPS market basket, reflect the relative share of input costs needed to provide skilled nursing and hospital care to Medicare beneficiaries based on the data reported on the respective provider cost reports.

While we understand that commenters may compare the annual updates in the ESRDB market basket to other Medicare market baskets, the ESRDB market basket is developed in accordance with section 1881(b)(14)(F)(i) of the Act requiring that the index reflect the composition of costs associated with providing renal dialysis services. These costs (and the subsequent cost distributions) are reported by ESRD facilities on the Medicare cost reports and may differ (appropriately) from the relative distribution of costs of other medical care providers such as inpatient hospitals or skilled nursing facilities. Additionally, the price proxies used in the ESRD market basket are intended to reflect the price pressures faced by ESRD facilities. While some price proxies may be similar to those used across other CMS market baskets, in most cases they are appropriately different because they reflect the price pressures faced by ESRD facilities. For example, the rate of increase in the ESRD market basket compensation category reflects the weighted average of the price increase for occupations employed by ESRD facilities.

At the time of the CY 2027 ESRD PPS proposed rule, based on the IHS Global Inc. first quarter 2026 forecast with historical data through the fourth quarter of 2025, the 2024-based ESRDB

market basket update was forecasted to be 2.6 percent for CY 2027, reflecting forecasted compensation price growth of 3.2 percent. In the CY 2027 ESRD PPS proposed rule, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final CY 2027 ESRDB market basket update for the final rule. For this final rule, we now have an updated forecast of the price proxies underlying the market basket that includes more recent historical data and reflects a revised outlook regarding the U.S. economy and expected price inflation for CY 2027. Based on IHS Global Inc.'s third quarter 2026 forecast with historical data through the second quarter of 2026, we are projecting a CY 2027 ESRDB market basket update of 2.9 percent and a final ESRDB productivity-adjusted market basket update of 1.9 percent (2.9 percent reduced by the 1.0 percentage point productivity adjustment) will be applicable, compared to the 1.6 percent productivity-adjusted market basket update that was proposed.

Comment: Many commenters stated that the ESRDB market basket has been consistently under-forecast relative to actual realized inflation, estimating a cumulative error ranging from 6.0 to 7.7 percent that a commenter did not believe were random. Many commenters continued to request that CMS adopt a forecast-error correction policy for the ESRD PPS similar to that used in the SNF PPS, including both a one-time retrospective adjustment to correct the accumulated error and a forward-looking policy triggered when the forecast error exceeds a threshold (most commenters proposed ± 0.5 percentage point). Several commenters requested greater transparency into IHS Global Inc.'s (IGI) forecasting methodology of the price proxies used in the market basket.

Response: We acknowledge commenters' continued concerns regarding market basket forecast error; however, the ESRDB market basket updates are set prospectively, which means that the update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. For instance, the CY 2027 market basket update in this final rule reflects historical data through the second quarter of CY 2026 and forecasted data through the fourth quarter of CY 2027. While there is no precedent to adjust for market basket forecast error in the ESRD PPS payment update, a forecast error can be calculated by comparing the actual market basket increase for a given year less the forecasted market basket

increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative, as has occurred since the implementation of the ESRD PPS in CY 2011. Over most of this history the forecast errors were smaller in magnitude, with the largest error (in absolute terms) prior to 2021 being an over forecast (the actual market basket increase is less than the forecasted market basket increase) of 0.8 percentage point in 2017. More recently the ESRDB market basket has been under forecast, as noted by the commenters, with larger errors occurring for 2021 through 2024. The cumulative forecast error since ESRD PPS inception (CY 2012 to CY 2025) is 5.5 percent. These recent forecast errors were largely a function of uncertainty in the overall economy and the health sector specifically due to the nature of the Public Health Emergency for COVID-19 and the unforeseen rapidly accelerating inflationary environment.

We understand the request for greater transparency into IGI's forecasting methodology of the price proxies used in the CMS market baskets; however, we continue to reiterate that CMS purchases independent forecasts of the price proxies used in the CMS market baskets from IGI, a nationally recognized economic and financial forecasting firm. The rationale for using an independent forecaster is to ensure neutrality in the update while reflecting comprehensive economic and health sector forecasting model capabilities that extend beyond CMS' expertise. As the forecasting models are proprietary in nature, we are not licensed to share information related to the detailed models. More information on the IGI economic forecasts can be found at the following website or by contacting the company directly <https://www.spglobal.com/market-intelligence/en/solutions/products/us-economic-modeling-forecasting-services>.

We recognize that forecast error under the ESRD PPS has been an important concern of commenters in recent years. We did not propose a policy to modify the ESRDB market basket update or ESRD PPS base rate for CY 2027 to address forecast error and are not finalizing any such policy in this final rule.

Final Rule Action: After consideration of the public comments we received, we are finalizing the CY 2027 ESRDB market basket percentage increase of 2.9 percent, based on the more recent data available for this CY 2027 ESRD PPS final rule (that is, IGI's third quarter 2026 forecast of the 2024-based ESRDB

market basket with historical data through the second quarter of 2026).

(2) CY 2027 Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRDB market basket percentage increase shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year (FY), year, cost reporting period, or other annual period), hereafter referred to as the "productivity adjustment".

BLS publishes the official measures of productivity for the United States economy. The productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is published by BLS as private nonfarm business total factor productivity (TFP) (previously referred to as multifactor productivity).⁹ We refer readers to <https://www.bls.gov/productivity/> for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on CMS's website at <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information>.

Based on IGI's first quarter 2026 forecast, the proposed productivity adjustment for CY 2027 (the 10-year moving average growth of TFP for the period ending CY 2027) was projected to be 1.0 percentage point. Furthermore, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 productivity adjustment in the final rule.

We invited public comments on the productivity adjustment. The following is a summary of the comments we received and our responses.

Comment: Several commenters had concerns regarding the application and magnitude of the productivity adjustment. Some commenters requested that CMS use its "special exceptions and adjustments" authority

⁹ <https://www.bls.gov/productivity/notices/2021/mfp-to-tpf-term-change.htm>.

to eliminate or reduce the 1.0 percentage point productivity cut for CY 2027. A commenter stated that the 1.0 percentage point productivity adjustment would be the largest applied in ESRD PPS history and stated that it does not reflect verifiable productivity gains specific to the dialysis sector.

Response: Section 1881(b)(14)(F)(i)(II) of the Act requires the application of the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II), to the ESRD PPS market basket increase factor. The CY 2027 productivity adjustment is derived based on the 10-year moving average growth in economy-wide, private nonfarm business total factor productivity for the period ending CY 2027. We recognize the concerns of the commenters regarding the appropriateness of the productivity adjustment; however, as we explained in response to similar comments in prior ESRD PPS final rules (90 FR 53076), we are required under section 1881(b)(14)(F)(i)(II) of the Act to apply the specific productivity adjustment described here.

Since 2015, we have provided information on the general method for calculating the productivity adjustment. This information includes providing a link (<http://www.bls.gov/productivity/>) to the most recent BLS historical TFP data, which currently allows interested parties to obtain historical TFP annual index levels for 1987 through 2025. We also provide the IGI projection model (https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/tfp_methodology.pdf), which for this CY 2027 ESRD PPS final rule is used to derive annual TFP growth rates for 2026 and 2027. The annual index level derived from this method is then interpolated to quarterly levels, and the CY 2027 productivity adjustment is equal to the percent change in the 40-quarter moving average projected level for the period ending December 31, 2027, relative to the 40-quarter moving average projected level for the period ending December 31, 2026. We believe our methodology for the productivity adjustment is consistent with section 1886(b)(3)(B)(xi)(II) of the Act, which states that the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

At the time of this final rule, the 2027 productivity adjustment reflects BLS

historical TFP data through 2025 (released on March 19, 2026) and IGI's forecasted TFP growth for 2026 and 2027. The average annual growth rate of historical TFP published by BLS for 2018 through 2025 is currently 1.0 percent and IGI is projecting average TFP growth of about 0.9 percent for 2026 and 2027 based on IGI's third-quarter 2026 forecast. Combining the historical and projected TFP data over the entire 10-year time period and interpolating into quarterly index levels results in a 10-year moving average growth rate of TFP of 1.0 percent for CY 2027 (unchanged from the CY 2027 ESRD PPS proposed rule). Interpolation of annual to quarterly data distributes the annual data across quarters by estimating the values between two known annual observations.

Final Rule Action: After consideration of the public comments we received, we are finalizing the CY 2027 productivity adjustment of 1.0 percent based on the IGI third quarter 2026 forecast.

(3) CY 2027 ESRDB Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we proposed to base the CY 2027 ESRDB market basket percentage increase on IGI's first quarter 2026 forecast of the 2024-based ESRDB market basket. We proposed to then reduce the ESRDB market basket percentage increase by the proposed productivity adjustment for CY 2027 based on IGI's first quarter 2026 forecast. Therefore, the proposed CY 2027 ESRDB market basket update was equal to 1.6 percent (proposed 2.6 percent ESRDB market basket percentage increase reduced by a proposed 1.0 percentage point productivity adjustment). Furthermore, as noted previously, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 ESRDB market basket percentage increase and productivity adjustment in the final rule. Accordingly, the final CY 2027 ESRDB market basket update is calculated using the CY 2027 ESRDB market basket percentage increase, based on IGI's third quarter 2026 forecast of the 2024-based ESRDB market basket, and the final productivity adjustment, based on IGI's third quarter 2026 forecast. Therefore, the final CY 2027 ESRDB market basket update is 1.9 percent (2.9 percent ESRDB market basket percentage

increase reduced by a 1.0 percentage point productivity adjustment).

2. CY 2027 ESRD PPS Wage Indices

a. Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, we established a policy to adjust the labor-related portion of the ESRD PPS base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. As discussed in detail later in this section, we later implemented an ESRD PPS specific wage index methodology in the CY 2025 ESRD PPS final rule (89 FR 89108 through 89117). Under current policy, we use the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117).¹⁰ OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. We most recently updated the CBSA delineations used for the ESRD PPS wage index in the CY 2025 ESRD PPS final rule (89 FR 89117) to the OMB delineations as described in OMB Bulletin No. 23–01, beginning with the CY 2025 ESRD PPS wage index.¹¹

Under § 413.231(d), a wage index floor value of 0.6000 is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values, as finalized in the CY 2023 ESRD PPS final rule (87 FR 67161). Currently, all areas with wage index values that fall below the floor are located in Puerto Rico and the U.S. Virgin Islands. However, the wage index floor value is applicable for any area that may fall below the floor. A further description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967) and the CY 2023 ESRD PPS final rule (87 FR 67161).

¹⁰ We define urban areas at § 413.231(b) as a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB. Rural areas are defined as any area outside an urban area.

¹¹ <https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf>.

An ESRD facility’s wage index is applied to the LRS of the ESRD PPS base rate. In the CY 2023 ESRD PPS final rule (87 FR 67153), we finalized the use of a LRS of 55.2 percent. In the CY 2021 ESRD PPS final rule (85 FR 71436), we finalized a temporary policy which applied a 5 percent cap on any decrease in an ESRD facility’s wage index from the prior CY. The transition would be phased in over 2 years, such that the reduction in an ESRD facility’s wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. In the CY 2023 ESRD PPS final rule (87 FR 67161), we finalized a permanent policy under § 413.231(c) to apply a 5 percent cap on any decrease in an ESRD facility’s wage index from the ESRD facility’s wage index from the prior CY. As outlined in section II.B.1.c. of the proposed rule, we proposed that the CY 2027 LRS to which the wage index would be applied is 63.5 percent. This LRS is based on the 2024-based ESRDB market basket as outlined in section II.B.1.b. of the proposed rule.

In the CY 2011 ESRD PPS final rule (75 FR 49116) and the CY 2011 final rule on Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B (75 FR 73486) we established an ESRD PPS wage index

methodology to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the hospital inpatient prospective payment system (IPPS). Historically, the ESRD PPS wage index values have been calculated without regard to geographic reclassifications authorized for acute care hospitals under sections 1886(d)(8) and (d)(10) of the Act and utilized pre-floor hospital data that are not adjusted for occupational mix. In the CY 2025 ESRD PPS final rule (89 FR 89116) we finalized a new ESRD PPS wage index methodology which uses mean hourly wage data from the BLS OEWS. This wage data is then weighted by a national ESRD facility occupational mix (NEFOM) which is derived from FTE data from freestanding ESRD facility cost reports. Treatment data from ESRD facility cost reports is also used to weight the mean hourly wage data when aggregating the wage data at a CBSA level. As set forth in § 413.196(d)(2), we update the ESRD PPS wage index using the most current wage data for occupations related to the furnishing of renal dialysis services from BLS and occupational mix data from the most recent full CY of Medicare cost reports submitted in accordance with § 413.198(b).

For a detailed explanation of the current ESRD PPS wage index methodology, see the discussion in the

CY 2025 ESRD PPS final rule (89 FR 89108 through 89117), and for a detailed explanation of the steps we use to calculate the ESRD PPS wage index according to this methodology see Addendum C of the CY 2025 ESRD PPS proposed rule available at <https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-payment-regulations-and-notice/cms-1805-p>.

b. National ESRD Facility Occupational Mix

Table 9 presents the NEFOM alongside the BLS occupation titles and codes for the occupations related to the furnishing of renal dialysis services. We noted in the CY 2027 ESRD PPS proposed rule that we were presenting the NEFOM to aid interested parties in their reconstruction of the proposed ESRD PPS wage index, but the actual ESRD PPS wage index uses the total FTEs for each occupation as described in the calculation in Addendum C of the CY 2025 ESRD PPS proposed rule rather than the rounded percentages presented in Table 9. The data in Table 9 is based on data from CY 2024 freestanding ESRD facility cost reports. We note that the rounded percentages in this table are unchanged from Table 10 of the CY 2027 ESRD PPS proposed rule (91 FR 38805), although the underlying FTE counts may have changed.

**TABLE 9: Crosswalk of BLS Occupation Codes to ESRD Facility Cost Reports
Occupation Classifications and the CY 2027 ESRD PPS Final Rule NEFOM**

ESRD PPS Colloquial Name	BLS Occupation Title	Occupation Code	ESRD Freestanding Facilities FTE Percentage*
Registered Nurses (RN)	Registered Nurses	29-1141	30.4%
Licensed Practical Nurses (LPN)	Licensed Practical and Licensed Vocational Nurses	29-2061	2.7%
Nurse Aides	Nursing Assistants	31-1131	3.2%
Technicians	Health Technologists and Technicians, All Other	29-2099	41.8%
Social Workers	Healthcare Social Workers	21-1022	4.7%
Dietitians	Dietitians and Nutritionists	29-1031	4.6%
Administrative Staff	Medical Secretaries and Administrative Assistants	43-6013	8.5%
Management	Medical and Health Services Managers	11-9111	4.1%

* Totals may not sum to 100.0 percent due to rounding

c. CY 2027 ESRD PPS Wage Index

For CY 2027, we proposed to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using the ESRD

PPS wage index methodology established in the CY 2025 ESRD PPS final rule (89 FR 89098 through 89107) and specified in § 413.196(d)(2). The ESRD PPS wage index is specific for

ESRD facilities as it uses specific wage data weighted by an ESRD facility occupational mix; this differentiates the ESRD PPS wage index from other Medicare PPSs, several of which utilize

the pre-floor, pre-reclassified IPPS wage index. We proposed to use the most recent available BLS OEWS mean hourly wage data for various occupations related to the furnishing of renal dialysis services weighted by FTE data from CY 2024 freestanding ESRD facility cost reports. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act. For CY 2027, the updated wage data used in the analysis for the proposed rule, and this final rule, are the May 2025 OEWS data released by BLS on May 15 2026, which represents data from six semiannual surveys spanning November 2022 through May 2025.¹²

For CY 2027, we proposed to update the ESRD PPS wage index to use the most recent available BLS OEWS wage data. We proposed that if more recent data became available after the analysis performed for the publication of the proposed rule and before the publication of this final rule (for example, an update to the May 2025 BLS OEWS mean hourly wage data or more complete CY 2024 cost report data), we would use such data, if appropriate, to determine the CY 2027 ESRD PPS wage index in the final rule. For this final rule, we used the most recently available CY 2024 cost report data. No update to the May 2025 BLS OEWS was published at the time of the development of this final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concerns about the current ESRD wage index methodology and stated that the legacy ESRD PPS wage index was more appropriate. A commenter expressed support for the wage index floor policy, but urged CMS to increase the floor from 0.6000 to 0.7000. Another commenter urged CMS to use its authority under section 1881(b)(14)(D)(iv) of the Act, which permits CMS to adopt such other payment adjustments as the Secretary determines appropriate, to establish a non-budget neutral wage index floor or supplemental payment adjustment for ESRD facilities in low-wage-index areas.

Response: We appreciate the concerns raised by the commenters regarding the ESRD PPS wage index methodology. We continue to believe that the ESRD facility-specific methodology is most appropriate for the ESRD PPS. We did

not propose any changes to the ESRD PPS wage index methodology for CY 2027, such as a return to the legacy ESRD PPS wage index methodology, and we are not finalizing any such changes in this final rule. We will continue to evaluate the ESRD PPS wage index methodology and consider whether changes may be appropriate through notice-and-comment rulemaking in future years.

Regarding the wage index floor, as we discussed in the CY 2023 ESRD PPS final rule, the 0.6000 wage index floor was based on a statistical analysis (87 FR 67161). We did not propose to change the wage index floor or establish any other supplemental policies to increase payments to ESRD facilities in low-wage-index areas, for CY 2027 and are not finalizing any such changes in this final rule. We will continue to monitor the appropriateness of the current wage index floor and consider whether further changes are warranted through notice-and-comment rulemaking in future years.

Comment: Some commenters expressed concern about the combined impact of the wage index and the increase to the LRS. A commenter urged CMS to consider changes to the wage index, LRS, and other adjusters together as one connected system rather than in silos.

Response: We appreciate the concerns that commenters raised about the impact of the updates to the wage index and the LRS on ESRD facilities in low-wage areas. As we discuss in section II.B.1.c. of this final rule, the increase to the LRS reflects the latest available estimates of the labor-related costs in the ESRDB market basket. We do not believe a delay to the implementation of the increase to the LRS is appropriate as the updated LRS will more accurately reflect labor costs as a percentage of the ESRD PPS bundled payment amount. Overall payment impacts, which take into account all payment changes in this final rule, are discussed in section VII.C.5.a. of this final rule.

Comment: A commenter urged CMS to revisit the ESRD-specific wage index methodology to incorporate wage data drawn specifically from the healthcare sector, or from ESRD facilities directly, rather than an all-industry BLS average, to evaluate whether the current occupational-mix weighting adequately compensates for that underlying data limitation.

Response: As we have previously noted, we recognize the limitations of the data source upon which the ESRD PPS wage index methodology is built. We discussed these limitations in the CY 2025 ESRD PPS proposed rule (89

FR 55769) and, in the CY 2025 ESRD PPS final rule (89 FR 89099, 89116), concluded that, even with these limitations, the methodology represents a significant improvement over the IPPS wage index for use in ESRD facilities. We wish to reiterate that the purpose of the wage index is to estimate the geographic variation in wages, and we believe that this wage index methodology does so appropriately. We note that although we use all-industry wages, the job codes are either for healthcare occupations, such as RNs, or are healthcare-specific occupations, such as Medical Secretaries and Administrative Assistants. Thus, we believe the ESRD PPS wage index is appropriately based on the specific occupations involved in furnishing renal dialysis services. We intend to continue to monitor the ESRD PPS wage index, including the wage data and occupational mix, and may consider future changes through notice and comment rulemaking, if appropriate.

After consideration of public comments, we are finalizing our proposal to update the ESRD PPS wage index following our established methodology. For CY 2027, the final wage index is based on wage estimates from the May 2025 BLS OEWS, which represents data from six semiannual surveys spanning November 2022 through May 2025, and the most recently available CY 2024 cost report data. The final CY 2027 ESRD PPS wage index is set forth in Addendum A and provides a crosswalk between the final CY 2026 wage index and the final CY 2027 wage index. Addendum B provides an ESRD facility level impact analysis. Both Addendum A and Addendum B are available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>.

3. CY 2027 Update to the Outlier Policy a. Background

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high-cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of ESAs necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care are frailty and obesity. A patient's specific medical condition, such as secondary hyperparathyroidism, may result in higher per treatment costs. The ESRD PPS recognizes that some

¹² <https://www.bls.gov/news.release/pdf/ocwage.pdf>.

patients require high-cost care, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

Section 413.237(a)(1) enumerates the following items and services that are eligible for outlier payments as ESRD outlier services:

- Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

- Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

- Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

- Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025.

- Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.¹³

- Renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171.

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the ESRD facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as ESRD outlier services were specified in Transmittal 2134, dated January 14, 2011.¹⁴ We use administrative issuances and guidance to continually update the renal dialysis service items available for outlier

payment via our quarterly update CMS Change Requests (CRs), when applicable. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Part D prior to 2011 to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based on our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. In past years, the MAP amount has reflected the average estimated expenditure per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted MAP per treatment plus the fixed dollar loss (FDL) amount. As described in the following paragraphs, the ESRD facility's predicted MAP amount is the national adjusted average ESRD outlier services MAP amount per treatment, further adjusted for case-mix and facility characteristics applicable to the claim. We use the term "national adjusted average" in this section of this final rule to more clearly distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient characteristics of the monthly claim. In accordance with § 413.237(c), ESRD facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for ESRD outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage—which is used to reduce the per treatment ESRD PPS base rate to account for the proportion of the estimated total Medicare payments under the ESRD PPS that are outlier payments—at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted ESRD

outlier services MAP amounts. The ESRD outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted ESRD outlier services MAP amounts for a patient are determined by multiplying the adjusted average ESRD outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the ESRD outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments.

In the CY 2023 ESRD PPS final rule, we finalized an update to the outlier methodology to better target 1.0 percent of total Medicare payments (87 FR 67170 through 67177). We explained that for several years, outlier payments had consistently landed below the target of 1.0 percent of total ESRD PPS payments (87 FR 67169). Commenters raised concerns that the methodology we used to calculate the outlier payment adjustment since CY 2011 results in underpayment to ESRD facilities, as the base rate has been reduced by 1.0 percent since the establishment of the ESRD PPS to balance the outlier payment (85 FR 71409, 71438 through 71439; 84 FR 60705 through 60706; 83 FR 56969). In response to these concerns, beginning with CY 2023, we began calculating the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years. We stated in the CY 2023 ESRD PPS final rule that we would continue to calculate the adult and pediatric MAP amounts for CY 2023 and subsequent years following our established methodology. In that same CY 2023 ESRD PPS final rule, we provided a detailed discussion of the methodology we use to calculate the MAP amounts and FDL amounts (87 FR 67167 through 67169).

Lastly, in the CY 2025 ESRD PPS final rule we finalized several methodological and policy changes to the ESRD PPS outlier policy to address concerns that interested parties have raised in recent years. First, we finalized an expansion of the definition of ESRD outlier services in § 413.237(a)(1) to include drugs and biological products that are Composite Rate Services as defined in § 413.171 (89 FR 89126). Second, we finalized a policy to include the case-mix adjusted post-TDAPA add-on payment adjustment amount in the calculation of the predicted MAP amounts when applicable (89 FR

¹³ Under § 413.237(a)(1)(vi), as of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

¹⁴ Transmittal 2033 issued August 20, 2010, was rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD PPS outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf>.

89127). Lastly, we finalized changes to the inflation factors for outlier eligible drugs and biological products, laboratory tests, and supplies. For ESRD outlier drugs and biological products, we use the projected inflation factor for ESRD outlier services that are drugs and biological products derived from the historical trend in average sales price (ASP) prices and utilization for ESRD outlier drugs (89 FR 89127 through 89130). For ESRD outlier laboratory tests and supplies, we use the growth in the Producer Price Index (PPI) Industry for Medical and Diagnostic Laboratories and the PPI Commodity for Surgical and Medical Instruments, respectively (89 FR 89129 through 89130).

b. CY 2027 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2027, we proposed to update the MAP amounts for adult and pediatric patients using the latest available CY 2025 claims data. We proposed to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2025 claims data, and to update the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2023, CY 2024, and CY 2025, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174) and the changes finalized in the CY 2025 ESRD PPS final rule (89 FR 89108 through 89130). The latest available CY 2025 claims data show that outlier payments represented approximately 0.9 percent of total Medicare payments. We proposed to update these values with the latest available data, if appropriate, in the final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concerns about the proposed increases to the FDL and MAP amounts for CY 2027. Some commenters recommended that CMS use more current 2026 utilization data instead of relying on 2025 projections. Other commenters recommended that CMS phase-in MAP and FDL amount increases more gradually rather than a single large jump.

Response: We appreciate the concerns raised by commenters regarding the projected increase in outlier payments in CY 2026 and corresponding increases in the FDL and MAP amounts for CY 2027. As we noted in the CY 2027 ESRD PPS proposed rule, these increases are primarily attributable to the projected

utilization of drugs currently paid for through the TDAPA in CY 2025, which will be ESRD outlier services in CYs 2026 and 2027. Specifically, we projected that payments under the outlier adjustment would be approximately 3.0 percent of total ESRD PPS payments in CY 2026 based on utilization from the latest available CY 2025 claims. As a result, we proposed to increase the MAP and FDL amounts to better achieve the 1.0 percent outlier target in CY 2027. Although the proposed CY 2027 adult FDL amount was higher than the CY 2026 adult FDL amount, we noted that the retrospective FDL methodology that we finalized in the CY 2023 ESRD PPS final rule accounts for the introduction of these new ESRD outlier services by calculating a retrospective trend line based on prior years' TDAPA or TPNIES utilization (87 FR 67174).

Regarding the recommendation to use more recent 2026 utilization data, we note that the latest available full CY of claims data is CY 2025, which is the source of the estimates used in the proposed rule. At the time of final rulemaking, CY 2026 utilization is only available through the end of the second quarter and does not incorporate any information about utilization or pricing patterns in the second half of CY 2026. We will take these comments into consideration to potentially inform future changes to the outlier methodology through notice and comment rulemaking.

We do not agree with the recommendation to phase-in the increases to the FDL and MAP amounts over time. As we have previously noted, we update the outlier FDL and MAP amounts each year to target outlier payments at 1.0 percent of total ESRD PPS payments. If we applied a lower FDL or MAP amount in CY 2027, we estimate that outlier payments would exceed 1.0 percent.

Comment: Several commenters urged CMS to change certain aspects of the ESRD PPS outlier policy. Some commenters stated that a lower target percentage, for example 0.5 percent of total payments, would be more appropriate. These commenters stated that section 1881(b)(14)(D)(ii) of the Act does not require the ESRD PPS outlier percentage to be 1.0 percent. Several commenters also stated that CMS should not include TDAPA and TPNIES payment amounts when calculating total ESRD PPS payments, of which outlier payments are targeted at 1.0 percent.

Response: We appreciate these comments, but we do not agree that either of the suggested revisions to the

outlier methodology would be more appropriate than the current outlier policy. As we have previously stated, while we agree that section 1881(b)(14)(D)(ii) of the Act provides the Secretary with discretion to set an appropriate outlier percentage under the ESRD PPS, we continue to believe the 1.0 percent target is more appropriate than a lower outlier percentage. As discussed in the CY 2011 ESRD PPS final rule (75 FR 49134), we established the 1.0 percent outlier percentage because it struck an appropriate balance between our objective of paying an adequate amount for the costliest, most resource-intensive patients and providing an appropriate level of payment for those patients who do not qualify for outlier payments. We continue to believe the 1.0 percent target strikes the appropriate balance, and as we further noted in the CY 2023 ESRD PPS final rule (87 FR 67171), a reduced outlier percentage may not provide the appropriate level of payment for outlier cases and may not protect access for beneficiaries whose care is unusually costly. This is because if we were to decrease the target outlier percentage, we would need to significantly increase the FDL amounts, which would make it more difficult for ESRD facilities to receive outlier payments based on their claims. We did not propose to reduce the outlier percentage for CY 2027, and we are not finalizing any such reduction in this final rule.

Likewise, we do not agree with the suggestion to exclude TDAPA and TPNIES payments from total ESRD PPS payments for the purposes of setting the FDL and MAP amounts for CY 2027. We believe that commenters incorrectly assume that excluding TDAPA and TPNIES payment amounts from this calculation would result in an increase to non-outlier payments (that is, total ESRD PPS payments other than those made as part of the outlier adjustment under the ESRD PPS). To the contrary, this suggested change to our calculations would only reduce the total amount of outlier payments, which would be 1.0 percent of a lower total ESRD PPS payment figure, without increasing other (non-outlier) payments under the ESRD PPS, since the base rate would continue to be reduced by 1.0 percent. This change would require us to increase the FDL amounts, which would make it more difficult for ESRD facilities to receive outlier payments based on their claims.

Comment: Some commenters expressed concerns about the interaction between outlier payments and new drugs. A commenter urged

CMS to develop a predictable, long-term approach for paying for new drugs after they transition out of a TDAPA period, particularly drugs within an existing ESRD PPS functional category. Another commenter encouraged CMS to reserve outlier payments for unusual clinical variation, not as a payment mechanism for new drugs, stating that new drugs are the primary driver for outlier payments in direct contrast to the purpose of the policy. This commenter stated that patients who require unusually higher-cost services are less likely to qualify for outlier payments under the current system.

Response: We agree with commenters that the outlier adjustment is intended to recognize unusual variations in cost due to the use of ESRD outlier services and is not intended as a payment mechanism for new renal dialysis drugs. Rather, the drug designation process under 42 CFR 413.234, which includes the TDAPA and post-TDAPA add-on payment adjustment, is the ESRD PPS mechanism for incorporating new renal dialysis drugs and biological products. As discussed in section II.B.6. of this final rule, we are finalizing our proposal to calculate the post-TDAPA add-on payment adjustment amounts more

frequently to reflect updated information beginning in CY 2027.

Final rule action: After consideration of public comments, we are finalizing our proposal to update the outlier FDL and MAP amounts based on the latest available data. Table 10 outlines the final FDL and MAP amounts for CY 2027. We note that these figures include all changes to the ESRD outlier services for CY 2027, including the incorporation of phosphate binders into the ESRD PPS base rate, which will mean phosphate binders are included as ESRD outlier services in CY 2027 as discussed in section II.B.7. of this final rule.

TABLE 10: Outlier Policy: Impact of Updated Data for the Final Outlier Policy

	Column I Final outlier policy for CY 2026 (based on 2024 data, price inflated to 2026) *		Column II Final outlier policy for CY 2027 (based on 2025 data, price inflated to 2027)**	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average ESRD outlier services MAP amount per treatment	\$50.64	\$24.83	\$66.33	\$43.71
Adjustments				
Standardization for ESRD outlier services	1.0113	0.9731	0.9734	0.9767
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average ESRD outlier services MAP amount	\$50.19	\$23.68	\$63.27	\$41.83
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	\$162.43	\$14.80	\$229.49	\$90.60
Patient-month-facilities qualifying for outlier payment	7.58%	14.10%	6.26%	7.51%

*Column I values match the values reported in column II of Table 3 from the CY 2026 ESRD PPS final rule (90 FR 53086).

**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2023, 2024, and 2025.

As demonstrated in Table 10, the FDL amount per treatment that determines the CY 2027 outlier threshold amount for adults (column II; \$90.60) is significantly higher than that used for the CY 2026 outlier policy (column I; \$14.80). The higher threshold amount is accompanied by an increase in the adjusted average MAP amount for ESRD outlier services from \$23.68 to \$41.83. These increases are primarily attributable to the projected utilization

of drugs that were paid for through the TDAPA in CY 2025, which will be ESRD outlier services in CYs 2026 and 2027. Specifically, we project that payments under the outlier adjustment will be approximately 2.6 percent of total ESRD PPS payments in CY 2026 based on utilization from the latest available CY 2025 claims. As a result, we are increasing the MAP and FDL amounts to better achieve the 1.0 percent outlier target in CY 2027.

Although the final CY 2027 adult FDL amount is higher than the CY 2026 adult FDL amount, we note that the retrospective FDL methodology that we finalized in the CY 2023 ESRD PPS final rule accounts for the introduction of these new ESRD outlier services by calculating a retrospective trend line based on prior years' TDAPA or TPNIES utilization (87 FR 67174). The retrospective FDL calculations for CYs 2023, 2024, and 2025 are \$116.21,

\$114.06, and \$102.63, respectively. Following the methodology we finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174), we use these retrospective FDL amounts to project a downward trend in the FDL amount for CY 2027, resulting in the final adult FDL amount of \$90.60.

For pediatric patients, there is also an increase in the FDL amount from \$162.43 to \$229.49. There is a corresponding increase in the adjusted average MAP amount for ESRD outlier services among pediatric patients, from \$50.19 to \$63.27. We noted that, as outlined in section II.B.7. of the final rule, we are including phosphate binders in the ESRD PPS base rate. Accordingly, phosphate binders will be eligible as ESRD outlier services for CY 2027, and we have included them in our calculations. Generally, including additional drugs and biological products results in increases to the MAP and FDL amounts, which is contributing to the increases to these figures for CY 2027.

We estimate that the percentage of patient-facility-months qualifying for outlier payments in CY 2027 will be 7.51 percent for adult patients and 6.26 percent for pediatric patients, based on the 2025 claims data.

c. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1.0 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. In the CY 2023 ESRD PPS final rule, we finalized a change to the outlier methodology to better achieve this 1.0 percent target (87 FR 67170 through 67174). Based on the CY 2025 claims available for this final rule, outlier payments represented approximately 0.88 percent of total payments, which is slightly below the 1.0 percent target.

4. Impacts to the CY 2027 ESRD PPS Base Rate

a. Background

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, the ESRD PPS base rate, and calculating the per-treatment payment amount, which are codified at §§ 413.220 and 413.230. The CY 2011 ESRD PPS final rule also included a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for

projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility-level adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, home and self-dialysis training add-on payment adjustment, the TDAPA, the TPNIES, the post-TDAPA add-on payment adjustment, and the TPEAPA for CYs 2024, 2025 and 2026.

b. Annual Payment Rate Update for CY 2027

We proposed an ESRD PPS base rate for CY 2027 of \$299.55. As discussed in section II.B.1.d. of this final rule, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 ESRDB market basket update in the final rule. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters who discussed ESRD PPS payment policy supported increasing the overall ESRD PPS payment rate. Many commenters, however, expressed an opinion that the proposed ESRD PPS base rate of \$299.55 was insufficient, which added to many commenters' concerns about current payment adequacy under the ESRD PPS. Some commenters noted that this represented an increase of \$17.84 over the CY 2026 base rate, \$15.96 of which is attributable to the increase to the base rate to account for phosphate binders, resulting in an increase to the base rate of only \$1.88 outside of the phosphate binder increase. As discussed in section II.B.7. of this final rule, many commenters supported the base rate increase for phosphate binders. Many commenters acknowledged that the reason why the proposed increase outside of the phosphate binder increase

was low was due to the application of various budget neutrality factors. Many commenters expressed support for implementing certain proposed policy changes non-budget neutrally.

Several comments discussed payment adequacy under the ESRD PPS. Multiple commenters listed figures published by MedPAC listing Original Medicare margins for ESRD facilities, noting that MedPAC has found low and occasionally negative margins in past reports.

Many commenters included current or potential future impacts of lower than appropriate ESRD PPS payments. These impacts included difficulty hiring and maintaining skilled staff, ESRD facility closures, difficulty providing certain expensive drugs and biological products, or other cost reductions. Some commenters provided data on ESRD facility closures, predominantly in rural areas, and attributed this trend to concerns about payment adequacy under the ESRD PPS. Several commenters attributed perceived lower than appropriate payment to historical under-forecasts of the ESRDB market basket, which they stated has resulted in a lower base rate than if forecasts had been accurate.

A few commenters indicated a belief that payment rates under the ESRD PPS were generally adequate. A few commenters raised concerns related to cost sharing under the ESRD PPS and noted that higher payment rates result in increased beneficiary cost sharing. A commenter requested CMS assess and publicly report the beneficiary level impact of ESRD PPS payment changes on cost sharing.

Response: We appreciate support for increasing the ESRD PPS base rate and recognize the concerns over the payment amounts set under the ESRD PPS. The final ESRDB market basket update is 1.9 percent, higher than the proposed value of 1.6 percent, which we believe addresses some of the commenters' concerns about payment adequacy. However, we want to clarify a few points about the proposed CY 2027 ESRD PPS base rate. The proposed ESRD PPS base rate of \$299.55 was derived from the CY 2026 ESRD PPS base rate of \$281.71, the proposed ESRDB market basket update of 1.6 percent, the proposed increase to incorporate phosphate binders of \$15.96, the proposed wage index budget neutrality factor of 1.00267, and the proposed budget neutrality factor of 0.98783 for the proposed policy changes to the LVPA, pediatric payment adjustments and training add-on adjustments. As highlighted by some commenters, the reason why the CY

2027 ESRD PPS base rate is not, excluding the increase of phosphate binders, 1.6 percent higher (or, 1.9 percent higher using the final ESRDB market basket update) than the CY 2026 ESRD PPS base rate is due to the budget neutrality factors applied. We discuss why we believe applying these budget neutrality factors is appropriate in the following comment and response.

We strongly caution commenters against using the ESRD PPS base rate as an estimate of payment adequacy or as a proxy for payment levels under the ESRD PPS. The proposed budget neutrality factor of 0.98783 reduced the proposed ESRD PPS base rate because the proposed policy changes to the LVPA, training add-on, and pediatric payment modifiers result in increases to the payment adjustment factors. If we did not apply this budget neutrality factor, then these policy changes would increase the overall payment rate. The ESRD PPS base rate is not intended to be an average payment amount for ESRD beneficiaries; it is a base unit of payment that is then adjusted by several adjustment factors, almost all of which increase payment. In practice, the ESRD PPS base rate represents the payment provided for an adult patient aged 70–79, with the average BSA of 1.9, has none of the applicable comorbidities, is not in the onset period, and is being treated in an ESRD facility that is neither rural nor low volume and that has a wage index value of 1.000. We acknowledge that the base rate, adjusted by the wage index and other adjustment factors (on a budget neutral basis), represents the payment for beneficiaries with AKI, as required by section 1834(r)(1) of the Act.

We acknowledge the quality concerns that commenters have raised and the data points cited by commenters. We note that in its March 2026 MedPAC Report to Congress¹⁵, MedPAC concluded that payment adequacy indicators for ESRD facilities were generally favorable and recommended that the Congress should eliminate the payment rate update for CY 2027. We agree with MedPAC that payment under the ESRD PPS is appropriate. We share the concerns of commenters regarding ESRD facility closures, especially in rural areas, and note that this was a significant motivator for our changes to the LVPA, which are finalizing, as discussed in section II.B.8. of this final rule.

We agree with the commenters who stated that payments under the ESRD PPS were generally adequate and recognize their concerns related to beneficiary cost sharing. We note that the increase to beneficiary cost sharing associated with the ESRDB market basket update is the result of a statutorily required payment rate update, but we will continue to be mindful of the impact of our payment policies on beneficiary out-of-pocket costs.

Comment: A commenter stated that CMS should reconsider our longstanding philosophy on applying budget neutrality factors. The commenter acknowledged that budget neutrality was appropriate for certain changes, like case mix adjustment factors, but believed it would not be appropriate for others. The commenter highlighted the new ESRD PPS wage index methodology implemented in the CY 2025 ESRD PPS final rule (89 FR 89198 through 89107) as an example of a policy which they believe should not be implemented budget neutrally.

Response: We appreciate the commenter's perspective regarding the application of budget neutrality under the ESRD PPS. Section 1881(b)(14) of the Act establishes the statutory framework for the ESRD PPS. Section 1881(b)(14)(A)(ii) of the Act established the aggregate payment level when the ESRD PPS was implemented in CY 2011, while section 1881(b)(14)(D) of the Act requires or authorizes various adjustments to payments under the ESRD PPS, including adjustments based on case mix, for high-cost outliers, for low-volume facilities, and such other payment adjustments as the Secretary determines appropriate.

Consistent with this statutory framework and our longstanding implementation of the ESRD PPS, we generally believe that it is appropriate to implement changes to payment adjustments in a budget-neutral manner when those changes are intended to redistribute payments to better account for differences in relative resource use for costs that are already reflected in the ESRD PPS base rate. In these circumstances, the purpose of modifying the adjustment is to improve the distribution of payments under the ESRD PPS rather than to increase or decrease the aggregate level of payment for renal dialysis services. This approach is consistent with how we have historically applied budget neutrality to payment adjustments under the ESRD PPS, including case-mix adjustments.

For example, we applied a budget neutrality factor when implementing the

new ESRD PPS wage index methodology in CY 2025 because labor costs are already reflected in the ESRD PPS base rate and the purpose of the wage index is to account for geographic differences in those labor costs (89 FR 89097 through 89116). The new ESRD PPS wage index methodology changed how the labor-related portion of the existing ESRD PPS payment is distributed among ESRD facilities based on geographic differences in wages; it did not add a new category of renal dialysis services or costs to the ESRD PPS bundle. Accordingly, we believe it was appropriate to implement that methodology in a budget-neutral manner so that the change in methodology itself would not increase or decrease aggregate ESRD PPS payments (89 FR 89109).

We believe it is appropriate to implement the modifications to the LVPA in this rule in a budget neutral manner. Section 1881(b)(14)(D)(iii) of the Act requires the ESRD PPS to include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities exceed the costs incurred by other facilities. The costs of furnishing renal dialysis services at low-volume facilities were represented in the data used to establish the ESRD PPS bundled payment (75 FR 49117 through 49125). The purpose of modifying the LVPA therefore is to better align relative payments with relative resource use among ESRD facilities, rather than to recognize a new category of costs or services that is not already reflected in the ESRD PPS base rate. Implementing such modifications without a corresponding budget neutrality adjustment would increase aggregate ESRD PPS payments solely as a result of a policy intended to recalibrate how payments for existing bundled costs are distributed. Our intention in proposing modifications to payment adjustments like the LVPA is generally to make payments that align relative payments with relative resource use, not to increase the ESRD PPS base rate.

By contrast, where a policy accounts for costs that are not already reflected in the ESRD PPS base rate, an increase in aggregate ESRD PPS payments may be appropriate. As discussed elsewhere in this final rule, phosphate binders were not included in the ESRD PPS base rate when the ESRD PPS was established in CY 2011 and were not subsequently incorporated into the base rate. Accordingly, we are increasing the ESRD PPS base rate to account for the costs of phosphate binders rather than offsetting that increase through a budget neutrality adjustment.

¹⁵ Medicare Payment Advisory Commission. March 2026. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC. <https://www.medpac.gov/document/march-2026-report-to-the-congress-medicare-payment-policy/>.

We therefore do not believe that all changes to the ESRD PPS necessarily should be treated identically for purposes of budget neutrality. Rather, in determining whether budget neutrality is appropriate for a particular policy, we consider the applicable statutory authority and the nature and purpose of the payment change. In general, where a change to an existing payment adjustment is intended to improve the allocation of payments for costs already reflected in the ESRD PPS base rate, we believe that implementing the change in a budget-neutral manner appropriately preserves the distinction between redistributing payments under the ESRD PPS and increasing the payment amount to account for additional costs or services. Where a policy instead incorporates costs or services that are not already reflected in the ESRD PPS base rate, an increase in aggregate ESRD PPS payments may be appropriate, subject to the applicable statutory authority.

Comment: Commenters expressed concerns over the estimated 1.1 percent increase to overall ESRD PPS payments. Commenters noted that this is lower than the proposed 1.6 percent ESRDB market basket update. Many commenters stated a belief that this 1.1 percent payment increase was insufficient, comparing it to a wide array of estimates for inflation.

Response: We want to clarify why the estimated year-over-year payment increase is less than the proposed 1.6 percent ESRDB market basket update. In our impact analysis, both for the CY 2027 ESRD PPS proposed rule and for this final rule, we simulate claims for CY 2026 and CY 2027 using available CY 2025 claims data. As part of this simulation, we applied the 1.6 percent ESRDB market basket update, as well as simulated the impact of other changes to ESRD PPS payment, including those resulting from policies proposed in the CY 2027 ESRD PPS proposed rule. There are several factors which contribute to the year-over-year estimated increase in payments being lower than the proposed ESRDB market basket update; however, the primary cause driving the lower year over year payment impact for CY 2027 presented in the CY 2027 proposed rule was the impact of the routine changes to the outlier policy as shown in Table 26 in the ESRD PPS CY 2027 proposed rule (91 FR 38860). We estimated and are currently estimating outliers being larger than 1 percent for 2026 and we proposed MAP and FDL amounts to better achieve the 1.0 percent outlier target for CY 2027 (91 FR 38808). So, it is not surprising that the proposed

change to the MAP and FDL amounts are expected to result in a year-over-year decrease in estimated outlier payments.

While we believe that the estimated year-over-year payment increase is an important metric that interested parties may consider when evaluating the impact of the rule, we caution interested parties to interpret it carefully. We include detailed impacts on each of the new policies and many of the routine and established policies in Table 30 in section VII.C.5.a. of this final rule. We note that table indicates that the year-over-year increase in ESRD PPS payments is 2.4 percent, which is higher than the 1.9 percent ESRDB market basket update. These figures are different for the same underlying reasons as the difference the commenters noted.

Comment: A commenter stated CMS should conduct and publish a comprehensive ESRD PPS base rate adequacy analysis using the most current available and representative facility cost-report data.

Response: We continually monitor the adequacy of payment rates under the ESRD PPS, which we have used to inform payment policies. We reiterate that we caution interested parties against using the base rate as a proxy for overall payment amount, as budget neutral increases to payment adjustments reduce the base rate while maintaining the overall payment amount. We note that in proposing the modifications to the LVPA, we published an analysis of payment-to-cost ratios using CY 2024 cost report data and CY 2025 claims data (91 FR 38822). However, in discussing that analysis, we also discussed the limitations of such an analysis in terms of evaluating payment adequacy. We will take into consideration the commenter's suggestion that we publish further analysis on payment rate adequacy.

Comment: A commenter stated that a market basket update cannot fully address payment adequacy since it is designed to measure changes in prices for a fixed mix of inputs. The commenter stated that even a perfectly calibrated market basket update would only preserve the purchasing power of the existing base rate but would not determine whether that original rate was adequate to start with.

Response: We agree with the commenter that the ESRDB market basket update, as required by section 1881(b)(14)(F) of the Act, represents the change in prices of the same mix of goods and services purchased in the base period. It is not intended to capture changes in the types of renal dialysis

services purchased by ESRD facilities. We recognize the extent to which this can create perceived payment adequacy concerns, especially as it pertains to new renal dialysis technologies that may be higher cost than those which were utilized when the base rate was established. Additionally, we recognize that it is not a measure of payment adequacy for the initial CY 2011 ESRD PPS base rate. The CY 2011 ESRD PPS base rate was established in the CY 2011 ESRD PPS final rule based on statutory requirements, which required that overall payments be equal to 98 percent of what they would have been under the composite rate system (75 FR 49071 through 49083). We believe that payments under the ESRD PPS are sufficient for ESRD facilities to furnish renal dialysis services to Medicare beneficiaries. Although the original payment rate from 2011 and the ESRDB market basket increases are based on that fixed bundle of goods and services; by providing a single bundled payment we allow ESRD facilities to provide whichever services are most appropriate for a patient. This gives ESRD facilities the flexibility to provide new technologies to patients when appropriate.

Final Rule Action: After consideration of public comments, we are finalizing a CY 2027 ESRD PPS base rate of \$297.52, which is approximately a 5.6 percent increase from the CY 2026 ESRD PPS base rate of \$281.71. The final CY 2027 ESRD PPS base rate is calculated as follows:

Wage Index Budget Neutrality Adjustment Factor: We compute a wage index budget neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2027, we did not propose and are not finalizing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the CY 2027 wage index budget neutrality adjustment factor using treatment counts from the 2025 claims and facility-specific CY 2026 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2026. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2027. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the CY 2027 ESRD PPS wage index and LRS for CY 2027. The total of these payments becomes the new CY 2027 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget neutrality factor is calculated as the target amount divided

by the new CY 2027 amount. When we multiplied the wage index budget neutrality factor by the applicable CY 2027 estimated payments, aggregate Medicare payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget neutrality adjustment factor ensures that the wage index updates and revisions do not increase or decrease aggregate Medicare payments. The final CY 2027 wage index budget neutrality adjustment factor is 1.00260. As we are not finalizing any changes to our established ESRD PPS wage index methodology, this final CY 2027 wage index budget neutrality adjustment factor reflects the impact of all established wage index policies, including the ESRD PPS wage index methodology based on BLS OEWS and freestanding ESRD facility cost report FTE data, the 5 percent cap on year-to-year decreases in wage index values, the 3-year rural phase-out for ESRD facilities in CBSAs which we currently consider urban that were considered rural prior to the new delineations adopted in CY 2025,¹⁶ and the final LRS.

We note that the final CY 2027 wage index budget neutrality factor does not include any impacts associated with the TPEAPA, as was the case with the CY 2024 combined wage index-TPEAPA budget-neutrality factor finalized for CY 2024. Although CY 2026 is the final year of the TPEAPA, as outlined in section II.B.9. of this final rule, we are finalizing budget neutral changes to the payment adjustments that apply for pediatric ESRD patients. Rather than calculating a combined TPEAPA-wage index budget neutrality factor, we are including the effect of the end of TPEAPA in the budget neutrality factor for those pediatric policy changes. This is more consistent with what we have done in past years where there were multiple budget neutral policy changes outside the wage index in a given year, such as in the CY 2016 ESRD PPS final rule (80 FR 69011). This final budget neutrality factor does not incorporate the budget neutrality impact of the end of the TPEAPA effective January 1, 2027. That budget neutrality impact is included in the budget neutrality factor for the

payment adjustments described in this final rule.

Budget Neutrality Factor for Certain Payment Adjustment Changes: As outlined in sections II.B.8., II.B.9., and II.B.10. of this final rule, under the authority granted by section 1881(b)(14)(D)(iv) of the Act, we are finalizing changes to the LVPA, payment adjustments for pediatric ESRD patients, and home and self-dialysis training add-on payment adjustment. We are finalizing that the changes to these payment adjustments will be budget neutral and result in a combined budget neutrality factor of 0.98864. This is calculated based on the combined budget neutrality factor of 0.98901 for the LVPA changes, 0.99999 for the pediatric changes, and 0.99964 for the changes to the home and self-dialysis training add-on payment adjustment. As noted previously, this budget neutrality factor also includes the budget neutrality impact associated with the end of the TPEAPA effective January 1, 2027.

Addition of Phosphate Binders to the ESRD PPS Base Rate: As outlined in section II.B.7. of this final rule, for CY 2027 we are finalizing our proposal to modify the ESRD PPS base rate in a non-budget neutral manner, by adding \$12.85 to account for phosphate binders in the ESRD PPS bundled payment. This application would yield a CY 2027 ESRD PPS base rate of \$294.56 (\$281.71 + \$12.85 = \$294.56), prior to the application of the market basket update and budget neutrality factors. We are finalizing the application of the budget neutrality factors to the base rate after the increase to the ESRD PPS base rate, as proposed. As noted in the CY 2027 ESRD PPS proposed rule, this is appropriate because those budget neutrality factors were calculated using estimated payments, which incorporated the increase to the base rate.

Market Basket Update: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase. As outlined in section II.B.1.d. of this final rule, the final CY 2027 ESRDB market basket increase based on IGI's third quarter 2026 forecast of the final 2024-based ESRDB market basket is 2.9 percent. For CY 2027, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As previously discussed in section II.B.1.d.(2) of this final rule, the final CY 2027 productivity adjustment is 1.0

percentage point based on IGI's third quarter 2026 forecast of the 10-year moving average of TFP for the period ending CY 2027, thus yielding a final CY 2027 ESRDB market basket update of 1.9 percent for CY 2027. Therefore, the final CY 2027 ESRD PPS base rate is \$297.52 ($(\$294.56 \times 1.00260 \times 0.98864) \times 1.019 = \297.52).

5. Updated Average per Treatment Offset Amount for Home Dialysis Machines

In the CY 2021 ESRD PPS final rule (85 FR 71427), we expanded eligibility for the TPNIES under § 413.236 to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. To establish the TPNIES basis of payment for these items, we finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to calculate a pre-adjusted per treatment amount, using the prices they establish under § 413.236(e) for a capital-related asset that is a home dialysis machine, as well as the methodology that CMS uses to calculate the average per treatment offset amount for home dialysis machines that is used in the MACs' calculation, to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate. For purposes of this final rule, we refer to this as the "TPNIES offset amount."

The methodology for calculating the TPNIES offset amount is set forth in § 413.236(f)(3). Section 413.236(f)(3)(v) states that effective January 1, 2022, CMS annually updates the amount determined in § 413.236(f)(3)(iv) by the ESRDB market basket update. The TPNIES for capital-related assets that are home dialysis machines is based on 65 percent of the MAC-determined pre-adjusted per treatment amount, reduced by the TPNIES offset amount, and is paid for two CYs.

There are currently no capital-related assets that are home dialysis machines set to receive the TPNIES for CY 2027, as the TPNIES payment period for the Tablo® System ended on December 31, 2023, and there are no TPNIES applications for CY 2027. However, as required by § 413.236(f)(3)(v), we proposed to update the TPNIES offset amount annually according to the methodology described previously.

We proposed a CY 2027 TPNIES offset amount for capital-related assets that are home dialysis machines of \$10.60, based on the application of the proposed CY 2027 ESRDB market basket update of 1.6 percent (proposed 2.6 percent ESRDB market basket percentage increase reduced by the

¹⁶ We note that the 3-year rural phase-out finalized in the CY 2025 ESRD PPS final rule (89 FR 89117 through 89119) ends December 31, 2026. As discussed in that rule, we will not apply a rural transition adjustment factor in CY 2027 or any future year for ESRD facilities that were rural in CY 2024 but were redesignated as urban for CY 2025. The final wage index budget neutrality factor for CY 2027 reflects the budget neutrality associated with the end of this policy.

proposed 1.0 percentage point productivity adjustment) to the CY 2026 TPNIES offset amount of \$10.43. We requested public comments on our proposal to update the TPNIES offset amount for capital-related assets for CY 2027.

We did not receive any comments on this proposal. We are finalizing an offset amount of \$10.63, based on the application of the final CY 2027 ESRDB market basket update of 1.9 percent (final 2.9 percent ESRDB market basket percentage increase, reduced by the final 1.0 percentage point productivity adjustment). We calculated the CY 2027 TPNIES offset amount using the most recent data available as proposed. The CY 2027 TPNIES offset amount for capital-related equipment that are home dialysis machines used in the home is \$10.63 (\$10.43 $\times$ 1.019).

6. Post-TDAPA Add-On Payment Adjustment Updates

In the CY 2024 ESRD PPS final rule we finalized an add-on payment adjustment for certain new renal dialysis drugs and biological products, which would be applied for 3 years after the end of the TDAPA period (88 FR 76388 through 76397). This adjustment, known as the post-TDAPA add-on payment adjustment, is adjusted by the patient-level case-mix adjusters and is applied to every ESRD PPS claim. In the CY 2024 ESRD PPS final rule we also clarified that for each year of the post-TDAPA add-on payment adjustment period we would update the post-TDAPA add-on payment adjustment amounts based on utilization and ASP of the drug or biological product. The post-TDAPA add-on payment adjustment amounts are calculated based on the methodology codified at § 413.234(g), which is the total drug expenditure divided by the total ESRD PPS treatments multiplied by the case mix standardization for the time period and the 0.65 risk sharing factor, and the ESRDB pharmaceutical price proxy for the payment year (88 FR 76396). In the CY 2025 ESRD PPS final rule (89 FR 89136) we finalized our proposal to publish the post-TDAPA add-on payment adjustment amount after the final rule in certain circumstances to ensure that the post-TDAPA add-on payment adjustment amount can be calculated using 12 months of utilization data.

For CY 2026 there is one drug, Korsuva® (difelikefalin), included in the calculation of the post-TDAPA add-on payment adjustment for each of the four calendar quarters and one drug, DefenCath®, included in the calculation for only the third and fourth calendar

quarters. In the CY 2026 ESRD PPS final rule (90 FR 53091 through 53092), we finalized that the post-TDAPA add-on payment adjustment amount for Korsuva® would be \$0.1131 for CY 2026 and we finalized a post-TDAPA add-on payment adjustment amount for DefenCath® of \$2.3710 for the third and fourth quarter of 2026.

a. CY 2027 Post-TDAPA Add-On Payment Adjustment Amounts

For CY 2027, there will be four drugs in the 3-year period following the end of their TDAPA period that are potentially eligible to be included in the calculation of the post-TDAPA add-on payment adjustment. Section 413.234(c)(3) states that, should CMS not receive the latest full calendar quarter of ASP data for a drug or biological product during the TDAPA or post-TDAPA add-on payment adjustment period, we will not pay any post-TDAPA add-on payment adjustment for such product in any future year. We refer to this policy at § 413.234(c)(3) as the conditional ASP policy, which was finalized in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76396) and is modeled off the conditional ASP policy for the TDAPA which was finalized in the CY 2020 ESRD PPS final rule (84 FR 60677 through 60681). The intention of these policies is to ensure that the TDAPA and post-TDAPA add-on payment adjustment are always based on the best available data, which we consider to be ASP (when ASP is available). The third quarter of 2026 reflecting the first quarter of 2026 sales would be the latest quarter of ASP data at the time of rulemaking for the proposed rule.¹⁷ As discussed in the CY 2026 ESRD PPS final rule (90 FR 53090), CMS did not receive ASP data for Jesduvroq® for the third quarter of 2025, which reflects sales for the first quarter of 2025. As such, we stated in the CY 2027 ESRD PPS proposed rule that we are not including Jesduvroq® in the calculation of the post-TDAPA add-on payment adjustment for CY 2027 (91 FR 38810). Therefore, there are three drugs included in the calculation of the post-TDAPA add-on payment adjustment for CY 2027, conditioned on the continued receipt of the latest full calendar quarter of ASP data for each renal dialysis drug.

The post-TDAPA add-on payment adjustment period for one of these drugs, Korsuva®, began on April 1, 2024, so Korsuva® would be included in the calculation for the post-TDAPA add-

on payment adjustment for only the first quarter of CY 2027. DefenCath® began its TDAPA period on July 1, 2024, so its post-TDAPA add-on payment adjustment period began on July 1, 2026. Vafseo® began its TDAPA period January 1, 2025, so its post-TDAPA add-on payment adjustment period will begin January 1, 2027. Both drugs would be included in the post-TDAPA add-on payment adjustment calculation for each quarter of CY 2027, conditioned on the continued receipt of ASP data.

In the CY 2027 ESRD PPS proposed rule, we presented the proposed post-TDAPA add-on payment adjustment amounts for each of these drugs based on the most recently available full year of utilization data at the time of rulemaking, which was from January 2025 to December 2025 for the CY 2027 ESRD PPS proposed rule. Consistent with the methodology finalized in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76389), we stated that we would update these calculations with the most recent available utilization and pricing data in the final rule. We invited public comments on the estimated CY 2027 post-TDAPA add-on payment adjustment amounts presented in Table 12 of the ESRD PPS CY 2027 proposed rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concern about our post-TDAPA add-on payment adjustment policy. Commenters expressed concern that lagged ASP data may not be reflective of current prices. Numerous commenters requested we modify our methodology for calculating the post-TDAPA add-on payment adjustment to be based on per-claim utilization and only apply to claims that include the drug or biological product in question and not be time limited. Commenters generally expressed the opinion that such a payment adjustment would better support innovation within the ESRD PPS. A commenter stated the belief that the current post-TDAPA add-on payment adjustment methodology has harmed patients by failing to provide a sustainable pathway for payment for new drugs and biological products and their suggested methodology would better support innovation.

Response: As we discussed in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76396) we do not agree that a methodology based on per-claim utilization would be appropriate for the post-TDAPA add-on payment adjustment, because it would directly

¹⁷ ASP quarters are based on calendar years, so 3rd quarter ASP reflecting 1st quarter data would reflect data from January to March of the given year.

incentivize utilization of a particular drug or biological product, which we noted can result in overutilization. While the TDAPA and post-TDAPA add-on payment adjustments share the goal of supporting access to new renal dialysis drugs or biological products used to treat or manage a condition in an ESRD PPS functional category, the TDAPA's short-term objectives are more consistent with a methodology that is based on per-claim utilization. As we discussed in the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56935; 84 FR 60654), for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate the new drugs and biological products and make appropriate changes in their business operations to adopt such products. We also explained that the TDAPA provides additional payments for such associated costs and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative. The TDAPA for renal dialysis drugs and biological products in existing ESRD PPS functional categories is inherently transitional in nature and therefore not permanent. We later finalized a post-TDAPA add-on payment adjustment beginning in CY 2024 that provides a glidepath for inclusion of such new renal dialysis drugs and biological products into the ESRD PPS. In the CY 2024 ESRD PPS proposed rule (88 FR 42460), we stated that a 3-year period for the post-TDAPA add-on payment adjustment would be consistent with the transition period that was finalized at the beginning of the ESRD PPS, when ESRD facilities were transitioned from receiving payments under the composite rate payment system to receiving payments under the ESRD PPS (75 FR 49162).

We believe that the current post-TDAPA add-on payment adjustment methodology provides the most appropriate incentives for ESRD facilities to be efficient with resources, while providing an appropriate level of payment that supports access to new renal dialysis drugs and biological products. We recognize that the policy would not permanently maintain increased payments for new renal dialysis drugs and biological products that receive the TDAPA, and we do not believe that such a permanent increase in payments would be appropriate. We did not propose any changes to the methodology used to calculate the post-TDAPA add-on payment adjustment, the 3-year timeframe of the adjustment

or the application of the post-TDAPA add-on payment adjustment to all ESRD PPS claims for CY 2027 and are not finalizing any such changes in this final rule.

Final Rule Action: After consideration of public comments, we are finalizing our proposal to maintain the post-TDAPA add-on payment adjustment calculation methodology for CY 2027.

b. Updating the Post-TDAPA Add-On Payment Adjustment Amounts Quarterly

As discussed in the CY 2024 ESRD PPS final rule (88 FR 76393) and codified at 42 CFR 413.234(g), we have finalized a post-TDAPA add-on payment adjustment which is based on the most recent year of utilization data and is calculated annually in each rulemaking cycle. Under § 413.234(g)(1), CMS bases the post-TDAPA add-on payment adjustment calculation on the most recent 12-month period of utilization for the new renal dialysis drug or biological product and the most recent available full calendar quarter of ASP data.

In the CY 2025 ESRD PPS final rule, we established a policy that, when there is less than a full year's utilization data at the time of rulemaking, we would publish the post-TDAPA add-on payment adjustment amount via Change Request (CR) once we have a full 12 months of data (89 FR 89135). Under this policy, we would still include an estimated post-TDAPA add-on payment adjustment amount in the proposed rule and update that estimated amount in the final rule, but we would note that the estimated amount presented in the final rule is subject to change. In the CY 2025 ESRD PPS final rule, we reiterated that we believe it is important to have a full year's utilization data when determining the post-TDAPA add-on payment adjustment amount so that the post-TDAPA add-on payment adjustment appropriately captures the utilization of the drug or biological product as required by § 413.234(g)(1) (89 FR 89135 through 89136). However, in that final rule, we did not finalize other circumstances where we would update the post-TDAPA add-on payment adjustment amount for a drug or biological product. Specifically, we stated that we did not intend to routinely update the post-TDAPA add-on payment adjustment amount quarterly, as we believed this would make it more difficult for ESRD facilities to estimate payments (89 FR 89136).

In response to the proposed post-TDAPA add-on payment amount published in the CY 2026 ESRD PPS proposed rule, we received a comment

requesting we finalize a policy to publish the post-TDAPA add-on payment adjustment for DefenCath® after the publication of the final rule (90 FR 53091). This commenter stated that publishing the post-TDAPA add-on payment adjustment amount for that drug later, such that data from the third and fourth quarter of 2025 could be included in the calculation, would be more appropriate as it would reflect more recent data that shows increased utilization compared to the third and fourth quarter of 2024. Specifically, they noted that they believed 2024 utilization for DefenCath® was depressed by several factors, which they stated would result in an undervaluing of the drug for the post-TDAPA add-on payment adjustment. The commenter highlighted that the 2024 data would be two years old by the time the post-TDAPA add-on payment adjustment would begin in quarter 3 2026. While we did not finalize any such changes in the CY 2026 ESRD PPS final rule, we noted that we would evaluate whether additional flexibilities may be warranted in the post-TDAPA add-on payment adjustment calculation.

Since the publication of the CY 2026 ESRD PPS final rule, interested parties have repeated their concerns with our established post-TDAPA add-on payment adjustment methodology and stated a belief that it undervalued new drugs and biological products. We understand the concerns raised by interested parties regarding the time delay of the post-TDAPA add-on payment adjustment calculation inherent in calculating the adjustment once per year during rulemaking and we have reevaluated our policy. Although it is important for ESRD facilities to be able to accurately plan for payments, we recognize that rapid changes in price or utilization might not be fully captured by the current methodology.

In the CY 2027 ESRD PPS proposed rule, we proposed to modify the post-TDAPA add-on payment adjustment methodology to routinely calculate the post-TDAPA add-on payment adjustment amounts each quarter. The proposed modification would not change the steps for the calculation of the post-TDAPA add-on payment adjustment, insofar as we would still be using the most recent quarter of ASP data and the most recently available full year of utilization data. We only proposed to perform the calculation more frequently and publish the amounts in CRs quarterly. We acknowledged that, in the past, we have stated that setting the post-TDAPA add-on payment amount once annually would improve ESRD facilities' ability

to estimate payments. However, after further consideration, we stated that we believe that setting the post-TDAPA add-on payment amount more frequently would better align the post-TDAPA add-on payment amounts with the actual utilizations and prices of the renal dialysis drugs and biological products. This would allow for the payment amount to consistently be based on the most recently available data, which we believe would address concerns which interested parties have raised that the post-TDAPA add-on payment adjustment amount was often based on outdated data. Under this proposal, we explained that we would still publish the first quarter post-TDAPA add-on payment adjustment amounts annually in the rule. We stated that we expect that generally the post-TDAPA add-on payment adjustment amounts would not change drastically throughout the year, which would allow ESRD facilities to reasonably estimate payments in advance.

As we proposed calculating the post-TDAPA add-on payment adjustment quarterly, we also proposed modifying the conditional ASP policy such that the post-TDAPA add-on payment adjustment would stop the next quarter after a non-submission of ASP data. We explained in the proposed rule that this is a change from current policy, in which we would wait until the next rulemaking year to discontinue the post-TDAPA add-on payment adjustment for a drug which failed to report ASP. We noted that the amount of time for processing a CR can vary and there are occasionally other factors which create additional lag in the use of claims data, so the time periods utilized in a given quarter could change from year to year. However, we stated that we intend to generally aim to include data from two quarters prior. For example, for the third quarter post-TDAPA add-on payment adjustment, which begins July 1 of a year, we would generally include data through December of the prior year, but depending on the year December data may not be available at the time of processing. We proposed that, if an update to the post-TDAPA add-on payment adjustment amount for a given quarter is not operationally feasible for

some currently unforeseen reason, the post-TDAPA add-on payment adjustment amount for the prior quarter would continue until such a time when updating it is operationally feasible. We stated that we intend to include the months from which the post-TDAPA adjustment was calculated, as well as the quarter of ASP we used for the calculation in the CR. We stated that we would also note any discontinuations of the post-TDAPA add-on payment adjustment due to failure to submit ASP data.

We proposed changes to § 413.234(c)(3) to state that the post-TDAPA add-on payment adjustment would be calculated quarterly and that if we stopped receiving ASP data, we would not calculate the post-TDAPA add-on payment adjustment for any subsequent quarter (rather than any subsequent year, as it currently reads). We also proposed changes to § 413.234(g) to state that we would calculate the post-TDAPA add-on payment adjustment quarterly.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concern that quarterly recalculation of post-TDAPA add-on payment amounts would negatively impact payment stability that facilities rely on for long-term planning. One LDO noted that CMS previously recognized, in prior rulemaking, that setting the post-TDAPA add-on payment adjustment amount annually supports ESRD facilities' long-term planning and budgeting for such drugs after the TDAPA period, and that facilities have operated under the expectation that a payment amount established for a calendar year remains fixed for that year. This commenter stated this predictability is crucial to ESRD facilities' pharmaceutical operations, which fundamentally rely on the ability to plan and budget over the longer term and expressed concern about the continued post-TDAPA add-on payment adjustment policy.

Some commenters stated that whereas annual updates to post-TDAPA add-on payment adjustment have provided

sufficient information to establish payment amounts and support accurate payment, quarterly recalculations add complexity and uncertainty without a commensurate benefit.

Response: While we agree with commenters that quarterly updates to the post-TDAPA add-on payment adjustment amount may result in more frequent changes to this adjustment; and therefore, would provide less certainty regarding the amount that will apply throughout an entire calendar year, we do not agree that more frequent recalculation necessarily results in greater payment instability. Rather, quarterly recalculation allows changes in price and utilization to be reflected incrementally as more recent data become available, instead of allowing those changes to accumulate until the next annual recalculation. As a result, quarterly calculation may produce smaller, more gradual changes in the post-TDAPA amount from one quarter to the next and reduce the potential for a larger change when the amount is recalculated for a new calendar year.

As we explained in the proposed rule, we proposed to change our policy to calculate the post-TDAPA add-on payment adjustment amount quarterly because rapid changes in price or utilization might not be fully captured by the current annual methodology. Table 11 demonstrates this distinction by comparing the actual post-TDAPA add-on payment adjustment amounts for the second, third, and fourth quarters of 2026 with what the post-TDAPA add-on payment adjustment amounts would have been if they were calculated on a quarterly basis based on the latest available data, as we proposed to do for CY 2027. As shown in this table, if the methodology that we proposed for CY 2027 were applied to CY 2026, it would have resulted in more gradual change in post-TDAPA add-on payment adjustment amounts from one quarter to the next than having a larger change between Q4 2026 and Q1 2027. This results in greater stability and directly addresses the key concerns that commenters raised in response to the CY 2026 post-TDAPA add-on payment adjustment amounts.

TABLE 11: Actual and Hypothetical Recalculated Post-TDAPA Add-on Payment Adjustment Amounts for Q2 2026 through Q1 2027

Quarter	Actual post-TDAPA add-on payment adjustment amount	Recalculated post-TDAPA add-on payment adjustment amount*
Q2 (April – June) 2026	\$0.1131	\$0.0644
Q3 (July – September) 2026	\$2.4841	\$5.6147
Q4 (October – December) 2026	\$2.4841	\$7.3963
Q1 (January – March) 2027	\$9.3983	\$9.3983

*The recalculated post -TDAPA add-on payment adjustment amounts reflect the drugs which were included in the calculation of the post-TDAPA add-on payment adjustment for each quarter. Thus, the Q1 2027 post-TDAPA add-on payment adjustment amount includes the amount calculated for Vafseo®.

We do not believe that the proposed quarterly calculation adds complexity with no commensurate benefit. As we demonstrate in Table 11, the proposed methodology has a clear benefit of capturing ongoing changes in price and utilization resulting in more appropriately adjusted payment. Furthermore, as we explained in the proposed rule, the proposed modification would not change the steps for the calculation of the post-TDAPA add-on payment adjustment, insofar as we would still be using the most recent quarter of ASP data and the most recently available full year of utilization data. We only proposed to perform the calculation more frequently and publish the amounts in CRs quarterly. Therefore, we do not believe that the proposed methodology increases the complexity of the calculation. Rather, we believe this more responsive approach appropriately balances ESRD facilities’ interest in payment predictability with the need for the post-TDAPA add-on payment adjustment amounts to reflect more current price and utilization data.

CMS appreciates commenters’ concerns about payment predictability and the administrative burden of more frequent updates. As we discussed in the CY 2024 ESRD PPS final rule establishing the post-TDAPA add-on payment adjustment, this policy was designed to balance two goals: supporting ESRD facilities’ long-term planning and budgeting for new renal dialysis drugs and biological products and ensuring the payment adjustment accurately reflects the actual prices and utilization of those products (88 FR 76393). We first adopted a policy of calculating post-TDAPA add-on payment adjustment amounts annually, because we believed this would sufficiently address changes in price and utilization over time. However, our

experience implementing the post-TDAPA add-on payment adjustment methodology since CY 2024 has shown that annual calculation, on its own, may not adequately serve the accuracy side of that balance. Specifically, as we noted in the CY 2027 ESRD PPS proposed rule, in response to the CY 2026 ESRD PPS proposed rule, we received a comment requesting that CMS delay publication of the post-TDAPA add-on payment adjustment amount for DefenCath® until later-quarter 2025 data could be incorporated, because the calculation otherwise relied on 2024 utilization data that would have been two years old by the time the adjustment took effect in the third quarter of CY 2026. While we did not finalize a change in response to that comment, we stated in the CY 2026 ESRD PPS final rule that we would evaluate whether additional flexibilities were warranted in the post-TDAPA add-on payment adjustment calculation (90 FR 53091). Since that rule was published, interested parties have continued to raise similar concerns, stating a belief that the post-TDAPA add-on payment adjustment policy’s core purpose of supporting continued access to these products could be better supported by using more recent data to establish the post-TDAPA add-on payment adjustment amounts. The proposed approach of recalculating post-TDAPA add-on payment adjustment amounts quarterly aligns with payment for Part B drugs more broadly, which is more dynamic and responsive to such changes. We believe the proposed post-TDAPA add-on payment adjustment methodology appropriately balances the twin goals of the policy, while allowing the payment amount to track actual drug pricing and utilization more closely than the annual approach has allowed.

Comment: Several commenters expressed concern about the proposed conditional ASP policy. Commenters stated that abruptly ending the post-TDAPA add-on payment adjustment due to a manufacturer’s non-submission of ASP data could create uncertainty around continued coverage and availability of these therapies.

Response: We appreciate the concerns that commenters have raised. As we discussed in the CY 2024 ESRD PPS final rule (88 FR 76393 through 76394), if drug manufacturers were to stop submitting ASP data for products that are included in the calculation of the post-TDAPA add-on payment adjustment, and we had to revert to basing calculation of the post-TDAPA add-on payment adjustment on WAC or invoice pricing, we believe we would be overpaying for the add-on payment adjustment. Therefore, we established a policy to make payment of the post-TDAPA add-on payment adjustment conditional on receiving ASP data. We continue to believe that our longstanding conditional ASP policy appropriately balances access to new renal dialysis drugs with responsible spending from the Medicare Trust Fund.

Final Rule Action: After consideration of public comments, we are finalizing our proposal to update the post-TDAPA add-on payment adjustment quarterly via CRs. As such, in this final rule we are only finalizing the post-TDAPA add-on payment adjustment amounts for the first quarter of CY 2027, however we note that these amounts also represent our estimate of the post-TDAPA add-on payment adjustment amount for all quarters of CY 2027 based on the best available current data. The cumulative estimated post-TDAPA add-on payment adjustment amount for each quarter is presented in Table 12.

TABLE 12: Estimated Post-TDAPA Add-on Payment Adjustment Amounts for CY 2027 by Quarter

Quarter	Add-on amount for Korsuva®	Add-on amount for DefenCath®	Add-on amount for Vafseo®	Total post-TDAPA add-on payment adjustment amount
Q1 (January – March)*	\$0.0793	\$8.3220	\$0.9970	\$9.3983
Q2 (April – June)	\$0	\$8.3220	\$0.9970	\$9.3190
Q3 (July – September)	\$0	\$8.3220	\$0.9970	\$9.3190
Q4 (October – December)	\$0	\$8.3220	\$0.9970	\$9.3190

*Q1 2027 Post-TDAPA add-on payment adjustment amounts are final.

7. Incorporation of Phosphate Binders Into the ESRD PPS Base Rate

a. Background

(1) Background on Oral-Only Renal Dialysis Drugs

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. Section 1881(b)(14)(B) of the Act defines renal dialysis services, and clause (iii) of such section states that these services include other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, and any oral equivalent form of such drug or biological.

As we explained in the CY 2011 ESRD PPS final rule (75 FR 49044), we interpret this provision as including not only injectable drugs and biological products used for the treatment of ESRD (other than ESAs) and any oral form of ESAs, which are included under clause (ii) of section 1881(b)(14)(B) of the Act, but also all oral drugs and biological products used for the treatment of ESRD and furnished under Title XVIII of the Act. We also concluded that, to the extent oral-only drugs or biological products used for the treatment of ESRD do not fall within clause (iii) of section 1881(b)(14)(B) of the Act, such drugs or biological products would fall under clause (iv) of such section, and constitute other items and services used for the treatment of ESRD that are not described in clause (i) of section 1881(b)(14)(B) of the Act.

We finalized and issued the payment policies for oral-only renal dialysis service drugs and biological products in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053), where we defined renal dialysis services at § 413.171 to include other drugs and biological products furnished to

individuals for the treatment of ESRD and for which payment was made separately prior to January 1, 2011, under Title XVIII of the Act, including oral-only drugs (75 FR 49044). We further described oral-only drugs as those that have no injectable equivalent or other form of administration (75 FR 49038 through 49039). Although we included oral-only renal dialysis service drugs and biological products in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS until January 1, 2014, and codified this delay at § 413.174(f)(6) (75 FR 49042). In the CY 2011 ESRD PPS proposed and final rules (74 FR 49929 and 75 FR 49038, respectively), we noted that the oral-only drugs and biological products that we identified were limited to phosphate binders and calcimimetics, which fall into the bone and mineral metabolism ESRD PPS functional category. We stated that there were certain advantages to delaying the implementation of payment for oral-only drugs and biological products, including allowing ESRD facilities additional time to make operational changes and logistical arrangements to furnish oral-only renal dialysis drugs and biological products to their patients. Accordingly, we codified the delay in payment for oral-only renal dialysis drugs and biological products at § 413.174(f)(6) and specified that payment to an ESRD facility for renal dialysis drugs and biological products with only an oral form will be incorporated into the ESRD PPS payment rate on January 1, 2014. Since oral-only drugs were generally not covered under Medicare Part B at this time, the delay of payment under the ESRD PPS allowed these drugs to continue being paid for under Medicare Part D until inclusion in the ESRD PPS, consistent with CMS's discussion at 75 FR 49052 through 49053.

On January 3, 2013, the American Taxpayer Relief Act of 2012 (ATRA) was enacted. Section 632(b) of ATRA precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2016. Accordingly, in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), we delayed payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS until January 1, 2016. We implemented this statutory change through revisions of the effective date at § 413.174(f)(6) from January 1, 2014, to January 1, 2016, as discussed in the applicable final rule. In addition, we changed the date when oral-only renal dialysis service drugs and biological products would be eligible as ESRD outlier services under the outlier policy described in § 413.237(a)(1)(iv) from January 1, 2014, to January 1, 2016.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) was enacted. Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA and precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2024. We implemented this statutory change in the CY 2015 ESRD PPS final rule (79 FR 66262) through revisions by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at § 413.174(f)(6) from January 1, 2016, to January 1, 2024. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs under the ESRD PPS from January 1, 2016, to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that, in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must

use data from the most recent year available.

On December 19, 2014, the Achieving a Better Life Experience Act of 2014 (ABLE) was enacted. Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, and precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2025. We implemented this statutory change in the CY 2016 ESRD PPS final rule (80 FR 69027 through 69028) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS through revisions at § 413.174(f)(6) from January 1, 2024, to January 1, 2025. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2024, to January 1, 2025.

(2) ESRD PPS Drug Designation Process and Phosphate Binders

In addition to delaying implementation of the policy for oral-only renal dialysis service drugs and biological products under the ESRD PPS, as discussed in the proposed rule, PAMA included section 217(c), which provided that as part of CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process that allows us to recognize when an oral-only renal dialysis service drug or biological product is no longer oral-only, and a process to include new injectable and intravenous (IV) products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount to reflect the costs of furnishing that product.

In accordance with section 217(c)(1) of PAMA, we established § 413.234(d), which provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by FDA (80 FR 69024 through 69027). We defined an oral-only drug at § 413.234(a) to mean a drug or biological product with no injectable equivalent or other form of administration other than an oral form.

Additionally, in accordance with section 217(c)(2) of PAMA, we codified the drug designation process at § 413.234(b). In the CY 2016 ESRD PPS

final rule (80 FR 69024), we finalized that the drug designation process is dependent upon the ESRD PPS functional categories, consistent with our policy since the implementation of the ESRD PPS in 2011, which we discussed in detail in the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053). We explained that, in the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053), to identify drugs and biological products that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services (defined at § 413.171) that would be included in the ESRD PPS base rate, we performed an extensive analysis of Medicare payments for Part B drugs and biological products billed on ESRD claims and evaluated each drug and biological product to identify its category by indication or mode of action. We stated in the CY 2011 ESRD PPS final rule that categorizing drugs and biological products on the basis of drug action allows us to determine which categories (and therefore, the drugs and biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047).

In the CY 2016 ESRD PPS final rule, we also explained that, in CY 2011 ESRD PPS rulemaking, we grouped the injectable and IV drugs and biological products into ESRD PPS functional categories based on their action (80 FR 69014). This was done for the purpose of adding new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. In the CY 2016 ESRD PPS final rule, we finalized the definition of an ESRD PPS functional category at § 413.234(a) as a distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69077).

We finalized a policy in the CY 2016 ESRD PPS final rule (80 FR 69017 through 69022) that, effective January 1, 2016, if a new injectable or IV product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. We stated that the new injectable or IV product qualifies as an outlier service. We further explained that the ESRDB market basket updates the ESRD PPS base rate annually and accounts for price changes of the drugs and

biological products reflected in the bundled payment.

We established at § 413.234(b)(2) that, if the new injectable or IV product is used to treat or manage a condition for which there is not an existing ESRD PPS functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the transitional drug add-on payment adjustment (TDAPA) described at § 413.234(c). Finally, the new injectable or IV product is added to the ESRD PPS base rate following payment of the TDAPA.

(3) Transitional Drug Add-On Payment Adjustment (TDAPA) Framework

The TDAPA is a payment adjustment under the ESRD PPS for certain new renal dialysis drugs and biological products, as codified at § 413.234(c). As discussed in the CY 2019 and CY 2020 ESRD PPS final rules, for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products. Furthermore, the TDAPA provides additional payments for such associated costs and promotes competition among the products within the ESRD PPS functional categories, while also focusing Medicare resources on products that are innovative (83 FR 56935 and 84 FR 60654, respectively). For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the TDAPA is a pathway toward a potential base rate modification (83 FR 56935).

In the CY 2016 ESRD PPS final rule, we finalized a policy at § 413.234(c) to base the TDAPA on pricing methodologies under section 1847A of the Act and pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than two years (80 FR 69019 through 69025). During the time a new injectable or IV product is eligible for the TDAPA, it is not eligible as an ESRD outlier service. We established that, following payment of the TDAPA, the ESRD PPS base rate will be modified, if appropriate, to account for the new

injectable or IV product in the ESRD PPS bundled payment.

(4) Payment Policy for Phosphate Binders and Calcimimetics

In the CY 2016 ESRD PPS final rule (80 FR 69024 through 69027), CMS also established an exception to the drug designation process for calcimimetics and phosphate binders. We noted that in the CY 2011 ESRD PPS proposed and final rules (74 FR 49929 and 75 FR 49038, respectively), the only oral-only drugs and biological products we identified were phosphate binders and calcimimetics, which fall into the bone and mineral metabolism ESRD PPS functional category. We stated that we defined these oral-only drugs as renal dialysis services in our regulations at § 413.171 (75 FR 49044), delayed the Medicare Part B payment for these oral-only drugs until CY 2014 at § 413.174(f)(6), and continued to pay for them under Medicare Part D. We explained in the CY 2016 ESRD PPS final rule that, under § 413.234(b)(1), if injectable or IV forms of phosphate binders or calcimimetics are approved by FDA, these drugs would be considered reflected in the ESRD PPS bundled payment because these drugs are included in an existing functional category. Therefore, CMS does not make additional payment to ESRD facilities for these drugs.

However, we recognized the uniqueness of these drugs and stated that we will not apply this process to injectable or IV forms of phosphate binders and calcimimetics when they are approved because payment for the oral forms of these drugs was delayed and payment was never included in the ESRD PPS base rate to account for these drugs (80 FR 69025 through 69027). Instead, we finalized a policy that once the injectable or IV phosphate binder or calcimimetic is FDA approved and has a Healthcare Common Procedure Coding System (HCPCS) code, we would issue a CR to pay for all forms of the phosphate binder or calcimimetic using the TDAPA based on the payment methodologies under section 1847A of the Act, which could include average sales price (ASP) + 6 percent (ASP + 6), for a period of at least two years. In the CY 2016 ESRD PPS final rule, we explained that this would allow us to collect data reflecting current utilization of both the oral and injectable or IV forms of the drugs, as well as payment patterns and beneficiary co-insurance, before we add these drugs to the ESRD PPS bundled payment. We stated that during this period we would not pay outlier payments for these drugs. We further stated that at the end of the two

or more years, we would adopt the methodology for including the phosphate binders and calcimimetics into the ESRD PPS bundled payment through notice-and-comment rulemaking (80 FR 69025).

(5) Evolution of TDAPA Policies and Payment for Calcimimetics

In the CY 2019 and 2020 ESRD PPS final rules (83 FR 56927 through 56949 and 84 FR 60653 through 60677, respectively), we revised the drug designation process regulations at § 413.234(a), (b), and (c) to reflect that the process applies to all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration (83 FR 56932). In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories (83 FR 56942 through 56943). Finally, we revised § 413.234(c) to reflect that the TDAPA would be based on 100 percent of ASP instead of the pricing methodologies available under section 1847A of the Act, which includes ASP + 6. We explained that historically, the six percent add-on to ASP was used to cover administrative and overhead costs. However, the ESRD PPS base rate includes dollars for administrative complexities and overhead costs for drugs and biological products, so we stated that we believe ASP, without + 6, was a reasonable basis for the TDAPA under the ESRD PPS (83 FR 56943 through 56944). In the CY 2020 ESRD PPS final rule, we revised the eligibility criteria for the TDAPA, including defining specific New Drug Application (NDA) categories that are excluded from the TDAPA (84 FR 60659 through 60673).

In 2017, FDA approved an injectable calcimimetic. In accordance with the policy finalized in the CY 2016 ESRD PPS final rule, we issued a CR to implement payment under the ESRD PPS for both the oral and injectable forms of calcimimetics using the TDAPA. CR 10065, Transmittal 1889, issued August 4, 2017, replaced by Transmittal 1999, issued January 10, 2018, implemented the TDAPA for calcimimetics effective January 1, 2018. The TDAPA for calcimimetics was paid at ASP + 6 for the first two years of the TDAPA period (83 FR 56944) and was paid ASP for the third year of the TDAPA period (84 FR 60676). In the CY 2020 ESRD PPS final rule we stated that after the first two years, sufficient time had passed for ESRD facilities to address any administrative complexities and overhead costs that may have arisen

related to furnishing calcimimetics (84 FR 60673). We then went through notice-and-comment rulemaking to incorporate calcimimetics into the ESRD PPS base rate beginning January 1, 2021, after the TDAPA payment period ended on December 31, 2020, using the methodology codified at § 413.234(f) (85 FR 71404 through 71410).

(6) TDAPA Implementation for Oral Phosphate Binders

In the CY 2025 ESRD PPS final rule, CMS finalized payment for oral phosphate binders under the ESRD PPS using the TDAPA, consistent with § 413.234(c), with incorporation into the ESRD PPS base rate to occur through future rulemaking after sufficient data collection (89 FR 89136 through 89153). This implementation fulfilled existing regulations at § 413.174(f)(6) that required oral-only drugs to be paid for under the ESRD PPS beginning in CY 2025, after multiple legislative delays (ATRA, PAMA, and ABLE) dating back to the original CY 2014 implementation date, as outlined in section II.B.7.a.(1) of the proposed rule.

Since January 1, 2025, oral phosphate binders have been paid under the ESRD PPS through the TDAPA, which is payable under our current regulations for a period of at least two years until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available. The TDAPA amount for phosphate binders currently includes 100 percent of ASP plus a flat rate increase of \$36.41 for monthly ESRD PPS claims to cover the operational costs associated with supplying phosphate binders to ESRD facilities. This \$36.41 figure was based on 6 percent of per-patient phosphate binder spending based on Part D cost and utilization data from before the beginning of the TDAPA period (89 FR 89148). CMS has stated that we would increase the ESRD PPS base rate to account for the average per-treatment phosphate binder spending, consistent with past policy for similar drugs (calcimimetics), after the end of the TDAPA period for phosphate binders (89 FR 89148).

b. Proposed Methodology for Incorporating Phosphate Binders Into the ESRD PPS Base Rate

(1) General Discussion of Claims Data and Intention

As we discussed previously, oral phosphate binders have been paid under the ESRD PPS through the TDAPA since January 1, 2025. In the CY 2016 ESRD PPS final rule, CMS discussed that phosphate binders fall

into the bone and mineral metabolism ESRD PPS functional category but are not accounted for in the base rate. We stated that we will utilize the TDAPA to collect utilization data before incorporating these drugs into the ESRD PPS base rate (80 FR 69025). We explained that this would allow CMS to collect data reflecting current utilization of oral phosphate binders, as well as payment patterns and beneficiary co-insurance, and after a period of at least 2 years, we would adopt the methodology for including these drugs in the ESRD PPS bundled payment through notice-and-comment rulemaking. This would be consistent with section 217(a)(2) of PAMA, which requires the Secretary to use data from the most recent year available when establishing payment for oral-only drugs under the ESRD PPS.

As discussed in the CY 2027 ESRD PPS proposed rule, we have collected sufficient claims data to conduct a rate-setting analysis for phosphate binders (91 FR 38815). Specifically, we have collected robust claims data since January 1, 2025, and analyzed the utilization of various oral phosphate binders, including sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate. We monitored the ASP data available during the specific utilization periods. Our overall analysis of ESRD claims data for CYs 2025 and 2026 indicated utilization patterns across the various phosphate binder formulations, with variations in ASP reflecting the different product types and market dynamics within this therapeutic class.

Therefore, we stated in the proposed rule that we believe we are at the step of the ESRD PPS drug designation process (outlined at § 413.234) where we propose the methodology for modifying the ESRD PPS base rate to account for phosphate binders in the ESRD PPS bundled payment for CY 2027. We noted that we believe that a base rate increase is warranted in the case of phosphate binders because, as discussed in the CY 2011 ESRD PPS final rule, oral-only drugs, which included phosphate binders, were not included in the ESRD PPS at the inception of the bundled payment system (75 FR 49043 through 49044) and currently remain unaccounted for within the ESRD PPS base rate. We proposed to add a per-treatment amount to the ESRD PPS base rate to include phosphate binders in the ESRD PPS bundled payment amount for dates of service on or after January 1, 2027.

In developing the proposed methodology for including phosphate

binders into the ESRD PPS base rate, we considered the methodology that we used when we incorporated calcimimetics into the ESRD PPS base rate beginning for CY 2021, as well as the methodology we used when we included Part B drugs and biological products in the ESRD PPS base rate as part of our initial implementation of the ESRD PPS. In the CY 2021 ESRD PPS final rule (85 FR 71404 through 71410), we discussed how we established the methodology for incorporating calcimimetics into the ESRD PPS base rate using utilization data from Medicare claims and applying ASP to establish the price for each drug form.

In addition, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49064), we established a dialysis treatment as the unit of payment. Consistent with the approach we used to include calcimimetics in the ESRD PPS base rate and the ESRD PPS unit of payment, we proposed a similar methodology in the CY 2027 ESRD PPS proposed rule to calculate a one-time modification to the ESRD PPS base rate on a per-treatment basis to account for phosphate binders. The proposed methodology is similar to the calcimimetics approach because we would determine utilization of the drugs, in this case, phosphate binders, along with the payment amounts associated with each phosphate binder product based on ASP, consistent with our established TDAPA pricing policy.

The following sections review each element of our proposed methodology in detail. As an overview, we proposed to calculate a per-treatment amount for phosphate binders that would be added to the ESRD PPS base rate. We proposed to apply 100 percent of the ASP value from the most recent calendar quarter ASP calculations to the utilization data for phosphate binders between April 1, 2025, and December 31, 2025, based on Medicare ESRD claims data, for the proposed rule. For the calculations in this final rule, utilization data is based on ESRD claims from between April 1, 2025, and June 30, 2026. This would provide the phosphate binder expenditure amount. We proposed to then multiply the phosphate binder expenditure amount by 1.06, consistent with the methodology that we used to calculate the flat rate add-on per-monthly claim amount of \$36.41 during the TDAPA period, to yield the adjusted phosphate binder expenditure amount. Next, we proposed to divide the adjusted phosphate binder expenditure amount by the total number of hemodialysis-equivalent dialysis treatments paid between April 1, 2025, and December 31, 2025, under the ESRD PPS (April 1, 2025, and June 30, 2026,

for this final rule). We proposed to reduce this average per-treatment amount by one percent to account for the outlier policy, since phosphate binders would be ESRD outlier services eligible for outlier payments beginning January 1, 2027, under the proposal. We proposed to add the resulting amount to the ESRD PPS base rate, as outlined in section II.B.4. of the proposed rule. We noted that this amount would stay in the base rate and be subject to the annual updates (ESRDB market basket update and application of wage index budget neutrality adjustment factor). Under the proposal, CMS would stop paying for these drugs through the TDAPA for dates of service on or after January 1, 2027.

We stated that, if finalized, this proposal would complete the implementation of § 413.174(f)(6), which provides that oral-only renal dialysis drugs are paid under the ESRD PPS beginning January 1, 2025, and that separate payment for oral-only phosphate binders is no longer provided beginning January 1, 2025. We described that the proposal, if finalized, would establish the methodology for incorporating phosphate binders into the ESRD PPS base rate following the TDAPA period. We proposed revising our drug designation regulation at § 413.234 by adding paragraph (h) to set forth the methodology for modifying the ESRD PPS base rate to account for the costs of phosphate binders. The proposed paragraph (h) would include the data sources and the steps we would take to calculate a per-treatment amount. We proposed that, for dates of service on or after January 1, 2027, oral phosphate binders would no longer be paid for under the ESRD PPS through the TDAPA (§ 413.234(c)) and would be paid for through the ESRD PPS base rate and be eligible for outlier payments as ESRD outlier services under § 413.237.

We noted that the methodology proposed in the proposed rule is only for modifying the ESRD PPS base rate to include phosphate binder drugs. This is consistent with our established policy for renal dialysis drugs and biological products that are not considered to be included in the ESRD PPS base rate, and as outlined at § 413.234(c) and (d). This policy states that we would propose and adopt the methodology for modifying the ESRD PPS base rate, if appropriate, to account for the products through notice-and-comment rulemaking after sufficient claims data collection through the TDAPA process.

(2) Determining Utilization of Phosphate Binders

For the CY 2027 ESRD PPS proposed rule calculation, we analyzed the utilization of phosphate binders reported on the ESRD facility claims for CY 2025. For the calculations in this final rule, we analyzed the utilization of phosphate binders reported on the ESRD facility claims between April 1, 2025, and June 30, 2026. ESRD facilities report this information to CMS on Medicare ESRD facility claims, that is, the 837-institutional form with bill type 072X. The various phosphate binders are reported using their respective HCPCS codes, including but not limited to codes for sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate. For purposes of this rate-setting analysis, we considered utilization of phosphate binders as the units of the products furnished to an ESRD beneficiary.

For purposes of calculating the proposed addition to the ESRD PPS base rate, we proposed to use the latest available claims data with dates of service from April 1, 2025, through December 31, 2025, rather than beginning January 1, 2025 (April 1, 2025, and June 30, 2026, for this final rule). We noted that we believe this approach is appropriate because the first quarter of CY 2025 (January 1, 2025, through March 31, 2025) reflects a transitional period during which oral phosphate binders moved from coverage under Medicare Part D to payment under the ESRD PPS as TDAPA-eligible renal dialysis drugs. Utilization patterns during this initial transition period may not be representative of stable, ongoing utilization under the ESRD PPS, as ESRD facilities were in the process of establishing billing, dispensing, and operational workflows for these products. To ensure that our base rate calculation reflects a more accurate and representative picture of phosphate binder utilization and costs under the ESRD PPS, we proposed to exclude first quarter 2025 data and begin our reference period on April 1, 2025. We stated that we believe this approach would produce a more reliable estimate of the costs that should be incorporated into the ESRD PPS base rate beginning January 1, 2027. We noted that claims which have been received, processed, paid, and passed to the National Claims History (NCH)¹⁸ file are considered “complete” because they have been

adjudicated, and that we proposed to consider only complete claims when calculating the ESRD PPS base rate addition for phosphate binders.

For the CY 2027 ESRD PPS final rule, we proposed to update this calculation with the most recent available claims data, which we anticipated to be claims with dates of service from April 1, 2025, through July 31, 2026 (that is, claims that were received, processed, paid, and passed to the NCH File as of July 2026).

We solicited comments on the proposed use of claims data with dates of service from April 1, 2025, through December 31, 2025, to determine the utilization of phosphate binders and our proposal to omit first quarter 2025 claims data for purposes of calculating the proposed addition to the ESRD PPS base rate to account for phosphate binders at the proposed § 413.234(h).

(3) Methodology for Determining the Price of Phosphate Binders

For use in the proposed calculation, we would set the price for phosphate binders using values from the most recent calendar quarter of ASP calculations available to the public, at 100 percent of ASP. This would be consistent with § 413.234(c)(1), which provides that TDAPA payment is based on 100 percent of ASP. The ASP-based value is a CMS-derived weighted average of all National Drug Code (NDC) sales prices submitted by drug manufacturers and assigned by CMS to the existing HCPCS codes for phosphate binders. For each billing code, CMS calculates a weighted ASP using data submitted by manufacturers, which includes the following: ASP data at the 11-digit NDC level, the number of units of the 11-digit NDC sold, and the ASP for those units. This calculation methodology is consistent with the approach described in the CY 2009 Physician Fee Schedule (PFS) final rule (73 FR 69752) and authorized in section 1847A of the Act.

Consistent with the TDAPA basis of payment established for oral phosphate binders in CY 2025, we proposed to use 100 percent of the weighted ASP value. As we explained in the CY 2020 ESRD PPS final rule, the ESRD PPS accounts for storage and administration costs and ESRD facilities do not have acquisition price variation issues when compared to physicians (83 FR 56946). We noted in the CY 2027 ESRD PPS proposed rule that we believe ASP is reasonable for phosphate binders because it reflects manufacturer sales prices net of applicable price concessions specified under section 1847A and provides a standardized measure for valuing phosphate-binder utilization. As we

discussed previously, the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for renal dialysis drugs and biological products. We proposed an increase to the base rate to account for the newfound responsibility and substantial pill volume associated with ESRD facility dispensing of phosphate binders, which we discussed in detail in the proposed rule.

We stated that we believe using a value based on the most recent calendar quarter ASP calculations available to the public for phosphate binders would provide an accurate representation of the price of these drugs for ESRD facilities because it uses manufacturer sales information that includes discounts (that is, rebates, volume discounts, prompt payment, and cash payment specified in section 1847A of the Act).

For the proposed rule, the values from the most recent calendar quarter of ASP calculations available to the public were from the second quarter of 2026, and due to a two-quarter data lag, these ASP calculations reflected manufacturer sales data submitted to CMS for the fourth quarter of 2025. For this CY 2027 ESRD PPS final rule, the most recent calendar quarter of ASP calculations available to the public is the fourth quarter of 2026, which reflects manufacturer sales data submitted into CMS for the second quarter of 2026, and we proposed to use that value for purposes of our final calculation.

We proposed to add § 413.234(h)(2)(ii), under which CMS would use 100 percent of the values from the most recent calendar quarter ASP calculations available to the public for phosphate binders to calculate a price for each product. We solicited comments on the proposed use of the values from the most recent calendar quarter ASP calculations available to the public for phosphate binders for setting the price and the proposed language at § 413.234(h).

(4) Methodology for Calculating the Addition to the ESRD PPS Base Rate To Include Phosphate Binders

To calculate the proposed amount for phosphate binders that would be added to the ESRD PPS base rate, we applied the values from second quarter of 2026 at 100 percent of ASP. We proposed to determine utilization based on the number of units billed during the TDAPA period. For each oral phosphate binder HCPCS code, the short description states what the billing unit is for that drug or biological product and is located in Table 13. Billing units are the standardized quantities used by

¹⁸ The National Claims History (NCH) file is a comprehensive CMS data repository containing all processed Medicare Part A and Part B claims since 1991.

providers and suppliers when submitting Medicare Part B claims and are specific to each HCPCS code. For example, for sevelamer carbonate billed under J0601, one billing unit equals 20 mg/tablet. We noted that billing units differ from revenue units, which are a commercial data construct used to standardize drug volume across dosage strengths for market analysis purposes. We determined that 5,547,594,800 total billing units of oral phosphate binders were used between April 1, 2025, and

December 31, 2025. Table 13 includes a column of billing units reported in claims data for each individual HCPCS code from throughout the study period. Our monitoring indicates that approximately 67 percent of ESRD beneficiaries received oral phosphate binders during the study period.

For the proposed rule, we used the values from the most recent calendar quarter ASP calculations available to the public, which was the second quarter of 2026. This information can be found on

the ESRD Payment website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug>. Table 13 also lists the per unit ASP for the various oral phosphate binder products based on their respective HCPCS codes and unit definitions. (We note that, for the CY 2027 ESRD PPS final rule, we are updating the ASP-based value on the most recent calendar quarter calculations available to the public, which is the fourth quarter of 2026.)

TABLE 13: Phosphate Binder HCPCS Codes and ASP for Proposed Rule

HCPCS	Short Description	ASP	Billing Units
J0601	Sevelamer carbonate 20 mg	\$0.003	2,487,026,286
J0602	Sevelamer carbonate powder 20mg	\$0.008	153,287,238
J0603	Sevelamer hydrochloride 20mg	\$0.011	52,533,278
J0605	Sucroferric oxyhydroxide 5mg	\$0.157	1,261,980,703
J0607	Lanthanum carbonate oral 5mg	\$0.009	304,664,818
J0608	Lanthanum carbonate powder 5mg	\$0.062	5,740,264
J0609	Ferric citrate oral 3 mg iron	\$0.086	666,183,329
J0615	Calcium acetate, oral, 23 mg	\$0.003	616,178,884
Total:			5,547,594,800

Multiplying the utilization of the oral phosphate binders by their respective ASP and then adding the expenditure amount for all forms of phosphate binders together yield the total calculated phosphate binder

expenditure amount. For the period of April 1, 2025, through December 31, 2025, that was evaluated for the proposed rule, CMS calculated the total phosphate binder expenditure amount to be \$269,634,395.87. We proposed to

update this amount in the CY 2027 ESRD PPS final rule using the most recent available data. The updated utilization and ASP is presented in Table 14.

TABLE 14: Final Rule Phosphate Binder Utilization and Price

HCPCS	Short Description	ASP	Billing Units
J0601	Sevelamer carbonate 20 mg	\$0.003	4,210,121,111
J0602	Sevelamer carbonate powder 20mg	\$0.007	273,128,715
J0603	Sevelamer hydrochloride 20mg	\$0.009	88,874,332
J0605	Sucroferric oxyhydroxide 5mg	\$0.122	2,176,776,833
J0607	Lanthanum carbonate oral 5mg	\$0.008	539,600,656
J0608	Lanthanum carbonate powder 5mg	\$0.061	8,293,834
J0609	Ferric citrate oral 3 mg iron	\$0.068	1,023,658,331
J0615	Calcium acetate, oral, 23 mg	\$0.004	999,397,814
Total:			9,319,851,626

For the period of April 1, 2025, through June 30, 2026, that was evaluated for this final rule, CMS calculated the total phosphate binder expenditure amount to be \$359,337,993.84 based on the 9,319,851,626 total billing units of oral phosphate binders used. Table 14 includes a column of billing units reported in claims data for each individual HCPCS code from throughout the final rule study period. Our monitoring indicates that approximately 66 percent of ESRD beneficiaries received oral phosphate binders during the study period.

(5) Accounting for Operational Costs

In addition to including direct drug costs, we proposed to incorporate an additional amount in the base rate to reflect the operational costs associated with supplying phosphate binders to ESRD facilities. During the TDAPA period, we provided a flat rate increase of \$36.41 for monthly ESRD PPS claims to cover these operational costs, which include storage, distribution, staffing, and administrative expenses unique to the high-volume, multi-product nature of phosphate binder therapy. We stated that we expect the ongoing provision of phosphate binders will continue to result in additional operational costs for ESRD facilities. Incorporating these operational costs into the base rate is consistent with our authority under section 1881(b)(14) of the Act to establish a bundled payment that reflects the costs of furnishing renal dialysis services, as CMS considers phosphate binders to be a renal dialysis service as described at § 413.171.

As discussed in the CY 2027 ESRD PPS proposed rule, the ESRD PPS base rate includes general overhead and administrative costs that apply broadly across renal dialysis services. Because of this, CMS did not establish a separate operational cost component for calcimimetics during the TDAPA period for calcimimetics or when calcimimetics were incorporated into the ESRD PPS base rate. However, as discussed in the CY 2025 ESRD PPS final rule, oral phosphate binders present unique, high-volume dispensing and logistical demands that are distinct from and not captured by the general overhead and administrative costs discussed previously (89 FR 89152). For example, in response to the CY 2025 ESRD PPS proposed rule, one interested party commented that phosphate binders represent an exponential increase in the volume of pills that dialysis providers need to acquire, distribute, store, and manage, and that the relative difference between managing 360 pills per year per patient for cinacalcet as compared with 3,240 pills per year per patient for calcium carbonate is 800 percent (89 FR 89141). CMS addressed this comment, among many others, in the CY 2025 ESRD PPS final rule, where we established a flat-rate TDAPA add-on of \$36.41 per monthly claim to address the circumstances¹⁹ associated with

¹⁹ In the CY 2025 ESRD PPS final rule, CMS stated that after consideration of all the comments received, we agree with commenters that there are additional costs associated with ESRD facilities furnishing phosphate binders that are not currently included in the ESRD PPS base rate and that were not addressed when the ESRD PPS base rate was developed in CY 2011. This differentiates

dispensing phosphate binders (89 FR 89152). Specifically, CMS stated that an increase in the payment adjustment amount that approximates 6 percent of ASP would provide the appropriate payment for incremental operational costs associated with ESRD facilities furnishing phosphate binders (89 FR 89152). As discussed previously, CMS expects that the ongoing provision of phosphate binders under Part B will result in a permanent expansion in operational costs for ESRD facilities. Therefore, we stated in the proposed rule, CMS believes proposing to incorporate an equivalent operational cost component into the base rate is not duplicative of existing base rate funds and is necessary to ensure that the base rate accurately reflects the cost of furnishing these renal dialysis services.

Based on our analysis of claims data from April 1, 2025, through June 30, 2026, (April 1, 2025, through December 31, 2025, for the proposed rule), we determined that 1,204,886 (711,875 during the proposed rule study period) monthly claims included phosphate binders. To account for operational costs in the base rate calculation, we considered two approaches: (1) applying the \$36.41 flat rate per monthly claim that was paid during the TDAPA period, and (2) calculating an operational cost component equal to an amount approximately equivalent to 6 percent of

phosphate binders from other drugs and biological products in existing ESRD PPS functional categories, which justifies a change to the TDAPA policy, as phosphate binders were excluded from the analysis performed for the CY 2011 ESRD PPS final rule due to a lack of data available at the time of rulemaking. (89 FR 89152).

observed ASP-based expenditures, derived from empirical TDAPA-period payment data rather than from the statutory ASP + 6 percent methodology under section 1847A of the Act. We emphasized that this proposed approach is not a methodology for pricing phosphate binders; as we discussed previously, we proposed to address the cost of phosphate binders using a weighted average of 100 percent of ASP for each phosphate binder type and dose.²⁰ Separately, we proposed to address the operational costs associated with ESRD facilities providing phosphate binders due to the large patient population and substantial pill volume. We proposed to estimate this cost by calculating a one-time increase to the ESRD PPS base rate consistent with the approach CMS adopted in the CY 2025 ESRD PPS final rule when establishing the \$36.41 flat-rate TDAPA add-on amount (89 FR 89152). We proposed to base this calculation on the price and utilization data collected during the TDAPA period, where oral phosphate binders were provided by ESRD facilities at scale.

We noted that, as discussed in the CY 2020 ESRD PPS final rule, we continue to believe that 100 percent of ASP is an appropriate basis for pricing renal dialysis drugs within the ESRD PPS because the bundled payment already incorporates general overhead and administrative costs (83 FR 56943 through 56944). However, phosphate binders present unique, high-volume dispensing and logistical demands that were not fully reflected in the historical base rate given that phosphate binders were excluded from the analysis performed for the CY 2011 ESRD PPS final rule (89 FR 89152).

Accordingly, rather than adopting a pricing methodology that includes an add-on to ASP, we proposed to use the TDAPA-period data to identify and incorporate a distinct, empirically observed operational cost component into the base rate. Multiplying the 1,204,886 (711,875 during the proposed rule study period) monthly claims that included phosphate binders by the \$36.41 flat rate yields a total operational cost amount of \$43,869,899.26 for the final rule reference period (\$25,919,368.75 during the proposed rule study period). As noted previously, the \$36.41 figure was based on 6 percent of the weighted average of Medicare expenditures for phosphate binders per month under Part D, for all phosphate

binders used in a month, based on estimates for CY 2025 phosphate binder utilization using utilization patterns in CY 2023 among Part D eligible beneficiaries (89 FR 89152). Alternatively, applying 6 percent to the total ASP-based drug expenditure for oral phosphate binders during the same period yields a total operational cost amount of \$21,560,279.63 (\$16,178,063.75 during the proposed rule study period).

We proposed to base operational costs associated with furnishing phosphate binders on 6 percent of total ASP-based drug expenditure for oral phosphate binders during the TDAPA period. While the flat rate add-on per-monthly claim amount of \$36.41 was administratively straightforward during the TDAPA period, we stated that we believe an operational cost component that scales with drug utilization better reflects the variable, volume-driven nature of phosphate binder dispensing. An operational cost component within the base rate would also be spread across all dialysis treatments, as intended with a PPS, and would ensure that these operational costs are updated annually as part of the ESRD market basket update.

Our analysis indicates that this utilization-based approach yields an amount approximately equivalent to 6 percent of ASP-based expenditures over the reference period.²¹ Therefore, we proposed this approach as a more data-driven and PPS-consistent method for incorporating operational costs into the base rate.

(6) Combined Calculation

In the CY 2027 ESRD PPS proposed rule, we presented a step-by-step calculation for the addition to the base rate for phosphate binders (91 FR 38815). For this final rule, we are updating those calculation steps with the most recent data. The total number of paid hemodialysis-equivalent dialysis treatments furnished to Original Medicare ESRD beneficiaries between April 1, 2025, and December 31, 2025, as mentioned previously, was 17,733,591. This total number of paid treatments reflects all paid dialysis treatments during the proposed rule study period, regardless of whether a phosphate binder was furnished. The updated data available at the time of this final rule displays the total number of paid hemodialysis-equivalent dialysis treatments furnished to Original

Medicare ESRD beneficiaries between April 1, 2025, and June 30, 2026, to be 29,341,805.

As discussed in the CY 2027 ESRD PPS proposed rule, to calculate the combined per-treatment amount, we add the direct drug expenditure amount of \$359,337,993.84 (\$269,634,395.87 during the proposed rule study period), multiplied by 1.06 to account for operational costs, \$21,560,279.63 (\$16,178,063.75 during the proposed rule study period), to get an adjusted phosphate binder expenditure amount of \$380,898,273.47 (\$285,812,459.62 during the proposed rule study period). Dividing this adjusted expenditure amount by the total number of paid hemodialysis-equivalent dialysis treatments, 29,341,805 (17,733,591 during the proposed rule study period) provides an average per-treatment payment amount of \$12.98 (\$16.12 during the proposed rule study period).

We proposed to reduce this amount by 1 percent to account for the outlier policy, consistent with the ESRD outlier policy at § 413.237(a)(1)(iv), which provides for budget neutrality adjustments associated with outlier payments, to get a total of \$12.85 ($\$12.98 \times 0.99 = \12.85), which is less than our proposed rule total of \$15.96. Under our proposal, we would apply this 1 percent reduction before increasing the base rate to account for outlier payments that would be paid beginning January 1, 2027, for phosphate binders since they would become eligible ESRD outlier services once the TDAPA period ends.

To determine the estimated costs in CY 2027, we would inflate the outlier-adjusted average per-treatment payment amount for phosphate binders (\$12.85) to 2027 using the CY 2027 ESRDB market basket update. As outlined in section II.B.4. of this final rule, the CY 2027 ESRD PPS base rate is \$297.52. This amount reflects a CY 2027 wage index budget-neutrality adjustment factor of 1.00260, a budget neutrality factor of 0.98864 for the budget neutral policies finalized in sections II.B.8., II.B.9., and II.B.10. of this final rule, a base rate addition of \$12.85 to include phosphate binders (including both direct drug costs and operational expenses), and the CY 2027 ESRDB payment rate update of 1.9 percent. We explained that we believe that using the annual payment rate update would effectively update the prices set for phosphate binders from CY 2026 to CY 2027 because this is consistent with how the other components of the base rate are updated for inflation each year, which includes drugs. We note that in section II.B.1.b. of this final rule, we

²⁰ This refers to the per-treatment spending amount for phosphate binders calculated using the ASP for all oral phosphate binder HCPCS codes weighted by utilization.

²¹ This refers to the per-treatment spending amount for phosphate binders calculated using the ASP for all oral phosphate binder HCPCS codes weighted by utilization.

finalized our proposal to rebase and revise the ESRDB market basket to a CY 2024 base year. The inflation factor used for drugs and biological products for the ESRDB market basket is a composite of various drug-related Producer Price Indexes as outlined in section II.B.1.b.(2) of this final rule.

We proposed to add a new paragraph § 413.234(h) regarding the data sources and methodology for modifying the ESRD PPS base rate to account for the costs of phosphate binders and the operational expenses associated with providing phosphate binders in the ESRD PPS bundled payment. This new paragraph would state that, for dates of service on or after January 1, 2027, CMS would determine the utilization of phosphate binders by aggregating total units from Medicare ESRD facility claims (837-institutional form with bill type 072X) for the second, third, and fourth quarters of calendar year 2025 and the first two quarters of calendar year 2026. CMS would price each phosphate binder at 100 percent of the most recent calendar quarter ASP calculations available to the public. CMS would then multiply the utilization of each phosphate binder by its respective price and sum the expenditure amounts across all phosphate binder products to calculate the total oral phosphate binder expenditure amount. CMS would then calculate an adjusted phosphate binder expenditure amount by multiplying the phosphate binder expenditure amount by 1.06 to account for operational expenses. CMS would divide the adjusted total expenditure amount by the total number of paid hemodialysis-equivalent dialysis treatments from Medicare ESRD facility claims during the same claims data period to calculate the average per-treatment payment amount. Finally, CMS would reduce the average per-treatment payment amount by 1 percent to account for the outlier policy under § 413.237 to determine the amount added to the ESRD PPS base rate.

Beginning January 1, 2027, phosphate binders would also be eligible ESRD outlier services under § 413.237. The fundamental principle of the ESRD PPS is that the costs of renal dialysis services, including drugs, are incorporated into the base rate and spread across all dialysis treatments rather than assigned only to those treatments for which a particular item or service is furnished (75 FR 49030). We stated that, in keeping with this principle, we believe the cost of phosphate binders should be spread across all dialysis treatments rather than be directed only to the treatments for

patients who are receiving phosphate binders.

We solicited comment on the proposed revisions to add paragraph (h) to § 413.234 to establish the data sources and methodology for modifying the ESRD PPS base rate to account for phosphate binders in the ESRD PPS bundled payment.

We received public comments on numerous aspects of these proposals to include phosphate binders in the ESRD PPS base rate. The following is a summary of the comments we received and our responses.

Comment: Several individual commenters, including registered dietitians, nurses, and other clinical staff, expressed strong support for including phosphate binders in the ESRD PPS bundled payment, citing reduced administrative burden, elimination of prior authorization requirements, and fewer delays related to insurance and pharmacy access. Commenters noted that direct access through the ESRD PPS bundled payment allows for faster response to elevated phosphorus levels, improved medication adherence, and the elimination of out-of-pocket costs that previously led some beneficiaries to ration their medication. Several commenters also noted that home delivery of phosphate binders through the ESRD PPS bundled payment addressed transportation barriers that had previously limited access for some beneficiaries.

Response: We thank the commenters for sharing their experiences with the TDAPA period for oral phosphate binders. We agree that incorporating these drugs into the ESRD PPS base rate should reduce administrative burden for ESRD facilities and improve timely access to phosphate binders for beneficiaries. We continue to believe that incorporating phosphate binders into the ESRD PPS base rate, consistent with the treatment of other oral-only drugs, appropriately reflects the goals of the ESRD PPS bundled payment methodology.

Comment: An interested party representing skilled nursing facility and nursing facility (SNF/NF) interests raised operational and clinical concerns regarding care fragmentation for beneficiaries in congregate care settings. The commenter identified timing gaps during weekend and evening discharges when ESRD facility staff are unavailable, a conflict between SNF federal medication timing requirements and the SNF's lack of direct purchasing authority for bundled phosphate binders, and administrative delays resulting from shifting billing pathways

between Part D, Part A, and ESRD facilities. The commenter recommended that CMS establish a 14- to 30-day "Transitional Care Access" exemption following a hospital discharge to a congregate care setting, during which the SNF or NF could bill directly under Part D or Part A rather than coordinate through the ESRD facility.

Response: We appreciate the commenter identifying these operational challenges for beneficiaries transitioning into SNFs and NFs. We recognize that care coordination between ESRD facilities and congregate care settings presents unique logistical considerations that differ from beneficiaries residing in the community. However, we do not believe it would be appropriate to establish a facility-type-specific exemption from the ESRD PPS bundled payment methodology, as doing so would create a parallel payment pathway that could complicate billing and undermine the consistency of the bundled payment across care settings. We encourage ESRD facilities and SNFs/NFs to work together, along with their contracted pharmacies, to establish protocols that support the timely delivery of phosphate binders around the time of discharge and other transitions of care. We will continue to monitor concerns related to care fragmentation in congregate care settings and will consider whether additional guidance or policy refinements are warranted in future rulemaking.

Comment: One LDO generally supported incorporating phosphate binders into the ESRD PPS bundled payment but emphasized that binder selection should continue to be driven by clinical effectiveness and adherence rather than cost alone. The commenter noted that one sucroferic oxyhydroxide product has a substantial body of real-world evidence demonstrating improved phosphorus control with a lower pill burden compared to alternatives such as sevelamer and calcium acetate. However, the commenter expressed concern that interested parties assuming widespread switching to generic products may be overestimating the ability of providers to achieve equivalent clinical outcomes using lower-cost alternatives. The commenter recommended that CMS finalize the proposed methodology for modifying the ESRD PPS base rate and confirm the policy's applicability to beneficiaries with AKI.

Response: We appreciate the commenter's perspective on the clinical considerations that inform phosphate binder selection. We agree that clinical effectiveness and beneficiary adherence

should remain the primary drivers of treatment decisions and note that our proposal was not intended to restrict a clinician's ability to prescribe the phosphate binder that best meets a beneficiary's clinical needs. We note that phosphate binders would be an eligible ESRD outlier service, which will help support access for unusual variations in the type or amount of medically necessary care. With respect to AKI beneficiaries receiving outpatient dialysis, we address this issue further in our next response to comments.

Comment: Several commenters including an LDO and a non-profit dialysis association requested that CMS clarify the responsibility for furnishing phosphate binders to beneficiaries with AKI who receive outpatient dialysis, noting that once phosphate binders are incorporated into the ESRD PPS base rate, this change will also affect AKI beneficiaries prescribed phosphate binders. The commenter requested that CMS clarify these issues in the CY 2027 ESRD PPS final rule or through subsequent guidance and asked that CMS ensure timely communication reaches MACs, ESRD facilities, nephrologists, Part D plans, Medicare Advantage plans, and beneficiaries prior to implementation.

Response: We thank the commenters for raising this issue and agree that clarity regarding the furnishing of phosphate binders for beneficiaries with AKI receiving outpatient dialysis is important to the implementation of this policy. As discussed in section III.B. of this final rule, the AKI dialysis payment rate applies to all renal dialysis services, and ESRD facilities are responsible for furnishing all medically necessary renal dialysis services to beneficiaries with AKI who are receiving dialysis as specified at § 413.374(a). While oral-only renal dialysis drugs and biological products have always met the definition of renal dialysis services, the statutory delays implemented in our regulations at § 413.174(f)(6) postponed their inclusion in the ESRD PPS bundled payment until January 1, 2025. During the TDAPA payment period for phosphate binders, the TDAPA did not apply to renal dialysis services furnished to beneficiaries with AKI, and ESRD facilities were not yet responsible for furnishing phosphate binders to beneficiaries with AKI (89 FR 89172). This is because phosphate binders were not originally included in the ESRD PPS base rate, and therefore were not reflected in the AKI dialysis payment rate that is based on the ESRD PPS base rate. As a result, during the TDAPA period, the AKI dialysis payment rate did not include any amount for

phosphate binders, so ESRD facilities had no payment mechanism through which to furnish them to beneficiaries with AKI.

Now that payment for phosphate binders is being incorporated directly into the ESRD PPS base rate, that payment is included in the AKI dialysis payment rate as well, because the AKI dialysis payment rate is based on the ESRD PPS base rate. As a result, ESRD facilities will be expected to furnish medically necessary phosphate binders to beneficiaries with AKI and receive payment under the AKI dialysis payment rate.

We recognize that the payment rate for renal dialysis services furnished to beneficiaries with AKI is based on the ESRD PPS base rate and that, beginning January 1, 2027, the ESRD PPS base rate will include an amount to account for phosphate binders. We intend to issue subregulatory guidance addressing the implications of this policy for the furnishing of phosphate binders for beneficiaries with AKI receiving outpatient dialysis. We will work to ensure that this guidance, along with other operational instructions related to this policy, is disseminated to MACs, ESRD facilities, treating clinicians, Part D plans, MA plans, and beneficiaries in advance of the January 1, 2027, implementation date. For further discussion of CMS policy pertaining to beneficiaries with AKI, please refer to section III.B.1. of this final rule.

Comment: MedPAC supported bundling phosphate binders into the ESRD PPS in principle but raised several methodological concerns. MedPAC recommended that CMS use a more conservative utilization methodology consistent with the approach taken under the MIPPA, specifically recommending that CMS use the lowest per-patient utilization year rather than utilization data from the TDAPA period to minimize the risk of overpayment. MedPAC also questioned whether the entry of generic alternatives, including an authorized generic in March 2025 and a generic version in March 2026, would affect the cost estimates underlying the proposed base rate increase, and noted that one LDO's product, without a generic alternative, accounts for approximately 73 percent of the proposed rate increase. Additionally, MedPAC recommended that CMS remove the proposed 6 percent operational cost multiplier, noting that operational costs associated with furnishing phosphate binders are already partially reflected in the existing ESRD PPS base rate and that including a separate add-on would be duplicative.

Response: We thank MedPAC for its continued support of incorporating phosphate binders into the ESRD PPS base rate and for the commission's detailed methodological feedback. Regarding the utilization methodology, CMS considered the approach used under MIPPA, but we continue to believe that using TDAPA-period utilization data provides the most accurate reflection of current phosphate binder use, as it captures a more recent and complete time period than using the single lowest-utilization year. We note that any claims that include the previously mentioned authorized generic in March 2025 and the generic version in March 2026 would be included in the 2026 fourth quarter ASP data and thus included in the final rule calculations for the base rate increase. We will, however, continue to monitor utilization trends, including the effect of generic alternatives on costs and utilization patterns, and will consider adjustments in future rulemaking if actual experience meaningfully diverges from our projections.

With respect to the proposed operational cost multiplier, we disagree that this adjustment is duplicative of costs already embedded in the base rate. As we discussed in the CY 2027 ESRD PPS proposed rule and previously in this final rule, we believe the additional operational costs associated with ordering, dispensing, and coordinating phosphate binders under the ESRD PPS bundled payment are distinct from the general administrative costs reflected in the existing base rate calculation and warrant additional payment. We note that CMS did not incorporate an equivalent operational cost component when calcimimetics were added to the ESRD PPS base rate, because calcimimetics do not present the same high-volume, multi-product dispensing and logistical demands as phosphate binders, which are typically administered several times daily across six or more distinct products with differing storage and handling requirements. This distinction is consistent with the rationale CMS articulated in the CY 2025 ESRD PPS final rule when establishing the \$36.41 flat-rate TDAPA add-on for phosphate binders, which recognized that dispensing fees and other operational costs were not included in the ESRD PPS base rate for phosphate binders and that every ESRD facility would incur distribution, storage, and staffing expenses not accounted for in ASP data alone (89 FR 55797 through 55829). Moreover, incorporating this operational cost component as a percentage of ASP-

based expenditures embedded in the base rate rather than as a separate flat-rate add-on reflects the same average, empirically observed costs that underlie the ESRD PPS more broadly, and ensures the base rate accurately captures the full cost of furnishing phosphate binders. We appreciate MedPAC's observation regarding the concentration of the proposed rate increase in a single product without a generic alternative and will continue to monitor market entry of generic and authorized generic alternatives as part of our ongoing evaluation of this policy.

Comment: Several commenters, including a regional dialysis organization, an ESRD facility, a coalition of dialysis organizations, and a drug manufacturer, expressed concern regarding CMS's proposal to recalculate the operational cost add-on amount for phosphate binders when converting it from a TDAPA-period flat fee into a permanent component of the ESRD PPS base rate. Commenters noted that the costs of storing, managing, and dispensing phosphate binders have not decreased since CMS established the \$36.41 monthly operational add-on under the TDAPA methodology, and expressed concern that CMS's proposed recalculation would result in a lower operational cost figure. A few commenters recommended that CMS instead maintain the operational add-on amount calculated during the TDAPA period using the ASP+6 percent methodology, rather than recalculate a new amount for CY 2027. A coalition of dialysis organizations similarly urged CMS to add an amount corresponding to the current TDAPA-period operational add-on. A drug manufacturer recommended that CMS adopt this alternative approach and retain the current operational expense add-on to account for distribution, mailing, and storage costs. A non-profit kidney care alliance more generally urged CMS to continue accounting for both drug and operational costs in future methodology updates.

Response: We thank the commenters for their feedback on our proposed approach to calculating the operational cost component of the phosphate binder base-rate addition. We clarify that the 6 percent adjustment is not an add-on to ASP for purposes of pricing phosphate binders. As described in the proposed rule, we proposed to price phosphate binders using 100 percent of ASP and separately account for the operational costs associated with furnishing phosphate binders in calculating the amount incorporated into the ESRD PPS base rate. We understand commenters' preference for maintaining the TDAPA-

period operational add-on amount for consistency and predictability. However, we continue to believe that recalculating the operational cost figure using more recent utilization and cost data provides a more accurate reflection of current operational costs than continuing to rely on the amount established earlier in the TDAPA period. We note that the operational cost add-on, like the drug cost component, is intended to reflect current, rather than static, cost experience, consistent with how we approach other bundled components of the ESRD PPS base rate. We appreciate commenters' support for continuing to account for both drug and operational costs in the base rate and confirm our intention to do so. We recognize the commenters' statement that operational costs associated with ESRD facilities furnishing phosphate binders have not changed since they were first added to the ESRD PPS bundled payment in CY 2025, however we believe that some of the initial costs associated with the transition should decrease over time. For example, we believe that certain costs associated with setting up systems or processes will likely decrease as those processes become standard. We note that the \$36.41 monthly operational add-on was based on part D data, and we believe that recalculating the amount based on actual spending and utilization through the TDAPA is more reflective of these costs under the ESRD PPS.

Comment: A network of dialysis organizations and regional offices and a provider advocacy organization raised concerns regarding whether the operational cost add-on, maintained or recalculated, adequately reflects the real-world costs that ESRD facilities incur in furnishing phosphate binders. The network of dialysis organizations and regional offices supported the proposed \$15.96 base-rate increase and associated 6 percent operational adjustment but urged CMS to revise the adjustment if it does not cover real-world dispensing, shipping, counseling, and adherence-support costs. The provider advocacy organization raised a more specific concern, noting that the \$36.41 monthly operational add-on was derived from 2023 Part D utilization patterns and does not reflect costs specific to small and independent facilities, including specialty pharmacy arrangements, rural and home delivery logistics, and adherence support. The commenter stated that any inadequacy in the original \$36.41 figure has been carried forward, uncorrected, into the

proposed permanent base-rate modification.

Response: We appreciate the commenters' detailed feedback on the real-world costs associated with furnishing phosphate binders. We recognize that ESRD facilities, particularly small and independent facilities, may incur costs related to specialty pharmacy arrangements, rural and home delivery logistics, and beneficiary adherence support that can vary based on facility size, location, and patient population. We do not believe it would be operationally feasible to establish a facility-specific or geographically adjusted operational cost add-on at this time, as doing so would introduce complexity inconsistent with the ESRD PPS's per-treatment bundled payment structure. We will, however, continue to monitor the actual operational costs ESRD facilities incur in furnishing phosphate binders under the base rate and will consider whether adjustments to the operational cost methodology are warranted in future rulemaking. We note that the ESRD PPS base rate is adjusted by several factors, including the wage index, several case-mix adjusters, and facility-level adjusters such as the LVPA. The LVPA is a long-standing policy mechanism through which small, low-volume ESRD facilities receive additional payment under the ESRD PPS. Additional payments made through the LVPA reflect the extent to which costs incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, which includes the costs of furnishing phosphate binders.

Comment: A pharmacy-related association raised concerns that incorporating phosphate binders into the ESRD PPS bundled payment would threaten beneficiary access to these therapies through community pharmacies. The commenter stated that, once phosphate binders are furnished exclusively through the ESRD facility under the ESRD PPS, community pharmacies that have historically dispensed these medications under Part D would be effectively excluded from this line of business. The commenter further noted that this shift could increase beneficiaries' out-of-pocket costs in certain circumstances and reduce the pharmacy touchpoints available to support medication counseling and adherence.

Response: We appreciate the commenter's concerns regarding the role of community pharmacies in furnishing phosphate binders to beneficiaries with ESRD. We recognize that incorporating

phosphate binders into the ESRD PPS on January 1, 2025, shifted the responsibility of furnishing these drugs from Part D pharmacy channels to ESRD facilities, consistent with the treatment of other oral-only renal dialysis drugs under the ESRD PPS. We do not believe that this shift increased beneficiaries' out-of-pocket costs, in part because the ASP for phosphate binders has decreased throughout the TDAPA period, and also because the Part D cost-sharing structure (supplemental insurance) no longer applies for these drugs. With respect to medication counseling and adherence support, we expect ESRD facilities, in coordination with their contracted pharmacy arrangements, to continue supporting beneficiaries in managing their phosphate binder regimen. We do not believe that ending the TDAPA period for phosphate binders and incorporating phosphate binders into the ESRD PPS base rate will negatively impact any of the expectations or observations outlined previously, however, we will continue to monitor beneficiary access and adherence outcomes following implementation and will consider whether further guidance is warranted in future rulemaking.

Comment: A provider advocacy organization raised concern regarding the data basis for the proposed \$15.96 base rate addition, arguing that CMS derived this figure from only nine months of TDAPA claims data (April through December 2025) and that this is a thin basis for a permanent, non-adjustable addition to the base rate.

Response: We appreciate the commenters' concern regarding the data period underlying the proposed base rate addition. We confirm that the proposed rule's calculation of \$15.96 relied on phosphate binder utilization data from April 1, 2025, through December 31, 2025, representing only nine months of TDAPA claims following our exclusion of first-quarter 2025 data. CMS notes that for this CY 2027 ESRD PPS final rule, we have updated our utilization calculations using claims data extending through June 30, 2026, expanding the utilization period to approximately fifteen months and significantly expanding the volume of claims data underlying the calculation compared to the proposed rule. We also updated our price calculations using data from the fourth quarter of 2026, consistent with our proposal to use the most recent calendar quarter of ASP data available. We believe this expanded claims period addresses the commenters' concern regarding the adequacy and timeframe of the data and provides a stronger

foundation for this permanent addition to the ESRD PPS base rate. We also note that the one-time amount incorporated into the base rate is not separately repriced each year based on phosphate-binder ASP or utilization, but once incorporated it becomes part of the base rate and is subject to applicable annual ESRD PPS updates.

Final Rule Action: After consideration of public comments, we are finalizing the incorporation of phosphate binders into the ESRD PPS base rate beginning January 1, 2027, with a base rate increase of \$12.85 per treatment, using the utilization methodology and operational cost multiplier alongside the most recent available claims (that is, claims from between April 1, 2025, and June 30, 2026) and fourth quarter 2026 ASP data, as proposed. We are also finalizing our proposal to add a new paragraph § 413.234(h) regarding the final data sources and methodology for modifying the ESRD PPS base rate to account for the costs of phosphate binders and the operational expenses associated with providing phosphate binders in the ESRD PPS bundled payment. We are finalizing a slightly modified version of new § 413.234(h)(2)(iv) to more clearly state the proposed methodology for calculating the operational cost component of the base rate increase for phosphate binders. We note that this slight modification is a change in language, not a change in policy. We intend to issue further subregulatory guidance addressing the furnishing of phosphate binders for beneficiaries with AKI receiving outpatient dialysis and will work to ensure timely communication of this guidance to affected interested parties prior to implementation.

8. Changes to the Low-Volume Payment Adjustment (LVPA)

a. Background on the LVPA

Section 1881(b)(14)(D)(iii) of the Act provides that the ESRD PPS shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent. Therefore, the ESRD PPS provides a facility-level payment adjustment to ESRD facilities that meet the definition of a low-volume facility.

Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation: (1) furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month costs reports, whichever is most recent, except as specified in paragraphs (g)(4) and (5) preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type or as specified in paragraph (g)(6)) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

In addition, under § 413.232(c), for purposes of determining eligibility for the LVPA, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question. To receive the LVPA, an ESRD facility must submit a written attestation statement to its MAC confirming that it meets the requirements as specified in § 413.232 and qualifies as a low-volume ESRD facility. For purposes of determining eligibility for the LVPA, "treatments" mean total hemodialysis equivalent treatments (Medicare and non-Medicare). For PD patients, one week of PD is considered equivalent to three HD treatments (80 FR 68994). Section 413.232(e) generally imposes a yearly November 1 deadline for attestation submissions, unless extraordinary circumstances justify an exception, and specifies exceptions for certain years where the deadline is in December or January. The November 1 attestation timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236). The ESRD facility would then receive the LVPA for all the Medicare-eligible treatments in the payment year. Once an ESRD facility is determined to be eligible for the LVPA, a payment adjustment factor is applied to the ESRD PPS base rate for all applicable treatments furnished by the ESRD facility (89 FR 89161).

In the CY 2011 ESRD PPS final rule (75 FR 49118 through 49125), we finalized the methodology used to target the appropriate population of ESRD facilities that were low-volume facilities based on a treatment threshold. After consideration of public comments, we originally established an 18.9 percent

adjustment for ESRD facilities that furnish less than 4,000 treatments annually and indicated that this increase to the base rate would encourage small ESRD facilities to continue providing access to care.

In the CY 2016 ESRD PPS proposed rule (80 FR 37819), we analyzed ESRD facilities that met the definition of a low-volume facility under § 413.232(b) as part of the updated regression analysis and found that these ESRD facilities still had higher costs compared to other ESRD facilities. A regression analysis of low-volume facility claims from CYs 2012 and 2013 and cost report data indicated a multiplier of 1.239; therefore, we proposed an updated LVPA adjustment factor of 23.9 percent in the CY 2016 ESRD PPS proposed rule (80 FR 37819) and finalized this policy in the CY 2016 ESRD PPS final rule (80 FR 69001). This update was implemented budget neutrally alongside numerous other changes to the case-mix and facility-level adjusters.

In the CY 2021 ESRD PPS final rule (85 FR 71443), we finalized a policy to allow ESRD facilities flexibility for LVPA eligibility due to the COVID-19 Public Health Emergency (PHE). Under § 413.232(g)(4), for purposes of determining ESRD facilities' eligibility for payment years 2021, 2022, and 2023, we only considered total dialysis treatments for any 6 months of their cost-reporting period ending in 2020. In the CY 2024 ESRD PPS final rule (88 FR 76344), we finalized changes to the LVPA regulation at § 413.232 that allow ESRD facilities affected by disasters and other emergencies to qualify for exceptions to certain eligibility requirements for the LVPA. Facilities may close and reopen if they experience an emergency, or they may temporarily exceed the 4,000-treatment threshold if they take on additional patients displaced by an emergency and still qualify for the LVPA.

In the CY 2025 ESRD PPS final rule (89 FR 89153 through 89162) we finalized a 2-tiered system for the LVPA. This system provided higher payment for ESRD facilities which furnished a median of fewer than 3,000 treatments over the past three years, and a lower amount for those which furnished a median treatment amount between 3,000 and 3,999 treatments. ESRD facilities in the first tier receive a 28.9 percent LVPA, and ESRD facilities in the second tier receive an 18.3 percent LVPA. We did not propose any changes to the LVPA criteria in that rule, as we stated the purpose of that policy was not to expand the LVPA to new ESRD facilities. We implemented this change budget neutrally by scaling the factors

down to maintain the total level of LVPA payments at the same amount. In that rule, we noted that we believed this scheme of budget neutrality was more appropriate because it contained the changes within the LVPA (89 FR 89159). In CY 2025, 342 ESRD facilities received the LVPA.

(1) Current LVPA Issues and Concerns

As discussed in the CY 2025 ESRD PPS final rule, CMS received longstanding input from interested parties, including MedPAC and the Government Accountability Office (GAO),²² recommending that we make refinements to the LVPA to better target ESRD facilities that are critical to beneficiary access to dialysis care in remote or isolated areas (89 FR 89154).²³ These interested parties also expressed concern that the strict treatment count used to determine eligibility introduces a “cliff effect” that may incentivize ESRD facilities to restrict patient volume to remain eligible.²⁴ These recommendations were a significant factor which led us to evaluate the LVPA and propose and finalize the changes in the CY 2025 ESRD PPS rulemaking.

Additionally, at that time, CMS considered several changes to the LVPA eligibility criteria to address the concerns that interested parties, including the GAO and MedPAC, raised about targeting LVPA payments to ESRD facilities that are necessary to protect access to care and are not located near other ESRD facilities. Specifically, these interested parties requested that we take into consideration the geographic isolation of an ESRD facility within the LVPA methodology. CMS considered incorporating geographic isolation into the LVPA. However, section 1881(b)(14)(D)(iii) of the Act requires that the LVPA reflect the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. CMS analysis did not find that isolated low-volume facilities incur higher costs than other low-volume facilities. Therefore, incorporating a metric for geographic isolation, for example distance to next nearest ESRD facility or number of

ESRD facilities in a geographic area, into the LVPA would not align with statutory requirements.

As discussed in the CY 2027 ESRD PPS proposed rule, CMS has been evaluating alternative approaches under section 1881(b)(14)(D)(iv) of the Act (91 FR 38820). We have been analyzing claims and cost data regarding dialysis treatment levels and cost to inform options for potentially tailoring our methodology to meet the requirements of the statute, while simultaneously collecting additional data on geographic isolation of ESRD facilities. The ESRD PPS has separate facility-level payment adjustments for low-volume facilities, as set forth in 42 CFR 413.232, facilities in rural areas, as set forth in § 413.233(a), and facilities in certain non-contiguous areas, as set forth in § 413.233(b). To avoid overlapping with these existing facility-level adjustments, we have been analyzing the impact of potentially creating a new payment adjustment and considering innovative methodological options, such as the local dialysis need methodology on which we requested information in the CY 2024 ESRD PPS proposed rule (88 FR 42441 through 42445).

Interested parties have also indicated that LVPA eligibility criteria and the attestation process may be administratively burdensome, particularly for small ESRD facilities (85 FR 71442) and believe it may discourage participation by small ESRD facilities with limited resources that would otherwise qualify for the LVPA.²⁵ CMS has been considering whether modification of these requirements could reduce burden, mitigate incentives for gaming, and better align payment for resource use.

As a part of our ongoing efforts to improve the LVPA, we have requested information on improvements to the LVPA in several instances.

(2) Technical Expert Panels and CY 2022 RFI

CMS's contractor has held three Technical Expert Panels (TEPs) to discuss potential refinements to the ESRD PPS.²⁶ During the 2018, 2019, and 2020 TEPs, panelists, including representatives from ESRD facilities, independent researchers, patient advocates, and representatives from professional associations and industry groups (86 FR 36397), discussed

²² https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf.

²³ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

²⁴ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

²⁵ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

²⁶ https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.

limitations of the current LVPA methodology and potential alternatives. In the CY 2022 ESRD PPS proposed rule, we included a RFI to inform LVPA payment reform (86 FR 36398 through 36399). All fourteen responses to the CY 2022 ESRD PPS RFI for LVPA wrote in support of either eliminating or revising the current LVPA or rural facility adjustment.²⁷ One small dialysis organization within a large non-profit health system responded that it is reliant upon the LVPA and the rural facility adjustment and supports both adjustments, albeit with modifications. MedPAC renewed its support for a new Low-Volume and Isolated (LVI) adjustment with a recommendation for a three-tiered approach for treatment thresholds, which would incorporate geographic isolation into its methodology and may disincentivize gaming. MedPAC called upon CMS to provide clear and timely criteria for ESRD facility eligibility and ensure the LVPA methodology is transparent. In concurrence with MedPAC, a coalition of dialysis organizations, three LDOs, a non-profit kidney organization, and a provider advocacy coalition commented that the rural facility adjustment should be eliminated and a LVI methodology should be adopted, as they considered a methodology based upon census tracts to be both complicated and lacking transparency. Numerous commenters wrote in support of a tiered adjustment to mitigate the cliff effect and gaming. Commenters raised concerns regarding the reliance of the census tract methodology used by the rural facility adjustment upon ‘driving time’ as a data measure, noting this presents legitimate equity issues. ESRD facilities that have relied upon both the LVPA and rural payment adjustments to remain operational expressed opposition to elimination of either adjustment.²⁸

In the CY 2022 ESRD PPS proposed rule LVPA RFI, we sought input on alternative approaches to the LVPA methodology (86 FR 36398 through 36399). Specifically, we requested input on: (1) whether a distinction other than census tract information should be considered; and (2) what criteria should be used to determine the threshold(s) of adjusted latent demand (in treatment counts) which determine LVPA eligibility. Additionally, we explored the LVI adjustment that MedPAC recommended in its June 2020 Report to Congress. Under the LVI methodology, a

determination that a facility is low volume and isolated would be based on that facility’s distance from the nearest facility and its total treatment volume. Regarding the LVI methodology, we requested input on the concerns for facilities that would lose the LVPA under the LVI methodology and the potential for gaming within the LVI methodology. In addition, we requested input regarding the extent that the LVI methodology captures more isolated (and most often rural) facilities, and whether a separate rural facility adjustment should be maintained. As previously discussed, our most recent analysis of cost report data does not support the claim that isolated low-volume ESRD facilities face higher costs than non-isolated ESRD facilities; therefore, the LVI methodology would not adhere to the statutory requirement for the LVPA set forth at section 1881(b)(14)(D)(iii) of the Act.

(3) CY 2024 RFI on Potential Changes to the LVPA

In the CY 2024 ESRD PPS proposed rule (88 FR 42430 through 42544), we issued an RFI regarding several possible modifications to the current LVPA methodology. We provided the option of maintaining a single LVPA threshold, establishing LVPA tiers, or utilizing a continuous function to commenters. Specifically, we presented four different tiered structures for the LVPA, all of which would expand the LVPA beyond the current threshold of 4,000 treatments per year. These four structures were presented as budget neutral, with two involving a reduction to the base rate and two involving “scaling” down the factors to maintain total LVPA payments.

We received 23 comments in response to the RFI, all of which had differing opinions. Most commenters expressed support for some type of a tiered LVPA, although some commenters expressed further concerns or opposition to such a policy. A coalition of dialysis organizations recommended a 2-tiered approach, while MedPAC reiterated their support for an LVI adjustment. A common theme among a handful of comments was concern about administrative burden and transparency regarding the methodology that is chosen. Most commenters believed that the issue of payment cliffs is substantial, but many did not believe any of the options presented in the RFI could successfully eliminate gaming completely. Several commenters expressed concern with LVPA changes that would impact the base rate. A full summary of responses to the RFI can be found at <https://www.cms.gov/>

medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-reports-and-educational-resources.

(4) CY 2025 LVPA Proposal

Informed by the comments on the CY 2024 LVPA RFI, we proposed a simpler, 2-tier methodology in the CY 2025 ESRD PPS proposed rule (89 FR 55797 through 55804) which did not expand the LVPA beyond the current treatment volume limit of fewer than 4,000 treatments per year. One reason why we proposed that option was to maintain the impact of the budget neutrality of that proposal within the LVPA without reducing the base rate. We noted that expanding the LVPA beyond 4,000 treatments would result in the adjustment factor being notably reduced for facilities with fewer than 4,000 treatments, and particularly facilities with fewer than 3,000 treatments (89 FR 55801). When we finalized this 2-tier methodology in the CY 2025 ESRD PPS final rule, some commenters highlighted that while it would reduce the impact of payment cliffs, it would not completely remove them (89 FR 89158 through 89161).

We requested further information in the CY 2025 ESRD PPS proposed rule (89 FR 55803 through 55803) on potential further improvements to the LVPA. These questions focused on administrative processes regarding the LVPA, specifically the attestation process. We did not receive any substantive responses to many of these questions (89 FR 89162).

b. Analysis of Payment Adequacy for ESRD Facilities by Treatment Volume

As discussed in the CY 2027 ESRD PPS proposed rule, CMS routinely evaluates payment adequacy under the ESRD PPS. While we often use outside information, such as public comment letters and MedPAC reports, we also conduct our own analysis of ESRD facility costs and ESRD PPS payments. While the ESRD PPS is not a cost-based system, analyses of Medicare-allowable ESRD facility costs provide insight into whether payments align with resource use. Additionally, the ESRD PPS has a long history of establishing payment adjustment factors based on cost data (occasionally combined with claims data), including the current 2-tiered LVPA (89 FR 89156) and most case-mix adjustment factors, such as adult age and onset of dialysis (80 FR 68973 through 68974 and 68984 through 68994).

CMS analyzed cost report and claims data from 2022 through 2024 to evaluate the ratio of payments to average costs

²⁷ <https://www.cms.gov/files/document/cy-2022-esrd-pps-rfi-summary-comments.pdf>.

²⁸ The materials from the TEPs and summary reports can be found at https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.

for ESRD facilities. We note that directly comparing ESRD PPS payments to ESRD facility costs is not a perfect analysis as it disregards other payors, including Medicare Advantage (MA) and private payors, which could be providing higher payments for specific high-cost services. Nonetheless, this analysis indicates that payments exceed costs for higher volume ESRD facilities, while lower-volume ESRD facilities, particularly those furnishing fewer than 10,000 treatments tend to have costs that exceed payments. Notably, ESRD facilities furnishing between 4,000 and 10,000 treatments exhibit costs that exceed payments, suggesting that cost differentials extend beyond the current LVPA threshold of 4,000 treatments.

Informed by this 2022–2024 cost to payment analysis, we conducted a further analysis to account for the ESRD PPS wage index methodology finalized in the CY 2025 ESRD PPS final rule (89

FR 89097 through 89116) and discussed in section II.B.2. of this final rule, as this policy significantly changed relative payments by geographic area. We conducted an additional analysis using available CY 2025 ESRD PPS payments instead, to capture these changes, and compared it to CY 2024 costs projected to CY 2025. We removed the TDAPA amounts from the CY 2025 payments used for this analysis as the TDAPA amounts for phosphate binders represented significant payments in CY 2025 which were not present in the CY 2024 costs to which we are comparing. To account for the fact that, due to the NAPA policy finalized in the CY 2026 ESRD PPS final rule (90 FR 53095 through 53102), ESRD facilities in certain noncontiguous areas receive higher non-labor payments, we further adjusted payments to Alaska, Hawaii, Guam, American Samoa, and the Northern Mariana Islands to account for

the increased non-labor payment. We updated CY 2024 costs to CY 2025 using the most recent forecast of the ESRDB market basket increase for CY 2025 of 1.029. For simplicity, in this analysis we did not reduce this factor by the most recent forecast of the productivity adjustment for CY 2025, which is 0.9 percentage point. However, we adjusted certain cost reports to account for a submission issue from an LDO wherein some costs were not fully reflected. For this analysis we further refined the volume categories from the prior analysis to differentiate between ESRD facilities with 5,000 to 7,999 treatments and 8,000 through 9,999 treatments. We stated that we believe that 8,000 treatments is a good boundary point for this analysis because the median treatment volume is slightly above 8,000. Results from this analysis are presented in Table 15.

TABLE 15: Payment to Projected Cost Analysis for CY 2025

Facility Size	Number of Facilities	Number of Treatments (in millions)	Treatment Weighted Mean Payment to Cost Ratio 2025	Median Payment to Cost Ratio 2025
Less than 3,000 treatments	476	0.42	0.76	0.72
3,000 to 3,999 treatments	391	0.52	0.84	0.82
4,000 to 4,999 treatments	479	0.77	0.88	0.85
5,000 to 7,999 treatments	1,827	3.93	0.93	0.92
8,000 to 9,999 treatments	1,131	3.29	0.99	0.99
10,000 or more treatments	3,062	14.37	1.06	1.05

We noted in the proposed rule that the previously described analysis may not be interpreted directly in the terms of payment adequacy for several reasons. First, the ESRD PPS is not a cost-based system, and we do not make payments based on costs. Consistent with section 1881(b)(14)(A) and 1881(b)(14)(F) of the Act, the ESRD PPS payment amount is based on 98 percent of what would have been paid in 2011 had the ESRD PPS not been implemented, annually updated by an ESRDB market basket update factor. Furthermore, as discussed previously, we had to make several adjustments to both costs and payments for this

analysis, which makes these results less directly applicable to actual costs and payments, although we believe they are a reasonable proxy for our purposes here. Lastly, ESRD facility cost reports include costs for payors other than Original Medicare, which may be higher for several reasons. We noted that we were not proposing to base any changes to the LVPA on this analysis, however, this analysis helped CMS identify ESRD facilities which may be receiving relative payments lower than their resource use and has informed the analysis presented in section II.B.8.c. of this final rule. Specifically, this analysis led us to reconsider our current LVPA

policy to evaluate whether expansion of the LVPA beyond 4,000 treatments would better align payment with resource use.

We also reviewed the patterns of ESRD facility closures over the past few years and found evidence that ESRD facilities which have closed are disproportionately small. We stated that, while we believe that the LVPA tier changes finalized in the CY 2025 ESRD PPS final rule help address this issue by scaling the factors to keep the effect of the policy within the LVPA and maintain budget neutrality, the LVPA factor for ESRD facilities which furnish fewer than 3,000 treatments is not as

large as it would be if we had not scaled the factors. Our payment-to-cost analysis indicates that these 3,000-treatment-and-fewer ESRD facilities have costs which exceed their payments.

c. Updated Expanded Tiered Analysis

To estimate cost differences across treatment volumes, CMS conducted a regression analysis using facility-level cost report data from 2022 through 2024. The dependent variable was cost per treatment, and the primary independent variable was facility size. The regression analysis was conducted at the facility level and controlled for the following characteristics: year, ownership, wage index, rurality, region, Medicare percent, home dialysis percent, pediatric share, and average non-LVPA payment adjustment multiplier.

Facility size was specified using the natural logarithm for total treatments and included both linear and quadratic (squared) terms. This specification is intended to estimate cost differences while reducing the influence of extreme values and capturing non-linear effects.

Cost estimations associated with size as the natural logarithm makes the scale of comparison smaller, which makes the results less subject to variance of high volume facilities, and including a quadratic term allows us to capture more than just a linear relationship, which is preferable in this instance as we believe the marginal cost-per-treatment difference of an additional treatment is likely different between low and high volume facilities.

CMS then calculated the predicted costs at the upper bound of each tier using the mean values for continuous variables and composite values for categorical variables wherein the value for the categorical variable was the proportion of the overall population of ESRD facilities which belong to that category. For example, if 10 percent of ESRD facilities are in rural areas, the value used for the rural term when determining the proxy would be 0.1. This allowed us to create a proxy facility per-treatment cost value for an ESRD facility based on treatment count. We noted in the proposed rule that, for our purposes of deriving LVPA factors, the values to construct the proxies do

not actually impact the final result, so long as the proxies are the same for all calculations; this is because we are using these relative cost values to find the relative difference between proxy values, so the terms cancel in the calculation. As the LVPA is based on the difference in cost between low-volume facilities and other facilities, we then calculated the adjusters by comparing the calculated results to a proxy that represents all non-LVPA facilities, by using the same mean value for continuous control variables and categorical control variables, and the median facility treatment count for non-LVPA facilities. For this non-LVPA proxy, the median facility treatment count was calculated only across non-LVPA facilities and all other values were kept the same. We explained that we are attempting to find the extent to which low-volume facilities faced higher costs than other such facilities; therefore, it is appropriate to have the only difference be the treatment count and it is appropriate for the comparison treatment count to include all non-LVPA facilities. We presented these results in Table 16:

TABLE 16: 6-Tier LVPA Analysis

Treatment Volume	Number of ESRD Facilities Expected to Receive the LVPA	72x Treatments CY 2025	Average EB Multiplier	Average WI Adjusted Base Rate	Updated Adjusters
0-2,999	189	157,407	1.135	\$265.3	1.368
3,000-3,999	223	305,754	1.115	\$265.1	1.249
4,000-4,999	299	495,920	1.118	\$263.5	1.173
5,000-5,999	296	556,387	1.117	\$265.2	1.120
6,000-6,999	307	685,388	1.113	\$265.0	1.080
7,000-7,999	175	416,923	1.113	\$263.8	1.050

As discussed in the proposed rule, the updated adjustment factors in Table 16 are derived from the regression by taking the ratio of the exponentiated outcome for the tier with the exponentiated outcome of the comparison value. That is, we calculated the proxy value for the tier and the comparison value, applied the exponential function for each, and then divided the proxy value for the tier by the comparison value. For example, the proxy per-treatment cost for a facility

with 8,000 treatments in our analysis is \$317.77 and the proxy per-treatment cost for a facility with the median non-LVPA treatment count of 10,332 is \$302.77. We calculated the adjustment factor for the 7,000–7,999-treatment tier by dividing \$317.77 by \$302.77 which equals 1.050. We noted that using these factors in the LVPA would increase payments to current LVPA facilities (those furnishing fewer than 4,000 treatments for each of the past 3 cost reporting years) by

approximately \$17 million and increase payments to facilities not currently eligible for the LVPA by approximately \$67 million. These estimated impacts include the proposed extension of the LVPA to pediatric patients discussed in section II.B.9. of the CY 2027 ESRD PPS proposed rule. We stated that these proposed increased adjustment factors, if finalized, would bring relative payments under the ESRD PPS more in line with relative costs, as demonstrated by our cost-to-payment analysis

discussed in the prior section. We noted that we proposed both policies as budget neutral by reducing the ESRD PPS base rate by a budget neutrality factor, as noted in section II.B.4. of the proposed rule.

d. Proposal for Expanded LVPA

Section 1881(b)(14)(D)(iii) of the Act provides that the ESRD PPS shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) exceed the costs incurred by other facilities. Under this authority, we proposed to revise the definition of a low-volume facility for purposes of § 413.232 to reflect updated empirical findings demonstrating higher costs among facilities furnishing fewer than 8,000 treatments annually, when controlling for various factors including geographic area, wage index, and average case-mix adjustment factor. This proposal is intended to better align ESRD PPS payments with the observed differences in resource use, and support access to care.

As noted in the CY 2016 ESRD PPS final rule (80 FR 68967 through 69077), we aim to target the benefit of the LVPA

to facilities that serve the access needs of patients in remote locations. CMS analysis indicates higher costs among facilities furnishing between 4,000 and 8,000 treatments per year. Proposing a revised methodology that would increase payment to these ESRD facilities would help protect access to care for ESRD services in areas served by these ESRD facilities. Additionally, we believe that additional tiers would further reduce the incentive for gaming, as the GAO described in its 2013 report.²⁹ This may reduce the incentive for some ESRD facilities to limit access to renal dialysis services to keep their treatment volume below the 4,000-treatment threshold. We would expand access through payments that incrementally align resource use with payment to ESRD facilities that furnish different volumes of treatment.

In the CY 2027 ESRD PPS proposed rule, for CY 2027 and subsequent years, CMS proposed to expand LVPA eligibility and implement a tiered structure based on median treatment volume over the prior three years. This expanded eligibility would apply to ESRD facilities that furnish more than 4,000 treatments per year. As discussed

in the previous section, we have data which demonstrates higher costs for ESRD facilities which furnish fewer than 8,000 treatments. Building on the tiered LVPA finalized in the CY 2025 ESRD PPS final rule, we proposed 6 tiers with decreasing adjustment factors as treatment volume increases. The proposed adjustment factors are presented in Table 17. Consistent with the current tiered LVPA, the tier determination would be based on the median treatment volume from the past three years. CMS proposed to apply this policy in a budget neutral manner by applying a factor of 0.98898 to the ESRD PPS base rate. We noted that ESRD facilities must attest to being eligible for LVPA to receive the payment adjustment, but our data indicates that not all ESRD facilities which are eligible for the LVPA attest for it. Since these ESRD facilities do not attest for the LVPA, they do not receive it. For the impact analysis from which this budget neutrality factor was derived, we used an attestation proxy to estimate attestation patterns so that our total estimated payments considers that not all eligible ESRD facilities would attest for and receive the LVPA.

TABLE 17: Proposed 6-tier LVPA

Treatment Volume Tier	Number of ESRD Facilities Expected to Receive the LVPA	Current Adjustment Factors	Proposed Adjustment Factors
0-2,999 treatments per year	189	1.289	1.368
3,000-3,999 treatments per year	223	1.183	1.249
4,000-4,999 treatments per year	299	1.000	1.173
5,000-5,999 treatments per year	296	1.000	1.120
6,000-6,999 treatments per year	307	1.000	1.080
7,000-7,999 treatments per year	175	1.000	1.050

We proposed to apply this policy as budget neutral outside of the LVPA, and, if finalized, we would apply the previously mentioned 0.98898 factor to the ESRD PPS base rate. When we established the 2-tiered LVPA methodology in the CY 2025 ESRD PPS final rule (89 FR 89161), we did not apply a budget neutrality factor for that methodological change. In the CY 2025 ESRD PPS proposed rule, we stated that we were not proposing to apply a budget neutrality factor because we were making changes only to the LVPA and believed at that time it was most appropriate to keep the impact of the

policy change contained to ESRD facilities that were receiving the LVPA (89 FR 55801). We stated that the purpose of that change was to better allocate relative payments within the LVPA and it was not our intention at that time to expand the LVPA beyond the facilities currently eligible for the LVPA (89 FR 55802). We also discussed that expanding the LVPA beyond 4,000 treatments while scaling the factors to maintain budget neutrality within the LVPA would reduce payments for the lowest volume facilities in a way which was not in alignment with the goals of the LVPA (89 FR 55801). In contrast, as

discussed in the CY 2027 ESRD PPS proposed rule, CMS believes applying budget neutrality to the base rate would be appropriate for this proposal because it would expand LVPA eligibility beyond currently qualifying facilities (that is, to ESRD facilities that furnish more than 4,000 treatments per year). We stated that we believe the proposed tiered structure balances concerns from interested parties regarding payment cliffs while maintaining alignment with statutory requirements.

In constructing this proposal, we carefully considered the responses to

²⁹ Government Accountability Office. 2013. End-stage renal disease: CMS should improve design

and strengthen monitoring of low-volume adjustment. Report 13–287. Washington, DC: GAO.

the CY 2024 RFI on the LVPA.³⁰ In this RFI, most respondents supported some sort of tiered system, although most respondents thought there were some issues with the tiered options presented in the RFI. Many of the respondents who supported a tiered system indicated specific support for a structure that included payments up to 6,000 treatments. Many explicitly supported a methodology that incorporated a metric for geographic isolation into the LVPA; however, as we noted in the CY 2025 ESRD PPS final rule our analysis did not find higher costs associated with low-volume facilities in isolated areas (89 FR 89159). Further analysis does not reveal higher costs associated with isolated low-volume facilities, although we noted that the CY 2026 ESRD PPS final rule contained an unrelated payment adjustment for facilities in certain non-contiguous states and territories, the NAPA. We stated in the CY 2027 ESRD PPS proposed rule that we believe the current NAPA addresses some of the concerns of these commenters (90 FR 53102).

In the CY 2024 RFI, we included two potential LVPA structures which both included up to 8,000 treatments per year, but these were 4-tiered and 8-tiered structures. Some respondents opposed the 8-tier LVPA presented in that RFI, with several raising concerns with the budget neutrality factor and others stating that the adjustment factors for the lower-volume tiers were too high and the factors for the higher-volume tiers were miniscule. We considered these comments when designing the 6-tier LVPA proposed in the CY 2027 ESRD PPS proposed rule. By eliminating the 1,000 and 2,000 treatment tiers, we explained, we have mitigated the overall budget neutrality impact of the proposal. Additionally, this reduces concerns related to the high factors associated with these lowest-volume tiers. We disagreed with those commenters that the higher-volume tiers' adjustment factors are miniscule. Our analysis indicates that a 5.0 percent increase is warranted for the 7,000-treatment count tier, and although the proposed adjustment factor is lower than others, it would still represent a substantial increase in payments to those facilities. Other commenters who supported the tiered approaches in response to that RFI indicated that higher-volume tiers with lower payment adjustments can serve to prevent

facilities that are on the border with the more substantial tiers to exceed the treatment volume threshold in one year and still be eligible for the higher payment adjustment tiers in the next year. Several other commenters raised concerns with the tiered system and indicated a belief that it would not eliminate gaming completely.

We noted that we believe that our proposed 6-tier LVPA strikes a balance between appropriately providing higher payment to these higher cost ESRD facilities and addressing the concerns raised by commenters. We believe that the tiered policy finalized in the CY 2025 ESRD PPS final rule (89 FR 89161) which uses the median treatment volume from the past three years helps to effectively reduce gaming by eliminating the incentive to lower treatment volume in any single year. We believe that our CY 2027 proposal to have 3,000 treatments be the lowest-volume treatment tier also prevents any concerns related to the high adjustment factors associated with potential lower-volume tiers and reduces budget neutrality concerns. We believe that the higher tiers from 6,000 to 7,999 treatments serve to act as a sort of transition phase allowing facilities to exceed the lower treatment tiers, while still receiving a data-supported payment adjustment. Lastly, these proposed payment tiers are evidence-based as they are derived from the analysis described previously to more fully represent the extent to which these low-volume facilities truly face higher costs.

To effectuate this change, we proposed modifications to our LVPA regulation at § 413.232 to update the current maximum LVPA threshold of 4,000 treatments to the proposed new threshold of 8,000 treatments. Specifically, we proposed modifications to § 413.232(b)(1), which contains the treatment volume threshold for the LVPA, and (g)(5), which notes the exceptions to the treatment volume threshold for disasters and other emergencies finalized in the CY 2024 ESRD PPS final rule, to indicate the new treatment threshold of 8,000. We proposed to update the threshold for the exception to the treatment volume threshold for disasters and other emergencies to ensure consistency with the threshold of § 413.232(b)(1). We noted that these proposed modifications would retain the requirements that an ESRD facility be below the treatment volume threshold in each of the prior three cost reporting years, and that the median treatment volume over the past three cost reporting years would only be used for tier determination for eligible ESRD facilities.

We proposed this policy change be effective January 1, 2027. However, we recognized that the LVPA requires an attestation process with which many ESRD facilities that furnish more than 4,000 treatments per year are likely unfamiliar. We solicited comments on how we can accommodate these facilities to allow them to properly attest for the LVPA for CY 2027, including delaying the effective date of this proposal or allowing attestations after the typical November 1, 2026, deadline. We noted that changes to the attestation deadline would require a modification to § 413.232(e), likely in the form of adding a new paragraph. We stated that we were not proposing any of these changes, but we noted that we may finalize them, or other changes to address any administrative challenges associated with this proposal in the CY 2027 ESRD PPS final rule, depending on comments we receive.

We requested comments on all aspects of the proposal, including the proposed expansion of the LVPA above 4,000 treatments per year, the proposal to extend the LVPA to ESRD facilities which furnish fewer than 8,000 treatments per year, the proposed 6-tiered structure and adjustment factors presented in Table 17, the proposed budget neutrality factor, the proposed effective date of January 1, 2027, and the proposed modifications to § 413.232. Additionally, we requested comments on the potential administrative challenges associated with this proposed change and the potential solutions discussed previously.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters who opined on the policy expressed support for the expanded LVPA. MedPAC supported the policy change but reiterated past suggestions for methodological improvements which are discussed in further detail later in this section. Some commenters highlighted the particular impact on certain patient populations. Several commenters expressed a belief that this policy would have positive impact on quality of care and access for ESRD patients. Some commenters stated a belief that this expanded policy would help mitigate the “cliff” effect for which interested parties had criticized the LVPA in the past. Additionally, some commenters stated that this expanded policy would recognize the financial pressures that exist for facilities which furnish 4,000 or more treatments per year. A commenter cited a MedPAC figure which stated that the lowest

³⁰ <https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-reports-and-educational-resources>.

quintile of treatment volumes operated at a –11.6 percent margin.

Response: We appreciate the support for the proposed expansion of the LVPA up to 8,000 treatments and the proposed 6-tier structure. We agree that this policy will have beneficial impacts on many critical populations who are only serviced by a low-volume facility. Likewise, we agree that adding in tiers between 4,000 and 8,000 treatment volume serves both to lower the impact of any “cliff” effect and address the higher costs those facilities face. We acknowledge the citation of MedPAC’s margin analysis; although we did not directly consider this analysis in our calculation of the adjustment factors, we believe that the updated LVPA would better align relative payments with resource use for low-volume facilities.

Comment: Several commenters discussed geographic isolation of ESRD facilities with regard to the LVPA. MedPAC reiterated its support for a low volume and isolated (LVI) methodology which would restrict the LVPA to only facilities in isolated geographic areas and several other commenters expressed support for this LVI methodology. A commenter acknowledged that CMS’s past analysis of cost report data did not show differences in cost between low-volume ESRD facilities in isolated and non-isolated areas but stated that there were different costs for ESRD patients in isolated areas, such as increased transportation costs. A commenter supported the fact that the LVPA does not incorporate geographic isolation and noted that specialized facilities can operate at a low volume even if they are in urban areas. Several commenters, including MedPAC, noted the overlap between the rural adjustment and LVPA and some requested that CMS discontinue the rural adjustment and use that money to fund the LVPA in lieu of, or supplementing, budget neutrality.

Response: We acknowledge the commenters’ array of opinions on whether the LVPA should incorporate geographic isolation. Section 1881(b)(14)(D)(iii) of the Act requires the LVPA to reflect the extent to which cost incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing renal dialysis services. As we have noted in the past (88 FR 76370, 89 FR 55800), our analysis has not found a correlation between geographic isolation and higher costs for low-volume facilities. As such we have not proposed to incorporate geographic isolation into our definition of low-volume or our requirements for the LVPA. We continue to acknowledge the suggestion of MedPAC and others, but

we believe that if a facility operates at low volume in an urban or otherwise non-geographically isolated area it is appropriate for it to receive the LVPA. We discuss budget neutrality in greater detail later in this section; however, we note that the relatively small rural adjustment factor of 0.8 percent which applies to approximately 14 percent of ESRD PPS treatments is not enough to counteract the budget neutrality of this proposal, which reduces the base rate for all treatments by greater than 1.0 percent. However, removing the rural factor would lessen the impact of the budget neutrality factor. We did not propose to eliminate the rural factor in the CY 2027 ESRD PPS proposed rule, and we do not believe that such a policy would be appropriate at this time. Although there is overlap between what facilities receive the LVPA and the rural adjustment, not all rural facilities receive the LVPA. The rural factor accounts for any higher costs that both LVPA rural and non-LVPA rural facilities face. In calculating the LVPA adjustment factors for the CY 2027 ESRD PPS proposed rule, we controlled for a facility’s rural status, as discussed in further detail in the next response.

Comment: Some commenters questioned whether CMS accounted for other ESRD PPS payment adjustments, such as the rural adjustment or NAPA, in developing the LVPA proposal. These comments often accompanied concerns that the proposed LVPA may overstate the costs associated with low volume. One of these commenters, an LDO, stated a belief that treatment volume may be serving as a proxy for other underlying factors, such as geographic isolation, and expressed concern that continuing to rely on treatment volume alone would not fully address these underlying factors.

Response: We did control for rurality and being located in a NAPA area in our analysis for the proposed rule. Section 1881(b)(14)(D)(iii) of the Act requires the LVPA to reflect the extent to which cost incurred by low volume facilities exceed the costs incurred by other such facilities. We recognize that there are likely other unknown factors which contribute to the LVPA; however, we believe that the analysis upon which the proposed 6-tier LVPA was based is the best available estimate of the extent to which low-volume facilities face higher costs. We acknowledge that it is possible that some other factors are contributing through the LVPA, however, to the extent that those factors result in low-volume facilities facing higher costs than other such facilities, we believe it is reasonable for the LVPA to account for them. While we control

for available factors, like rurality and geographic area, it is impossible for our analysis to control for every single potential covariable. We continue to believe our analysis for calculating the LVPA effectively estimates the extent to which low-volume facilities face higher costs than other such facilities. However, we welcome additional information from interested parties on other potential confounders and covariables which we can control for in a future analysis, as appropriate.

Comment: A commenter recommended that CMS continue to monitor the LVPA and its effectiveness in addressing its goals.

Response: We thank the commenter for the recommendation. We intend to continue to monitor the LVPA and will make further changes, if appropriate, in potential future rulemaking.

Comment: A commenter noted that the analysis we included in the CY 2027 ESRD PPS proposed rule indicated that for the 2022 to 2024 data range most Medicare facilities experienced per-patient costs that exceeded Original Medicare payments for patient care. The commenter emphasized that data point was applicable beyond the context of the LVPA to the broader ESRD PPS.

Response: We appreciate the insight into the data analysis we included in our proposed rule. We agree that considering Medicare cost data is applicable when considering policies outside the LVPA. However, we note that in the analysis we published, which is included earlier in this section in Table 15, we found that the facilities that tend to have costs exceeding payments are those with less than 8,000 treatments, which helped inform our proposal to expand the LVPA up to 8,000 treatments. Although we did not include this result in the CY 2027 ESRD PPS proposed rule, the analysis from which Table 15 was derived also found that the overall treatment weighted facility level mean payment to cost ratio was 1.01 and the median was 0.98. We reiterate that these figures should not be interpreted directly in terms of payment adequacy for the reasons discussed in the context of Table 15, most notably because they reflect costs for payors other than Original Medicare, which may be different. We believe that the overall payment rate under the ESRD PPS is appropriate and that this LVPA policy will better align payments with resource use.

Comment: Several commenters specifically discussed the implementation timeline for the proposed 6-tier LVPA. A few of those commenters recommended delaying the attestation deadline for 2026. A

commenter recommended delaying the implementation of the policy to CY 2028 but also expressed support for delaying the attestation deadline as an alternate recommendation.

Response: We appreciate the insight and recommendation into the operation timeline for this proposed policy change. In the proposed rule we solicited comments on potential changes to the operational timeline for this policy, including the options recommended by the commenters. We believe that extending the attestation deadline would allow for the ESRD facilities to submit attestations for payment year 2027 and for the MACs to process those attestations in time for CY 2027 payments. After considering these comments and evaluating the potential operational difficulties associated with this change, we are finalizing an extension to the attestation deadline for payment year 2026 to December 31, 2026. This is consistent with past extensions to the attestation deadline in 42 CFR 413.232(e) which impacted LVPA attestations for payment years 2015, 2016, and 2021. We are finalizing modifications to § 413.232(e) to add a new paragraph to effectuate this delayed attestation deadline.

Comment: Numerous commenters opined on the proposed budget neutrality of this LVPA proposal. Many commenters requested CMS implement this policy in a non-budget neutral manner. Others requested CMS budget neutralize the policy by removing the rural adjustment factor; some of those requests were combined with requests for an LVI methodology that directly incorporated isolation. A few commenters noted that some high-volume urban facilities treat vulnerable or medically complex patient populations. Many commenters noted the relatively large impact this policy would have on the base rate and stated that such a reduction could have adverse impacts on care. Many commenters highlighted that there is no statutory requirement for budget neutrality for the LVPA.

Response: We understand the concerns raised by commenters regarding the budget neutrality of this LVPA proposal, as the proposed budget neutrality factor of 0.98898 is relatively large compared to the budget neutrality factors of past changes to adjustment factors. However, budget neutrality is appropriate for this proposal. The LVPA is a longstanding, statutorily required part of the ESRD PPS. When the payment system was implemented in 2011, low-volume facilities were considered in creating the base rate. Thus, the higher costs that low-volume

facilities face are included in the ESRD PPS payment rate. The proposed LVPA appropriately recognizes the higher relative costs of low volume facilities, and the application of the budget neutrality factor reduces relative payments to high-volume ESRD facilities.

We considered removing the rural adjustment factor as part of the budget neutrality of this proposal, although we note that it would not be nearly enough to offset the impact of the budget neutrality factor. However, we believe that ensuring access for rural populations is important. While the LVPA addresses some factors which may cause costs to be higher in rural areas, we believe the rural adjustment is still useful in protecting access for higher-volume or otherwise LVPA ineligible ESRD facilities in rural areas.

We likewise recognize that there are some urban facilities with high volume and high costs per treatment. We note that urban areas generally have higher wage index values and receive higher relative payments accordingly. Additionally, the ESRD PPS includes many case-mix adjustment factors which provide higher payment to any ESRD facility which furnishes care to certain medically complex patients as specified at § 413.235. Lastly, for patients whose medical complexity is not addressed by the patient level case-mix adjustment factors, we have an outlier adjustment that can provide increased payment for higher-than-expected use of certain eligible ESRD outlier services as specified at § 413.237. The purpose of the LVPA is to account for the extent to which low-volume facilities face higher costs than other such facilities, and we believe that these other payment adjustments address the concerns of commenters related to high-cost urban ESRD facilities.

The reason this budget neutrality factor is larger than many past budget neutrality factors is because it is reallocating a larger amount of payments. Our analysis indicates that higher volume ESRD facilities have lower costs, and our comparison of Original Medicare payments to costs indicates that payments are notably above costs for these facilities. The purpose of this change is not to increase overall payments, but to better allocate payments within the ESRD PPS. Based on our analysis, this update to the LVPA accomplishes that goal.

We acknowledge and agree with commenters who note that there is no statutory budget neutrality requirement for changes to the LVPA. However, as noted previously, we believe it is most

appropriate to implement this policy change in a budget neutral manner.

Comment: A commenter noted that the payment to cost ratio presented in the proposed rule for facilities with between 8,000 and 10,000 treatments was 0.99 and that a budget neutrality factor would lower payment adequacy for this group of ESRD facilities.

Response: As discussed previously, the analysis presented in the CY 2027 ESRD PPS proposed rule was not a comprehensive margin analysis and should not be interpreted in terms of payment adequacy. The average cost per treatment for that analysis was derived from Medicare cost report data, which reflects costs for payers other than Original Medicare. As MA and private plans may pay higher for renal dialysis services, it is reasonable to believe that beneficiaries may be getting different care. As such, we do not believe that the budget neutrality factor would inappropriately lower payment adequacy for the 8,000–10,000 treatment ESRD facility group. As noted previously, budget neutrality is appropriate for this proposal because it is aligning payments under the ESRD PPS with relative resource use. Our analysis has found that those facilities that furnish more treatments have lower costs-per-treatment, on average. As such, a budget neutrality factor that, when combined with the impact of this policy, reallocates money from higher cost to lower cost facilities is appropriate.

Comment: A commenter stated that it was appropriate for CMS to use an attestation proxy for determining budget neutrality but requested more information and asked if CMS assumed that attestation rates would vary by treatment tier. That commenter noted that higher volume LVPA eligible facilities could be less likely to attest if they determine that the adjustment is not worth the administrative burden. Another commenter recommended that we monitor LVPA participation and make changes in future years if the budget neutrality reduction overestimated LVPA payments.

Response: We appreciate the thoughtful insight into the attestation proxy. We did not account for varying attestation rates for different tiers, as we have no data for the higher volume tiers upon which to base that attestation proxy. Our attestation proxy was by ownership type. We believe that this is the most appropriate as we observe different attestation rates for certain categories of facility ownership and, while we cannot identify specific reasons for why a seemingly eligible ESRD facility does not attest for the

LVPA, we can posit two potential reasons which are both related to ownership. The first potential reason is that an ESRD facility lacks the administrative support or resources to attest. We believe that it is reasonable to assume that administrative support would correlate with ownership type. That is, a facility owned by an LDO would likely have more administrative support than an independent facility, and that hospital-based facilities likely

also have different levels of administrative support and different administrative hurdles. The second potential reason is that our data may not be identifying all instances of common ownership among ESRD facilities, which is relevant as the determination of treatment volume for the LVPA considers nearby facilities with common ownership. While we can plainly identify some instances of common ownership from our data, there are

likely some instances where a seemingly eligible ESRD facility is not attesting for the LVPA because it is not actually eligible due to the common ownership volume aggregation. Using a proxy based on ownership likely catches some of the correlation between an ESRD facility having nearby unidentified commonly owned facilities. The attestation simulation we used for the budget neutrality impacts for this final rule are in Table 18.

TABLE 18: Attestation Proxy Used for Budget Neutrality Calculation

Ownership	Number of Potentially Eligible Low-Volume Facilities*	Observed Attestation Rate
Large Dialysis Organization	230	91.7%
Regional Chain	35	65.7%
Independent Facilities	96	54.2%
Hospital-Based ESRD Facilities	111	45.9%

*This column includes facilities that appear to be eligible for the LVPA based on our data but do not attest. Eligibility for determining the attestation proxy was based on the 4,000-treatment count threshold that applied for the observation period.

We generally do not make retrospective budget neutrality changes as the intention of a budget neutrality factor is to capture the impact attributable to the change itself and not any related or unrelated trends in utilization. For example, if more low-volume ESRD facilities were to open based on this policy, we would not consider that as part of the budget for the proposal, even though overall payment would change. We believe it is appropriate to use the earlier attestation

rates observed for currently eligible LVPA facilities for these newly eligible LVPA facilities. However, we recognize that there is no observed data for attestation rates among these mid-sized 4,000 to 8,000 treatment ESRD facilities, which differentiates this proposal from other past proposals where we have historical data. As such, we intend to monitor the actual attestation rates and actual payments under the LVPA. If attestation patterns differ significantly from our observed historical-rate-

derived attestation rates, we would consider making changes, if appropriate, in potential future rulemaking.

Final Rule Action: After consideration of public comments, we are finalizing the 6-tier LVPA as proposed. We are recalculating the budget neutrality factor with our updated impacts simulation. The updated budget neutrality factor is 0.98901. The final LVPA tiers are presented in Table 19.

TABLE 19: Final 6-tier LVPA

Treatment Volume Tier	Number of ESRD Facilities Expected to Receive the LVPA	Current Adjustment Factors	Final Adjustment Factors
0-2,999 treatments per year	189	1.289	1.368
3,000-3,999 treatments per year	223	1.183	1.249
4,000-4,999 treatments per year	299	1.000	1.173
5,000-5,999 treatments per year	296	1.000	1.120
6,000-6,999 treatments per year	307	1.000	1.080
7,000-7,999 treatments per year	175	1.000	1.050

Additionally, we are finalizing an extension to the attestation deadline to December 31, 2026, for the LVPA for payment year CY 2027. We are finalizing the addition of a new paragraph § 413.232(e)(5) and finalizing conforming edits to paragraphs § 413.232(e)(3) and (e)(4) to effectuate

this change. We note that these modifications to the LVPA and attestation deadline for payment year 2027 also apply to payments for renal dialysis services furnished to pediatric ESRD patients, as discussed in section II.B.9.d.(3) of this final rule.

9. Payment for Pediatric Patients With ESRD Receiving Renal Dialysis Services

a. Background and History of Pediatric ESRD Payment

Section 1881(b)(14)(D)(iv)(I) of the Act provides that the ESRD PPS may include such payment adjustments as

the Secretary determines appropriate, including a payment adjustment for pediatric providers of services and renal dialysis facilities. Historically, determining an appropriate payment adjustment for pediatric ESRD patients³¹ has been challenging due to limited data. The Medicare pediatric ESRD patient population receiving dialysis is small compared to the adult ESRD population; the pediatric ESRD patient population represents approximately 0.16 percent of Original Medicare treatments in 2024 from Common Working File data ending June 27, 2025.

In the past, CMS has considered various payment adjustments for pediatric patients with ESRD, including different Medicare payments by sex or comorbidities (74 FR 49984 through 49986). However, many of these adjustments were not used as we were unable to get acceptable precision due to the small sample size of pediatric patients with ESRD.

Prior to the establishment of the ESRD PPS, payment for pediatric ESRD renal dialysis services was generally the same rate as adult ESRD renal dialysis services, unless the ESRD facility qualified for an exception to the composite rate. Section 1881(b)(7) of the Act stated that, subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) (BIPA), the Secretary shall provide for exceptions as may be warranted by unusual circumstances (including the special circumstances of sole facilities located in isolated, rural areas and of pediatric facilities). During this time, CMS received many comments and concerns regarding the payment rate for renal dialysis services furnished to pediatric patients with ESRD. Section 623(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) later amended section 422(a)(2) of BIPA to provide that any pediatric ESRD facility would be eligible for an exception to the composite rate, effective October 1, 2002. This statute defined pediatric ESRD facilities as facilities with at least 50 percent patients under the age of 18. These policies enabled pediatric ESRD facilities to receive payments recognizing the higher cost associated with furnishing renal dialysis services to pediatric ESRD patients (69 FR 47530).

We finalized a basic case-mix adjustment to the composite payment rate in the CY 2005 Physician Fee Schedule (PFS) final rule published on November 15, 2004 (69 FR 66327). This included a 62 percent pediatric ESRD payment increase (that is, an adjustment factor of 1.62) applied to the composite payment rate per treatment for any facility when furnishing outpatient renal dialysis services to pediatric patients with ESRD. This factor was derived from the average exception amounts for 20 ESRD facilities that had received exceptions for pediatric patients. This was intended to be a temporary measure, which would be eliminated once we developed the case-mix methodology that would apply for the ESRD PPS bundled payment. The use of this methodology allowed CMS to provide additional payment for the pediatric ESRD population under the composite rate in a data-driven manner to account for the higher costs pediatric ESRD patients faced (69 FR 66327).

Section 153(b) of MIPPA added section 1881(b)(14) of the Act, which required CMS to implement an ESRD bundled PPS beginning January 1, 2011, under which a single payment for renal dialysis services is made in lieu of any other payment. Renal dialysis services generally include items and services included in the composite rate for renal dialysis services as of December 31, 2010, and services furnished to individuals for treatment of ESRD, which were formerly separately billable, including drugs and biological products and laboratory tests. In the CY 2011 ESRD PPS proposed rule, we proposed a single composite rate factor of 1.199 for all pediatric ESRD patients receiving renal dialysis services (74 FR 49982 through 49983). We also proposed an eight-group system for separately billable renal dialysis services furnished to pediatric ESRD patients with two subdivisions for each of the following factors: age (under 13, 13 to 17), modality (HD, PD) and number of comorbidities (none, one or more) (74 FR 49983 through 49987).

The CY 2011 ESRD PPS proposed rule then calculated an “expanded bundle” factor, which combined the composite rate factor of 1.199 and the separately billable factors for each of the eight groups (74 FR 44987). These expanded bundle factors were the proposed pediatric ESRD patient-specific case-mix adjustment factors that would be applied to the base rate under the ESRD PPS. These factors were based on a regression of costs for all renal dialysis services furnished to pediatric ESRD patients. Comments on this proposed rule indicated that many interested

parties believed the expanded bundle factor was insufficient (75 FR 49128). In the CY 2011 ESRD PPS final rule, we responded to those comments by implementing the first iteration of the current four-group system for both the expanded bundle and the separately billable services. This methodology was data driven, but unlike the simple regression for composite rate costs, allowed for different Medicare payment amounts based on two sets of two characteristics: age of the patient (under 13 or 13 to 17) and modality of the treatment (HD or PD). Additionally, this methodology used the same groups for the expanded bundle and separately billable factors (75 FR 49134). We codified the pediatric ESRD patient payment adjustment in § 413.235(b), which states that CMS adjusts the per treatment base rate for pediatric ESRD patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act, to account for patient age and treatment modality. These multipliers were updated in the CY 2016 ESRD PPS final rule using the same methodology (80 FR 69001 through 69002).

b. Transitional Pediatric ESRD Add-On Payment Adjustment (TPEAPA)

As discussed in the CY 2024 ESRD PPS final rule (88 FR 76375), despite these changes intended to improve payment accuracy for renal dialysis services furnished to pediatric ESRD patients, CMS continued to receive comments and concerns from interested parties that payment amounts for renal dialysis services furnished to pediatric ESRD patients are insufficient. In addition to comments received through the annual ESRD PPS rulemaking, we also solicited comments from interested parties on several occasions. During the Technical Expert Panel (TEP) of December 2020, we queried a panel of experts on how to improve payment for pediatric dialysis care under the ESRD PPS. Panelists generally preferred creating more refined case-mix adjusters over creating an entirely new pediatric ESRD PPS, citing the costs of creating an entirely new system both on CMS and the ESRD facilities and the need for new legislation to be able to increase payment through a separate pediatric ESRD PPS. Panelists also pointed to labor costs as a major reason for higher costs among pediatric dialysis clinics because these patients need more nursing attention and specialized pediatric nutritionists.³² In the CY 2023

³¹ A “Pediatric ESRD Patient” is defined in § 413.171 as an individual less than 18 years of age who is receiving renal dialysis services. In this section of the final rule, we use the term “pediatric ESRD patient” except when referring to the regulatory language.

³² <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

ESRD PPS proposed rule (87 FR 38529), we issued a request for information regarding equitable access for pediatric patients with ESRD. We noted that interested parties have emphasized the higher labor costs, including the need for increased nursing attention and specialized clinical staff. They noted that Medicare payment for pediatric ESRD patients is too low and that the ESRD PPS bundled payment does not target the unique issues facing ESRD facilities furnishing renal dialysis services to pediatric ESRD patients.

We explained that CMS sought to improve payment accuracy for renal dialysis services furnished to pediatric ESRD patients by better aligning payments with observed costs. Ensuring Medicare payments are appropriate and align costs for renal dialysis services furnished to pediatric ESRD patients would support more ESRD facilities in providing quality care to this vulnerable population. The main barrier to aligning payment has been the lack of sufficient data to determine the relative costs associated with furnishing renal dialysis services to pediatric ESRD patients. To improve payment rate accuracy for pediatric ESRD patients, CMS issued changes to the cost reports for hospital-based and freestanding ESRD facilities effective October 1, 2022, and January 1, 2023, respectively (87 FR 26760).^{33 34}

Nevertheless, accurate payment for pediatric ESRD renal dialysis services under the ESRD PPS remains challenging due to small sample sizes and systematic differences between pediatric and adult renal dialysis services. Pediatric renal dialysis treatments often occur in hospitals which have lower volumes and higher costs. This complicates cost estimation. To address these challenges, we conducted an alternative analysis which used propensity score matching (PSM) to estimate costs accurately. Findings presented in the CY 2024 ESRD PPS final rule indicated facilities that only serve pediatric ESRD patients incur 40 percent higher costs per patient than those not serving pediatric ESRD patients (88 FR 76376). Medicare accounted for the current adjustments for higher pediatric costs from established case-mix adjusters, which were about 10 percent higher for pediatric renal dialysis services than adults in 2022.

In the CY 2024 ESRD PPS final rule, CMS finalized the Transitional Pediatric

ESRD Payment Adjustment (TPEAPA) which increased payments for all pediatric ESRD patients under 18 years of age (88 FR 76344). CMS finalized the budget neutral 30 percent add-on payment adjustment in the CY 2024 ESRD PPS final rule effective January 1, 2024, for CYs 2024 through 2026 (88 FR 76380). CMS finalized the TPEAPA as a time-limited payment adjustment, so we could collect more targeted pediatric data. The time-limited 3-year payment adjustment provided enough time to evaluate data from updates to cost reports specific to pediatric treatments. The TPEAPA is codified at § 413.235(b)(2). Beginning January 1, 2024, the ESRD PPS provided a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230 for renal dialysis services furnished to Pediatric ESRD Patients, as defined in § 413.171, during calendar years 2024, 2025, and 2026. CMS continued to analyze payment and cost data throughout the implementation of TPEAPA to determine whether to extend the TPEAPA past December 31, 2026, or propose an alternative approach after additional data analysis.

c. Analysis of Additional Pediatric ESRD Cost Data

As noted previously, payment accuracy historically has been difficult for pediatric ESRD renal dialysis services because of the small sample size of pediatric ESRD patients receiving renal dialysis services under the ESRD PPS. Pediatric ESRD renal dialysis treatments differ from adult ESRD renal dialysis treatments in several crucial ways. For example, pediatric ESRD facilities³⁵ are more likely to be hospital-based and, on average, have lower treatment volume and are in higher wage index areas. These systematic differences in the treatment site, when combined with the small sample size, make it very difficult to obtain low variance estimates of the differences in costs between pediatric and adult ESRD dialysis patients.

As discussed in the CY 2027 ESRD PPS proposed rule (91 FR 38827), to

better understand these differences, CMS analyzed cost reports from both freestanding (CMS-265-11) and hospital-based (CMS-2552) facilities for 2023 and 2024 following cost report revisions. We found relatively few freestanding facilities reported unique pediatric staff. Additionally, approximately 30 percent of children's hospitals as defined at 42 CFR 412.23(d) reported pediatric ESRD nursing staff and 25 percent reported pediatric ESRD staff other than registered nurses on the cost report. For non-children's hospitals these figures were 1 percent and 0.5 percent, respectively.

CMS observed increased reporting of pediatric-specific supply costs in hospital-based ESRD facilities between 2023 and 2024. In 2023, the mean pediatric ESRD patient supply cost per treatment in hospital-based ESRD facilities was \$138.23; in 2024, it was \$321.22. We noted that this increase in pediatric ESRD patient supply cost per treatment likely reflects increased reporting, rather than increases in pediatric costs of greater than 100 percent. Prior to 2024, the hospital-based (CMS-2552) facilities cost report lacked the specificity to consistently delineate pediatric ESRD patient supply cost from adult ESRD patient supply cost. Additionally, CMS provided interested parties with additional guidance on the completion of cost reports to share with children's hospitals that provide renal dialysis services.

Despite continued limitations in pediatric-specific ESRD reporting, CMS observed statistically significant higher costs associated with the furnishing of renal dialysis services to pediatric ESRD patients. As discussed in the following section, an updated regression analysis of composite rate costs found the incremental cost impact of pediatric ESRD treatment share was approximately 33 percent. Specifically, using data from CYs 2022 and 2023, CMS estimates that the difference in total cost per treatment between facilities with no pediatric ESRD treatments and those furnishing exclusively pediatric ESRD treatments is approximately 33 percent. This does not mean that every pediatric ESRD treatment represents a 33 percent increase in cost.

d. Proposals To Modify Payment for Pediatric ESRD Patients

(1) Updated Regression Analysis for CY 2027

In the CY 2011 ESRD PPS final rule, we established the pediatric ESRD case-mix adjustments based on two age

³³ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r7p242>.

³⁴ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r18p240i>.

³⁵ The term "pediatric ESRD facility" is used at § 413.170(b) in the context of exceptions to the composite rate prior to 2011. This section specifically refers to § 413.184 for the specification of pediatric patient mix, which includes the qualification at § 413.184(a)(1) that at least 50 percent of the patients are under 18 years of age, alongside other requirements. Consistent with that section, for our proposal and this final rule, we use this term to mean ESRD facilities with at least 50 percent of patients under 18 years of age, but we are not including the other qualifications of § 413.184(a) which were requirements for the exceptions to the composite rate payments.

categories (age <13, 13–17) and two dialysis modalities (PD or HD). We used the resulting four case-mix categories as the basis for classifying pediatric ESRD patients (75 FR 49132). The adjustment factors for each of these case-mix categories were based on the product of two factors representing the cost of composite rate services and another representing the costs of formerly separately billable services. Specifically, the formula used the average payment differential between adults and pediatric ESRD patients (P), the average case-mix multiplier for adults (C), the ratios for composite rate (W_CR) and separately billable services (W_SB), and the separately billable modifiers for each pediatric category (Mult_SB). The expanded bundle payment multiplier established in the CY 2011 ESRD PPS final rule (75 FR 49133) for CR and SB

services for each of the four pediatric classification cells can be calculated as:

$$\text{Mult_EB} = P * C * (W_CR + W_SB * \text{Mult_SB})$$

The pediatric multipliers were most recently recalculated using this established methodology in the CY 2016 ESRD PPS final rule (80 FR 69002). These multipliers are presented in Table 21.

We explained in the CY 2011 ESRD PPS final rule that additional payments currently provided for pediatric ESRD patients under the basic case-mix composite payment system are likely to reflect higher costs for smaller dialysis facilities. Based on that calculation, we noted the application of the low-volume payment adjustment (LVPA) for pediatric ESRD patients would be duplicative. Therefore, the LVPA was

only applicable to adult ESRD patients and was not used in calculating the payment rate per treatment for pediatric dialysis patients. Facilities qualifying for the LVPA which treat both adult and pediatric ESRD patients, have only received the LVPA for adult renal dialysis patients (75 FR 49134).

For the CY 2027 ESRD PPS proposed rule, CMS revised its regression model to evaluate the relationship between cost per treatment and facility characteristics. CMS analyzed a logarithmic regression model using 2022 and 2023 cost report data and controlled for geographical and facility level characteristics (ownership, facility type, rurality, treatment volume, and percentage of home dialysis training treatments) to estimate cost differences based on pediatric share. These results are presented in Table 20.

TABLE 20 Regression Results

Facility Characteristic	Adjustment Factor ⁺	Significance Level ⁺
Pediatric Share	1.3298	**
Ownership - LDO	1.1019	**
Ownership - Regional	1.1400	**
Ownership - Unknown	1.1996	*
Ownership - Independent	1.0000	N/A
Hospital Based	1.6177	**
Rural	0.9589	**
LN (facility size) ³⁶	0.1404	**
LN (facility size) squared	1.1008	**
Training percentage	1.1388	Not statistically significant

⁺ The factors presented in Table 20 are the exponentiated regression coefficients. Significance at p=0.01 is notated with (**) and significance at p=0.05 is notated with (*).

As shown in Table 20 both pediatric ESRD treatment share and ESRD facility treatment volume, are statistically significant predictors of cost. These findings indicate that facilities furnishing a higher share of renal dialysis services to pediatric ESRD patients incur higher per-treatment costs. These increased expenses are

primarily attributable to the need for specialized equipment, dedicated staffing, and unique clinical protocols required for ESRD patients under 18 years of age. However, hospital-based ESRD facilities, which are the primary sites for pediatric dialysis, incur significantly greater operational costs in comparison to freestanding ESRD facilities. Furthermore, this analysis demonstrates that ESRD facilities with lower treatment volume incur higher

costs, independent of their share of pediatric patients. Unlike the payment analysis conducted for the CY 2011 ESRD PPS final rule, this analysis has separately isolated the marginal costs of treating pediatric ESRD patients from the marginal costs associated with low volume. As discussed in the following section, after considering the results of our latest analysis, we proposed revisions to the pediatric ESRD case-mix adjusters and proposed to change our

³⁶ LN denotes the natural logarithm which is to say the logarithm of base (e).

longstanding LVPA policy to appropriately reflect these two main drivers of pediatric ESRD cost.

(2) Revision of Pediatric Adjusters

We proposed to update the pediatric ESRD adjustment factors using the calculation established in the CY 2011 ESRD PPS final rule (75 FR 49133). The updated calculation formula is as follows:

$$\text{Mult}_{EB} = D * C * (W_{CR} + W_{SB} * \text{Mult}_{SB})$$

As discussed in the previous section, the CY 2011 calculation utilized the

estimated separately billable adjustments as well as 4 factors: average payment differential between adults and pediatric ESRD patients (P), the average case mix multiplier for adults (C), the weight for composite rate (W_CR) and the weight for separately billable services (W_SB). We proposed to update these figures according to the most recent data, as follows. We noted that instead of using the average payment differential P, we proposed to use the average cost differential between adults and pediatric ESRD patients as derived from our regression model, which we refer to as D. As previously discussed,

we conducted an updated regression analysis for the separately billable adjustments using data from CYs 2022 and 2023. These figures are presented in the “Proposed SB Multiplier” column in Table 21. Using the same data, we updated the weights for the CR and SB costs to 0.915 and 0.085, respectively. From CY 2023 claims data, we determined that the average case-mix adjustment factor for adult ESRD beneficiaries is 1.1045. Lastly, as discussed previously, we calculated that the average difference in pediatric to adult ESRD patient costs is 1.3298 (that is, 32.98 percent).

TABLE 21: Proposed Pediatric Payment Multipliers

Category	Current SB Multiplier (2016)	Current EB Multiplier (2016)	Proposed SB Multiplier	Proposed EB Multiplier
Age 12 or under, PD	0.410	1.063	0.523	1.410
Age 12 or under, HD	1.406	1.306	1.269	1.503
Age 13-17, PD	0.569	1.102	0.734	1.436
Age 13-17, HD	1.494	1.327	1.531	1.536

The CMS regression analysis presented previously in this section, using cost report data with fields for more accurate reporting of pediatric costs from 2022 and 2023, indicates 32.98 percent higher costs incurred in treating pediatric ESRD patients compared to adult ESRD patients. These findings suggest that the 30 percent TPEAPA, which was based on a 40 percent cost differential, is approximately the same order of magnitude with observed cost differentials. The current regression analysis verifies the need for establishing more permanent payment adjustments to account for higher pediatric costs on an ongoing treatment basis.

We proposed to update the SB (outlier) and EB (case-mix) multipliers for pediatric patients according to the established methodology as presented in Table 21.³⁷ We noted that these proposed updates would result in functional adjustment factors for pediatric ESRD patients below those established for purposes of the TPEAPA.

We stated that we believe that this is reasonable for two reasons. First, as discussed in the CY 2024 ESRD PPS final rule, the TPEAPA was based on a relatively high variance analysis, and our new 33 percent cost differential falls within the confidence interval of that analysis (88 FR 76376 through 76377). Second, as discussed in the following section, we proposed to extend the LVPA to treatments furnished to pediatric ESRD patients. Taken together, these two proposed modifications, updating the SB (outlier) and EB (case-mix) multipliers for pediatric patients and extending the LVPA to payments for treatments furnished to pediatric ESRD patients, would provide a similar overall level of support while more directly targeting the underlying cost drivers. Under this proposed approach, low-volume facilities would receive higher payments for treatments furnished to pediatric ESRD patients, while high-volume facilities would receive somewhat lower payments relative to current policy.

We received comments from patient and caregiver representatives, patient advocacy organizations, professional associations, dialysis facilities and organizations, and other interested parties regarding the proposed revisions to payment for renal dialysis services furnished to pediatric patients. Commenters generally agreed that

furnishing renal dialysis services to pediatric patients is more resource-intensive than furnishing renal dialysis services to adult patients and supported continued recognition of those additional costs under the ESRD PPS. Commenters differed, however, regarding the appropriate methodology for recognizing those costs, including the proposed pediatric case-mix adjustment factors, the adequacy of the data used to develop the proposed adjustments, continuation of the TPEAPA, and application of budget neutrality. We summarize these comments and provide our responses below.

Comment: Several commenters supported CMS’s recognition that renal dialysis services furnished to pediatric ESRD patients are more resource intensive than renal dialysis services furnished to adult ESRD patients and generally supported establishing a permanent payment methodology following expiration of the TPEAPA. Commenters stated that pediatric dialysis requires specialized pediatric nephrologists, nurses, dietitians, social workers, pharmacists, child life specialists, and other multidisciplinary personnel, as well as pediatric-specific equipment and supplies, specialized clinical protocols, extensive family and caregiver education, psychosocial and nutritional support, care coordination,

³⁷ The EB, or expanded bundle, multipliers are the case-mix adjustment factors that apply to the overall payment. The SB, or separately billable, multipliers are the outlier services multipliers which apply only in the calculation of the outlier payment. As discussed earlier, we use the SB multipliers in the calculation of the EB multipliers, consistent with the calculation established in the CY 2011 ESRD PPS final rule (75 FR 49133).

and infrastructure necessary to care for infants, children, and adolescents with complex medical needs. Some commenters noted that pediatric renal dialysis services also must address growth, nutrition, bone health, development, and preparation for kidney transplantation.

Some commenters specifically supported the proposed permanent pediatric case-mix adjustments and application of the LVPA to qualifying pediatric renal dialysis treatments and urged CMS to finalize these policies. Other commenters agreed that a permanent increase in pediatric payment is necessary but disagreed with the proposed methodology for providing that additional payment.

Response: We appreciate commenters' support for appropriately recognizing the additional resources associated with furnishing renal dialysis services to pediatric ESRD patients. We agree that pediatric renal dialysis patients constitute a small and clinically complex population and that furnishing renal dialysis services to these patients may require specialized staffing, equipment, supplies, clinical expertise, family and caregiver support, and other resources that differ from those required for many adult beneficiaries with ESRD.

The purpose of our pediatric payment policy is to account appropriately for differences in expected resource use within the ESRD PPS while maintaining a methodology that is empirically based, administratively feasible, and consistent with the structure of the ESRD PPS. We appreciate commenters' descriptions of the clinical and operational resources necessary to furnish pediatric renal dialysis services and considered these comments in determining the appropriate payment methodology for CY 2027.

While some commenters disagree with the payment methodology in the CY 2027 proposed rule (91 FR 38826 through 38830) for pediatric ESRD patients, we note that the methodology is based on long-standing policy for calculating the case-mix adjusters for the pediatric ESRD PPS payment. We calculated that the average difference in pediatric to adult ESRD costs is 1.3298 (that is, 32.98 percent). This does not mean that every pediatric renal dialysis service should receive an increased payment as has been the case with the TPEAPA while CMS gathered and analyzed data. We proposed to update the SB (outlier) and EB (case-mix) multipliers for pediatric ESRD patients according to the established methodology as presented in Table 21. We noted that these proposed updates would result in functional adjustment

factors for pediatric ESRD patients below those established for purposes of the TPEAPA. However, extending the LVPA to pediatric renal dialysis services results in a substantially larger payment increase for hospital-based facilities (8.16 percent) than freestanding facilities (2.06 percent). Additionally, ESRD facilities with greater than 50 percent of pediatric ESRD patients saw a 6.54 percent increase in projected payments across all CY 2027 proposed policy changes. According to data analysis these combined policy changes are targeted at hospital-based ESRD facilities that specialize in providing pediatric renal dialysis services.

We believe the regression methodology remains appropriate for the CY pediatric update. As noted previously, the regression methodology targets PD which the pediatric population uses at a higher rate. The pediatric patients 12 and under PD case-mix factor increased by 32.6 percent, and the PD case-mix adjuster for 13–17 increased by 30.3 percent. Hemodialysis for both age groups is less than the increase resulting from the 30 percent TPEAPA based on the propensity score matching (PSM) analyses presented in the CY 2024 ESRD PPS final rule which indicated facilities that only serve pediatric ESRD patients incur 40 percent higher costs per patient than those not serving pediatric patients (88 FR 76376). CMS accounted for the current adjustments for higher pediatric costs from established case-mix adjusters, which were about 10 percent higher for pediatric renal dialysis services than adults in 2022. We continue to believe that it is appropriate to adjust the case-mix for pediatric ESRD patients according to the regression analysis for CY 2027 which is more refined and targeted than the TPEAPA. We note that the decrease in case-mix occurs as the pediatric population moves toward the more traditionally used adult therapy, HD, and as they age. We believe this is a logical progression for payment to follow. While we have not proposed to concurrently update the adult case-mix, we believe this is justified to address the finding that pediatric ESRD patients have higher costs than adult ESRD patients.

Comment: Commenters expressed concern regarding the proposal to replace the TPEAPA with updated pediatric case-mix adjustment factors and to apply the LVPA to treatments furnished to pediatric ESRD patients. Commenters stated that pediatric renal dialysis requires specialized staffing, supplies, and other resources and that these costs are incurred by both low-

and high-volume pediatric ESRD facilities. Commenters noted that treatment volume is not an appropriate proxy for the complexity or cost of pediatric renal dialysis care and noted that higher-volume pediatric ESRD facilities may serve as referral centers for more complex pediatric patients while continuing to incur substantial fixed costs associated with specialized pediatric care. Commenters requested that CMS establish a permanent payment adjustment applicable to pediatric ESRD treatments regardless of facility volume or, alternatively, extend the TPEAPA while collecting additional data.

Response: We appreciate commenters' concerns regarding the unique resource needs associated with furnishing renal dialysis services to pediatric ESRD patients, including the need for specialized clinical staff and supplies. We agree that pediatric ESRD patients have distinct care needs and that furnishing renal dialysis services to pediatric patients is associated with higher costs. Indeed, our updated analysis was specifically intended to quantify those higher costs using more recent cost data and forms the basis for the proposed updates to the permanent pediatric case-mix adjustments.

We clarify, however, that our proposal does not use facility treatment volume as a proxy for the clinical complexity of pediatric ESRD patients or for the additional costs attributable specifically to furnishing pediatric renal dialysis services. Rather, our analysis identifies pediatric ESRD treatment share and facility treatment volume as separate characteristics associated with cost per treatment. As discussed in the proposed rule, after controlling for facility volume and other facility characteristics, we estimated that the difference in total cost per treatment between facilities with no pediatric ESRD treatments and facilities furnishing exclusively pediatric ESRD treatments was approximately 33 percent. This analysis provides the basis for recognizing the additional costs associated with pediatric renal dialysis services through the permanent pediatric case-mix adjustments, independently of the LVPA.

We also conducted additional analysis in response to comments concerning whether the relationship between facility volume and cost observed among ESRD facilities generally is also present among ESRD facilities primarily furnishing pediatric renal dialysis services. For this analysis, we examined facilities with more than 50 percent pediatric ESRD treatment share using cost report and claims data

from CYs 2022 through 2025. The descriptive results demonstrate a clear inverse relationship between facility treatment volume and median cost per treatment within this pediatric ESRD facility sample.

We additionally estimated regression models using the pediatric ESRD facility sample. These models similarly indicate that, within pediatric ESRD facilities, higher facility treatment volume is associated with lower cost per treatment over the range of treatment volumes represented in the data. We recognize that the relatively small number of pediatric ESRD facilities limits the precision of these estimates. Nevertheless, the regression results are consistent with the strong pattern observed in the descriptive data and with our broader analysis of the relationship between facility volume and cost.

We therefore disagree that extending the LVPA for pediatric renal dialysis service assumes that low volume is a proxy for pediatric complexity. The two adjustments address distinct cost relationships. The updated pediatric case-mix adjustments recognize the higher costs associated with furnishing renal dialysis to pediatric ESRD patients, while the LVPA recognizes the higher per-treatment costs associated with lower facility treatment volume. A pediatric ESRD facility may therefore receive the pediatric adjustment for each qualifying pediatric treatment and, if the facility meets the applicable low-volume criteria, also receive the LVPA.

We also recognize commenters' observation that some higher-volume pediatric ESRD facilities may serve as referral centers for medically complex patients and may incur substantial specialized staffing and supply costs. The additional analysis does not establish that every high-volume pediatric ESRD facility has lower costs than every low-volume pediatric ESRD facility, nor does treatment volume measure patient complexity. Rather, the analysis demonstrates an average relationship between facility treatment volume and per-treatment cost among pediatric ESRD facilities. To the extent that pediatric ESRD facilities generally incur additional costs associated with furnishing pediatric renal dialysis services, including at higher-volume facilities, those costs are reflected in the data used to estimate the pediatric cost differential and are recognized through the permanent pediatric payment adjustments.

Finally, we do not believe it is necessary to extend the TPEAPA to recognize these costs. The TPEAPA was established as a temporary adjustment

for CYs 2024 through 2026 while CMS collected and evaluated additional pediatric-specific cost information (88 FR 76377). The TPEAPA's 30 percent add-on was developed using an analysis that CMS previously recognized had substantial statistical uncertainty. The additional data now available permit CMS to establish permanent pediatric payment adjustments based on more recent observed costs while separately recognizing the relationship between low facility volume and higher per-treatment costs through the LVPA. We believe this approach better distinguishes and targets these separate cost drivers than continuing the temporary adjustment.

Comment: Several commenters urged CMS not to replace the TPEAPA with the proposed combination of revised pediatric case-mix adjustment factors and application of the LVPA. These commenters recommended that CMS either make the TPEAPA permanent or extend it while CMS collects additional pediatric-specific cost data and develops and validates a permanent pediatric payment methodology. Some commenters stated that the approximately 30-percent TPEAPA more appropriately reflects CMS's finding that pediatric renal dialysis services costs are approximately 30 to 33 percent higher than adult renal dialysis services costs.

Other commenters recommended using CMS's existing analyses to establish a permanent pediatric adjustment of approximately 30 to 33 percent rather than relying on a combination of case-mix and volume-based adjustments.

Response: We appreciate commenters' support for ensuring adequate payment for pediatric renal dialysis services and their recommendations concerning continuation of the TPEAPA. As discussed when the TPEAPA was established, the TPEAPA was intended to be a temporary payment adjustment while CMS obtained and analyzed additional information concerning the relative costs of furnishing renal dialysis services to pediatric ESRD patients. In the CY 2024 ESRD PPS final rule, we noted that it was possible that a future permanent adjustment could result in a lower adjustment factor for pediatric ESRD patients (88 FR 76377). However, we note that our proposed adjustment factors based on a 33 percent payment differential and the proposed application of the LVPA to pediatric ESRD patients result in approximately the same overall payment level, with distributional changes. We agree with commenters that a permanent methodology should appropriately

reflect the resources associated with pediatric renal dialysis services and should be supported by the best data reasonably available.

We do not believe, however, that an aggregate estimate that pediatric renal dialysis treatment costs are approximately 30 to 33 percent more than adult treatments necessarily demonstrates that every pediatric ESRD treatment or every facility furnishing pediatric renal dialysis services incurs costs that are uniformly 30 to 33 percent higher. A payment methodology must also consider variation in expected resource use among pediatric ESRD patients and facilities.

Comment: Several commenters questioned whether the available data are sufficiently reliable to establish a permanent pediatric ESRD payment methodology. Commenters stated that pediatric-specific cost reporting remains limited, particularly for hospital-based pediatric ESRD facilities, and noted that the 2022 and 2023 data used in CMS's analysis preceded or did not fully reflect more recent cost-reporting guidance. Commenters explained that children's hospitals may have difficulty allocating the costs of personnel who provide services to both dialysis and non-dialysis patients.

Several commenters recommended that CMS revise the hospital cost report to include pediatric-specific staffing, supplies, and other costs. Commenters stated that more granular pediatric cost reporting would improve CMS's ability to measure the costs of specialized personnel, equipment, supplies, and other resources.

Response: We appreciate commenters' concerns regarding the availability and reporting of pediatric-specific cost information, particularly for hospital-based facilities. We recognize the challenges associated with identifying and allocating costs for personnel and resources that may support both renal dialysis services and other hospital services.

In developing the proposed pediatric payment adjustments, we used the most appropriate cost and claims information available to us and considered the limitations of those data. We agree that continued improvement in pediatric-specific cost information could support future refinements to the ESRD PPS. We will consider commenters' recommendations regarding additional pediatric-specific ESRD cost-reporting fields and other mechanisms for improving the accuracy and consistency of pediatric ESRD cost information in future policy development.

We do not believe that the existence of limitations in pediatric cost reporting

necessarily requires CMS to continue a temporary payment adjustment indefinitely where the available data permits us to develop an appropriate permanent methodology. Nevertheless, we agree that continued monitoring and data development are important given the small size and clinical heterogeneity of the pediatric renal dialysis population.

Comment: Several commenters recommended that CMS convene a technical expert panel (TEP) before establishing a permanent pediatric ESRD payment methodology, or if CMS determines that additional data are needed. Commenters recommended that a TEP include pediatric nephrology clinicians and other providers and, in some cases, pediatric ESRD patients and families. They suggested that the TEP identify remaining gaps in pediatric cost and utilization data, recommend improved data-collection strategies, evaluate alternative payment methodologies, and ensure that the ESRD PPS reflects the clinical and operational characteristics of pediatric renal dialysis.

Response: We appreciate commenters' recommendation to convene a TEP and agree that input from clinicians, facilities, patients, families, and other interested parties can provide useful information concerning pediatric renal dialysis resource use and payment. While we believe we have accurate and appropriate data to develop these methodological changes, we will consider whether additional technical expert input would be useful in evaluating future refinements to the pediatric ESRD PPS case-mix adjustments and improving pediatric-specific data collection in future rulemakings.

Comment: A commenter recommended that CMS recalibrate the pediatric and adult ESRD case-mix adjustment factors simultaneously using more recent data. The commenter expressed concern that updating pediatric ESRD adjustment factors using 2022 and 2023 data while retaining adult ESRD adjustment factors based on older data could result in different beneficiary populations being calibrated using different periods of resource use. The commenter also reiterated its recommendation that CMS replace the two-equation regression methodology with a single-equation methodology based on costs for the full ESRD PPS bundled payment.

Other commenters recommended recalibrating the pediatric modifiers using CMS's existing data so that the resulting payment adjustment more directly reflects the approximately 33-

percent difference between pediatric and adult renal dialysis services costs.

Response: We appreciate commenters' recommendations regarding the methodology used to develop the pediatric case-mix adjustment factors. The purpose of the CY 2027 pediatric analysis is to update payment for renal dialysis services furnished to pediatric ESRD patients in light of the expiration of the TPEAPA and the availability of more recent information concerning pediatric renal dialysis resource use. We disagree with the commenter stating that as we are adjusting the pediatric case-mix adjusters we should also adjust the adult case-mix adjusters. Because pediatric case-mix adjusters are scaled to the average adult case-mix adjuster, the impact to pediatric ESRD PPS payments does not depend on the adult case-mix adjusters. We did not propose to update the adult case-mix adjusters, and we are not finalizing a change to those adjusters in this final rule. We recalibrated the pediatric case-mix adjusters for CY 2027 to address the difference in cost for pediatric ESRD patients. We will continue to monitor the adult and pediatric case-mix adjusters for potential refinement in future rulemaking including a potential one-equation cost model.

Comment: Several commenters questioned the proposed case-mix adjustment factors for younger pediatric ESRD patients. Commenters stated that younger and smaller children may require more resources than older pediatric ESRD patients, including substantially greater nursing intensity, educational and behavioral support, caregiver involvement, and specialized equipment. A commenter noted that patients under 10 kilograms may require one-to-one nursing. Commenters therefore requested that CMS reexamine whether the proposed adjustment factors adequately account for the resource intensity associated with the youngest and smallest pediatric ESRD patients.

Response: We appreciate commenters' descriptions of the additional resources that may be required to furnish renal dialysis services to younger and smaller pediatric ESRD patients. We agree that the clinical care of these ESRD patients can involve substantial nursing, caregiver, educational, behavioral, and technical resources.

The proposed pediatric case-mix adjustment factors were derived from the observed relationships in the data using the methodology described in the proposed rule; they were not established based on a policy assumption that older pediatric ESRD patients are inherently more resource intensive than younger

pediatric ESRD patients. Therefore, differences among the proposed factors reflect the results of the empirical analysis rather than a judgment concerning the relative clinical complexity of particular age groups.

Our proposed calculations indicate that revisions to the case-mix adjustment will result in an increase for pediatric ESRD patients 12 and under with PD as a modality of 32.6 percent, those 12 and under with HD as a modality will receive a 15.1 percent increase. Pediatric ESRD patients 13–17 with PD as a modality will receive a 30.3 percent case-mix increase and those 13–17 with HD as a modality will receive a 15.7 percent case-mix increase. Additionally, these changes are driven by the separately billable (SB) multipliers which are also used in calculating the outlier adjustment. The SB multiplier increases 12 and under PD 27.6 percent, 13–17 PD increases 29.0 percent, and 13–17 HD increases 2.5 percent. The only SB multiplier which decreases is the factor for 12 and under HD which decreases by 9.7 percent based on empirically observed spending in the data. Essentially, all case-mix adjustments increased appropriately based on our regression analysis for each age group with the exception of the 12 and under HD group.

We will continue to monitor the relationship between pediatric ESRD patient characteristics and resource use, including whether future data demonstrate that the payment methodology should be refined to better account for the costs associated with younger or smaller pediatric ESRD patients. CMS will consider proposing any changes that may be warranted through future rulemaking.

Final Rule Action: After consideration of public comments CMS is finalizing the proposed pediatric case-mix factors without any modifications, because we believe that the case-mix factors are based on the best available data. These updated factors accurately target most fragile pediatric ESRD patients, those 12 and under, by increasing the PD factor by 32.6 percent. We are allowing the TPEAPA to expire as scheduled. We are confident in the regression analysis that targeted increased payment for PD in both age categories. We will continue to collect and refine data for analysis to ensure the most appropriate payment for pediatric ESRD patients. We do not currently plan to convene a TEP as we believe that the available data and notice-and-comment rulemaking process provided adequate information for the basis of the CY 2027 policy, and

we will continue to listen to the pediatric ESRD community.

(3) Expansion of the LVPA

Historically, the ESRD PPS has not applied the LVPA for treatments furnished to pediatric ESRD patients. Section II.B.8. of this final rule provides background on the LVPA. In the CY 2011 ESRD PPS final rule, we codified the pediatric ESRD patient payment adjustment in § 413.235(b), which states that CMS adjusts the per treatment base rate for pediatric ESRD patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act, to account for patient age and treatment modality (75 FR 49134). Additionally, we finalized the elimination of several exceptions including the pediatric facility exception, which allowed for higher cost pediatric ESRD facilities to receive additional payments when costs exceeded payment amounts under the composite rate payment system. In other words, the pediatric ESRD facility exceptions terminated for ESRD treatment on or after January 1, 2014 (75 FR 49178). Finally, the LVPA was only applicable to adult ESRD patients and was not directly used in calculating the payment rate per treatment for pediatric dialysis patients. Facilities qualifying for the LVPA that treat both adult and pediatric ESRD patients have only received the LVPA for adult dialysis patients (75 FR 49134). As noted in section II.B.8. of this final rule, small ESRD facilities incur higher costs than larger ESRD facilities, in part because they do not benefit from the same economies of scale as many large ESRD facilities. Due to the low incidents of pediatric ESRD patients most pediatric units are small, which makes accounting for higher costs associated with facility size accurately in payments important; however, the small number of pediatric ESRD patients also makes separate analysis on the costs of treating pediatric ESRD patients difficult. As discussed previously, for the CY 2011 ESRD PPS final rule we finalized an alternative methodology which was based on the average payments for pediatric treatments under the composite rate system (75 FR 49132 through 49134), including those exceptions to the composite rate system for high-cost pediatric facilities. The LVPA was only extended to payments for adult ESRD patients in ESRD facilities because facilities that primarily treat pediatric ESRD patients are typically small, so the higher pediatric payments from which the methodology in the CY 2011 ESRD PPS final rule derived the pediatric case-mix adjusters included any higher costs

associated with low volume. As such, we concluded that extending the LVPA to payments for pediatric ESRD patients would be duplicative with the calculation of the pediatric case-mix adjusters under the methodology used for the CY 2011 final rule (75 FR 49134). However, for this final rule, we included facility size as a separate characteristic in our regression model. As noted in Table 20, the pediatric ESRD share is an independent indicator of cost from the size of the ESRD facility.

As discussed previously, smaller ESRD facilities experience the greatest financial burden, and our latest analysis finds that this holds for pediatric ESRD facilities and adult ESRD facilities. As shown in Table 20, the natural logarithm of facility size (based on the total volume of treatment counts) is associated with a statistically significant reduction in cost. This means that regardless of a facility's share of pediatric ESRD patients, we observe that cost per treatment decreases as the facility's total number of treatments increases and, conversely, the cost per treatment increases as the facility's total number of treatments decreases. Based on this analysis, we believe that expanding the LVPA to include treatments furnished to pediatric ESRD patients would be appropriate.

Therefore, for CY 2027, we proposed to revise § 413.232(f) to state that the LVPA is applicable for renal dialysis treatments furnished to all ESRD patients. As outlined in section II.B.8. of the proposed rule, we proposed to make budget-neutral changes to the LVPA tier structure and adjustment factors, and we proposed that those changes would be applicable to payments for all ESRD patients beginning in CY 2027. We estimated that this change would appropriately increase payments to ESRD facilities that treat a large share of pediatric ESRD patients, which our data demonstrates face higher costs due to low volume status in addition to the specific costs associated with treating pediatric ESRD patients. Our analysis of the distributional impacts associated with the proposed LVPA changes and the proposed expansion of the LVPA to pediatric ESRD patients can be found in section II.B.8. of the proposed rule.

Additionally, we noted that although the LVPA does not currently apply to pediatric ESRD PPS claims, ESRD facilities that provide renal dialysis services to pediatric ESRD beneficiaries are nevertheless permitted to attest to low-volume status and receive the LVPA for any adult ESRD beneficiaries they treat, under current regulation. Among the 32 dedicated children's

hospitals furnishing ESRD treatments, two children's hospitals currently receive LVPA payments. Similarly, four of the 52 ESRD facilities that provide most of their treatments to pediatric ESRD patients are also receiving the LVPA for their adult ESRD patients. As discussed in the proposed rule, we believe that the relatively low rates of low-volume attestation among pediatric ESRD facilities is primarily because the LVPA is not applied to most of the treatments furnished to these ESRD facilities' patients. We estimated that approximately 24 pediatric ESRD facilities could be eligible for the LVPA based on the current 4,000 -treatment threshold. We stated that we expect that if we finalize our proposal to expand the LVPA to pediatric ESRD patients beginning for CY 2027, then additional ESRD facilities like these, which are not currently attesting to low-volume status, would begin to attest and would begin receiving the LVPA in CY 2027.

We also considered that small pediatric ESRD facilities within larger institutions could be small, high-cost centers specializing in care for pediatric ESRD patients. We recognized that in some cases, common ownership with other ESRD facilities that are located 5 road miles or less from the pediatric ESRD facility could create barriers to LVPA eligibility for some pediatric ESRD facilities. Under § 413.232(c), for purposes of determining eligibility for the LVPA, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question. To receive the LVPA, an ESRD facility must submit a written attestation statement to its MAC confirming that it meets the requirements as specified in § 413.232 and qualifies as a low-volume ESRD facility. For purposes of determining eligibility for the LVPA, "treatments" mean total HD equivalent treatments (Medicare and non-Medicare). For PD patients, one week of PD is considered equivalent to three HD treatments (80 FR 68994).

We considered the nature of pediatric ESRD facilities, those ESRD facilities with at least a 50 percent pediatric ESRD patient mix, which are uniquely equipped to meet the specialized needs of a small subset of patients that other nearby adult-focused ESRD facilities may not be able to treat, including ESRD facilities under common ownership. We noted that we believe it would be appropriate to allow pediatric ESRD

facilities to request an exemption from the aggregation of volume for ESRD facilities under common ownership. While we did not propose a categorical exemption from these regulations, we proposed that a pediatric ESRD facility that is seeking low-volume status could request an exception from the aggregation of treatment volume for ESRD facilities under common ownership at § 413.232(c) through its MAC. To request such an exception, we proposed that an ESRD facility would need to submit documentation to the MAC demonstrating that: (1) the ESRD facility is either owned and operated by a Medicare-certified children's hospital under § 412.23(d) or the ESRD facility provides at least 50 percent of its total treatments (Medicare and non-Medicare) to ESRD patients who are under the age of 18 and (2) the ESRD facility is under common ownership with an ESRD facility that does not provide at least 50 percent of its total treatments (Medicare and non-Medicare) to ESRD patients who are under the age of 18. If approved, the MAC would not consider the treatment volume of the commonly owned ESRD facility when calculating the treatment volume for the excepted ESRD facility. Once approved, the exception would continue for all future years so long as the ESRD facility continues to either be a Medicare-certified children's hospital or provides at least 50 percent of total treatments to ESRD patients who are under the age of 18.

The excepted ESRD facility would still have to meet all other requirements for the LVPA, including the treatment volume threshold described at § 413.232(b)(1). As this exception is only for the purposes of the aggregation of volume of commonly owned ESRD facilities, it is possible for an ESRD facility to receive this exception and not be eligible for the LVPA if it furnished 8,000 treatments or more (or 4,000 had the change in section II.B.8. of this final rule not been finalized) in one of the past three cost reporting years. The aggregation of volume for ESRD facilities under common ownership would still apply for the excepted ESRD facility and any other commonly owned ESRD facilities within 5 road miles for which an exception has not been approved. An ESRD facility could receive exceptions for multiple commonly owned ESRD facilities, should the requirements for the exception be met for each of them. We proposed the addition of paragraph § 413.232(g)(7) to effectuate this proposed exception and detail the process for requesting the exception.

We solicited comments on our proposed expansion to apply the LVPA to payments for pediatric ESRD patients. We also solicited comments on the proposed exception to the aggregation of volume for ESRD facilities under common ownership, the administrative process required to request such an exception, and whether such an exception is needed. We noted that we believe extending the LVPA to these facilities could alleviate financial pressures. The LVPA is designed to offset the disproportionate costs encountered by low-volume ESRD facilities. Expanding its application would help ensure that pediatric ESRD facilities, which typically operate at lower volumes due to the specialized nature of their ESRD patient populations, receive essential financial support not fully addressed by current payment adjustments under the ESRD PPS.

We received comments from ESRD patient and caregiver representatives, patient advocacy organizations, professional associations, ESRDs facilities and organizations, and other interested parties regarding the proposed revisions to payment for renal dialysis services furnished to pediatric ESRD patients. Commenters generally agreed that furnishing renal dialysis services to pediatric ESRD patients is more resource intensive than furnishing such services to adult ESRD patients and supported continued recognition of those additional costs under the ESRD PPS. Commenters differed, however, regarding the application of the low-volume payment adjustment (LVPA), use of treatment volume as an indicator of resource use, the adequacy of the data used to develop the proposed adjustments, continuation of TPEAPA, and application of budget neutrality. We summarize these comments and provide our responses in the following section.

Comment: One pediatric professional organization provided examples of critically ill pediatric ESRD patients with multiple comorbidities from high-volume pediatric nephrology programs to illustrate that treatment volume is not a proxy for the cost of pediatric renal dialysis services.

Response: We understand the incredible dedication and talent it requires to manage these pediatric ESRD patients. However, the pediatric case-mix does not address comorbidities. The costs for these complicated cases are incorporated into the case-mix that addresses age and modality. We have not removed any money from the case-mix adjustment. The pediatric ESRD case-mix adjustment has increased for every age category. Additionally, these

complicated cases would potentially qualify for the ESRD outlier adjustment. The LVPA is in addition to the ESRD case-mix and outlier adjustments.

Comment: Several commenters expressed concern that the proposed methodology could result in lower payments relative to the TPEAPA for certain higher-volume pediatric ESRD programs. Commenters stated that these ESRD facilities often serve as tertiary referral centers for children with rare genetic or metabolic diseases, cancer, organ transplantation, or other complex conditions and may require broader multidisciplinary teams and subspecialty expertise. Commenters stated that payment reductions could threaten the financial viability of pediatric renal dialysis programs and access to specialized pediatric care.

A commenter reported that its internal comparison suggested that the cost difference between pediatric and adult renal dialysis services was greater than CMS's estimate, although the commenter acknowledged limitations in directly comparing the populations and settings.

Response: We appreciate commenters' concerns regarding payment adequacy and access to specialized pediatric renal dialysis services. We agree that higher treatment volume does not necessarily indicate lower clinical complexity and recognize the important role that tertiary pediatric centers play in caring for children with complex conditions.

The ESRD PPS methodology is intended to establish payment based on expected resource use across categories of ESRD patients and facilities rather than to reimburse each facility's individually reported costs. Nevertheless, we agree that significant payment changes affecting a small number of highly specialized ESRD facilities warrant careful consideration. We intend to monitor pediatric renal dialysis services utilization, facility participation, and access to care following implementation of the final policy and will consider future refinements through rulemaking if the data indicate unintended effects on access to pediatric renal dialysis services.

Comment: Numerous commenters opposed using ESRD facility treatment volume as a basis for determining the amount of additional payment for pediatric renal dialysis services. Commenters stated that pediatric renal dialysis programs incur substantial fixed costs for specialized staff, equipment, supplies, multidisciplinary care, and infrastructure regardless of treatment volume. Commenters also stated that higher-volume pediatric

ESRD centers may serve as regional or national referral centers for the most medically complex children and therefore may have higher, rather than lower, costs.

Commenters expressed concern that the proposed LVPA methodology could reduce payment to larger pediatric ESRD programs, including tertiary children's hospitals, even though those programs furnish highly specialized care. Some commenters also expressed concern about facilities that predominantly treat adults but furnish renal dialysis services to a small number of pediatric ESRD patients, stating that the facility's total treatment volume does not reduce the resources required for its pediatric ESRD patients.

Response: We appreciate commenters' concerns regarding the relationship between treatment volume and pediatric renal dialysis services costs. We agree that treatment volume is not a direct measure of an individual patient's clinical complexity and that high-volume pediatric ESRD programs may treat highly complex patients. We also recognize that pediatric renal dialysis programs may incur certain fixed or semi-fixed costs associated with maintaining specialized staff, equipment, supplies, and infrastructure.

The LVPA, however, is intended to recognize the relationship between ESRD facility treatment volume and per-treatment costs associated with spreading fixed costs across a smaller number of treatments. The proposed application of the LVPA to pediatric renal dialysis treatments was not based on an assumption that low volume captures all differences in pediatric clinical complexity. Rather, the LVPA and the pediatric case-mix adjustment factors address different dimensions of expected resource use. We will continue to monitor whether facility volume appropriately identifies systematic differences in per-treatment costs for pediatric renal dialysis services and whether additional refinements may be warranted as more pediatric-specific data become available.

Comment: Several commenters recommended that, if CMS proceeds with the proposed framework, the agency apply an LVPA to all pediatric renal dialysis services regardless of facility treatment volume. Some commenters recommended applying the LVPA to all pediatric renal dialysis treatments using the adjustment associated with facilities furnishing between 5,000 and 5,999 treatments annually. Commenters stated that pediatric renal dialysis services are inherently a low-volume and highly specialized service and that applying an

adjustment to all pediatric renal dialysis treatments would prevent larger pediatric referral centers from being disadvantaged.

Response: We appreciate commenters' recommendations. Applying the LVPA to all pediatric renal dialysis treatments without regard to facility volume would effectively convert the adjustment, in whole or in part, from a low-volume facility adjustment into a broadly applicable pediatric ESRD patient payment adjustment. Such an approach would not target the adjustment based on the relationship between facility volume and per-treatment costs that the LVPA is designed to recognize. While the pediatric ESRD patient population is inherently small, data analysis has shown that there is a cost difference between pediatric ESRD facilities that provide under 8,000 treatments per year, and those pediatric ESRD facilities that provide over 8,000 treatments per year.

Comment: A commenter expressed concern that ESRD facilities furnishing a high volume of adult renal dialysis treatments but treating only a small number of pediatric ESRD patients may not receive sufficient additional payment for their pediatric ESRD patients under a facility-volume methodology. The commenter stated that efficiencies associated with treating a large number of adult ESRD patients do not eliminate the specialized resources necessary to furnish care to pediatric ESRD patients and that families should not be disadvantaged for obtaining pediatric renal dialysis from a facility that also treats adults.

Response: We appreciate the commenter's concerns. We agree that pediatric ESRD patients may require specialized resources regardless of whether the facility also treats adult patients. This rule increases the case-mix adjusters for all age categories as discussed earlier, which addresses the increased cost of pediatric ESRD patients. At the same time, there are certain facility-level costs and economies of scale may impact costs across treatments, and the ESRD PPS must distinguish between patient-level differences in expected resource use and facility-level differences associated with treatment volume. We will monitor the effects of the policy on ESRD facilities furnishing both adult and pediatric renal dialysis services, including whether the methodology creates unintended access or payment concerns.

Comment: A commenter supported the proposed exception from the common-ownership treatment-volume aggregation requirement for qualifying pediatric ESRD facilities. The

commenter stated that specialized pediatric ESRD programs may be located within larger health systems while continuing to operate as small, high-cost programs serving a clinically distinct population.

Response: We appreciate the commenter's support. We agree that application of common-ownership aggregation requirements without consideration of the circumstances of qualifying pediatric ESRD facilities could cause the volume attributed to a pediatric ESRD program to reflect treatments furnished by other ESRD facilities within a larger organization rather than the operating circumstances of the pediatric ESRD facility itself.

Comment: A commenter supported implementation of the expanded pediatric LVPA beginning in CY 2027 and recommended providing an expanded or later LVPA attestation window rather than delaying implementation until CY 2028. The commenter stated that timely LVPA eligibility would help avoid a payment discontinuity following expiration of the TPEAPA.

Response: We appreciate the comment. We agree that ESRD facilities should have sufficient time to understand applicable eligibility requirements, submit required attestations, and allow MACs sufficient time to process those attestations. We also recognize the importance of avoiding unnecessary disruption as CMS transitions from the temporary pediatric ESRD payment policy to the permanent methodology. As discussed in section II.B.8.d. of this final rule, we are finalizing an extension of the LVPA attestation deadline for payment year 2027 to December 31, 2026. This extension would equally apply for adult and pediatric ESRD patients.

Comment: A commenter requested that CMS monitor whether changes in pediatric renal dialysis services payment affect access to pediatric nephrology expertise, home dialysis training, transplant education, mental health services, nutrition support, and family-centered care. The commenter also recommended monitoring access for children from rural communities, low-income families, racially and ethnically diverse communities, and families whose primary language is not English.

Response: We appreciate the commenter's recommendations regarding access and the range of services needed by pediatric renal dialysis patients and their families. We agree that Medicare payment policy should support continued access to medically necessary renal dialysis

services and that the effects of payment changes on vulnerable and underserved populations are important considerations.

We will consider available claims, enrollment, facility, quality, and other data in monitoring the effects of the pediatric ESRD payment methodology. We also will consider feedback from interested parties concerning access to pediatric renal dialysis services, including services furnished by specialized pediatric ESRD programs and services needed to support home dialysis and transplantation.

Comment: A commenter stated that pediatric home dialysis frequently requires extensive parent or caregiver training, competency validation, and ongoing support and requested that CMS consider whether its analysis adequately captures the additional resources associated with caregiver-dependent pediatric home dialysis relative to adult home dialysis.

Response: We appreciate the comment. We recognize that home dialysis for pediatric ESRD patients may require substantial caregiver involvement and training. The issues raised by the commenter concerning the resources associated with home dialysis training are relevant both to the pediatric payment methodology and to the policies governing payment for home dialysis training. As noted in section II.B.10.e. of this rule, we are adjusting the home and self-dialysis training payment adjustment from \$95.60 to \$138.00. The case-mix adjustments for PD have increased for both age groups. For the 12 years old and under pediatric ESRD patients the case-mix is 32.6 percent and for those pediatric ESRD patients between 13–17 years of age would have a case-mix increase is 30.3 percent.

Comment: A commenter urged CMS to prioritize simplicity and predictability in the pediatric ESRD payment methodology. The commenter stated that changes in pediatric renal dialysis payment policy and associated administrative requirements can create burdens, particularly for pediatric ESRD programs embedded within facilities that predominantly serve adults.

Response: We appreciate the comment. We agree that administrative simplicity and payment predictability are important considerations, particularly for a small patient population and the relatively limited number of ESRD facilities furnishing pediatric renal dialysis services. At the same time, payment accuracy may require adjustments that account for meaningful differences in expected resource use.

In developing the proposal and final policy, we sought to balance payment accuracy with administrative feasibility and to rely, to the extent practicable, on existing ESRD PPS mechanisms rather than creating unnecessary new reporting or billing requirements. There are no new reporting requirements for the pediatric case-mix adjusters and only a yearly attestation for low-volume which many adult ESRD programs are familiar with submitting.

Comment: A commenter requested that CMS more clearly explain the payment effects of ending the TPEAPA, updating the pediatric case-mix and outlier multipliers, and applying the LVPA to pediatric renal dialysis services. The commenter requested information concerning the effects of these policies individually and in combination and their effects on both pediatric and adult beneficiaries, particularly in light of budget neutrality.

Response: We appreciate the request for additional transparency concerning the individual impact and interaction of the pediatric ESRD payment policies. We believe the ESRD PPS payment policy for pediatric ESRD patients and extending the LVPA to pediatric ESRD PPS payments has been explained in detail throughout the CY 2027 ESRD PPS proposed rule and this final rule. Because the expiration of the TPEAPA, revised pediatric adjustment factors, application of the LVPA, and budget-neutrality calculations affect different components of the ESRD PPS bundled payment, we agree that describing their combined effects is useful for understanding the final policy. We refer the commenter to Table 22 of this section that indicates the impacts on pediatric ESRD facilities collectively. ESRD facilities that provide 50 percent or more of their treatments to pediatric ESRD patients can view the individual effects of the ESRD PPS pediatric ESRD payment changes and extension of the LVPA to pediatric ESRD payments in Appendix B to this final rule. The impact to ESRD facilities providing most treatments to adult beneficiaries with ESRD collectively is provided in the final impacts in Table 30 in section VII.C.5.a. of this final rule. ESRD facilities providing most treatments to adult beneficiaries with ESRD can view the individual effects of the ESRD PPS pediatric ESRD payment changes and extension of the LVPA to pediatric ESRD payments in Appendix B to this final rule. We will monitor and report the effect of payment policy revisions such as ending the TPEAPA, updating the pediatric case-mix and outlier multipliers, and applying the LVPA to pediatric renal dialysis services on

pediatric ESRD facilities as warranted in the future.

Comment: Several commenters opposed implementing the pediatric payment changes on a budget-neutral basis. Commenters stated that the higher costs of pediatric renal dialysis services do not imply that the costs of treating adult dialysis patients have decreased and stated that improving payment for pediatric care should not require reductions in payments for other ESRD patients. A commenter noted that pediatric Medicare beneficiaries constitute a small share of ESRD PPS treatments and noted that the cost of financing pediatric payment improvements without budget neutrality, therefore, would be small relative to total ESRD PPS expenditures.

Other commenters supported the substance of the proposed pediatric case-mix and LVPA policies but specifically requested that CMS implement those policies on a non-budget-neutral basis.

Response: We appreciate commenters' concerns regarding the effects of budget neutrality on payments for other ESRD PPS treatments. We agree that the clinical need for additional resources for renal dialysis services furnished to pediatric ESRD patients does not imply that adult dialysis patients require fewer resources.

However, we believe that the application of a budget neutrality factor to the ESRD PPS base rate is appropriate for this payment change as it would ensure that changes in payment adjustments do not result in an unintended change in aggregate ESRD PPS expenditures solely as a result of recalibration. We stated that the TPEAPA applies primarily to costs included in the data used to establish the CY 2011 ESRD PPS bundled payment. Because the methodology attributed pediatric renal dialysis services costs to the general population, the ESRD PPS base rate would be reduced to reflect the reallocation of pediatric renal dialysis services costs. We noted that we believe that future modifications to the pediatric case-mix adjusters must also maintain budget neutrality. We refer the commenter to Table 22 of this section that indicates the impacts on pediatric ESRD facilities. The impact to adult ESRD facilities is provided in the final impacts in Table 30 in section VII.C.5.a. of this final rule. We will continue to monitor the effectiveness of budget-neutral payment adjustments to the impacts of both pediatric and adult ESRD facilities and will potentially revise payment methodologies as warranted in future rulemaking (88 FR 76378). Further

discussion of budget neutrality is noted in section II.B.4. of this final rule.

Comment: Several commenters requested continued data collection and monitoring after implementation of any permanent pediatric ESRD payment methodology. Commenters recommended that CMS evaluate payment adequacy, staffing, specialized resource needs, access to pediatric renal dialysis services, the experience of high-volume tertiary centers, and the resource intensity associated with younger and medically complex ESRD patients. Some commenters requested future changes if experience demonstrates that the finalized methodology does not adequately reflect pediatric renal dialysis services costs.

Response: We agree that continued monitoring is particularly important for pediatric renal dialysis services because the pediatric ESRD population is small and the facilities furnishing these services vary in size, organizational structure, and patient complexity. The relatively small number of pediatric renal dialysis treatments also can make estimates more sensitive to changes in patient mix, facility characteristics, and reporting practices.

We intend to continue evaluating available pediatric cost, claims, utilization, and facility data following implementation of the CY 2027 policy. We will also consider information submitted by pediatric renal dialysis providers, professional organizations, patients, caregivers, and other interested parties. If future data indicate that the pediatric payment methodology does

not appropriately reflect resource use or creates unintended access concerns, we may consider additional refinements to cost reports or action through future notice-and-comment rulemaking.

Final Rule Action: After consideration of public comments, available data and additional feedback from interested parties provided directly to CMS, we are finalizing the pediatric payment changes for CY 2027 as proposed, without modification. Our analysis demonstrates a consistent relationship between facility volume and pediatric per-treatment costs, with higher-volume pediatric referral centers and mixed adult/pediatric facilities incurring distinct resource demands. In response to concerns raised by commenters regarding these centers, CMS has evaluated the impact of volume thresholds and the LVPA methodology. We are maintaining the proposed volume thresholds and tiers for pediatric ESRD facilities, as they accurately reflect observed cost differences and ensure payment aligns with pediatric resource use regardless of facility type. Under the finalized LVPA methodology, pediatric renal dialysis treatments and total facility volume are considered, with the aggregation exception for common ownership ensuring qualifying pediatric ESRD facilities are not disadvantaged.

CMS is finalizing the pediatric exception to the common-ownership aggregation requirement as proposed, without modification. The CY 2027 implementation date will be January 1, 2027. As discussed previously, the

attestation deadline for payment year CY 2027 is extended to December 31, 2026. That is, ESRD facilities, including those that primarily furnish treatment to pediatric ESRD patients, must submit an attestation by December 31, 2026, to receive the LVPA for payments in CY 2027. The extension to the attestation deadline also allows pediatric ESRD facilities to submit any requests for exceptions to the common ownership aggregation by December 31, 2026. Impact analyses indicate expected payment changes for pediatric ESRD facilities based on volume, facility type, and other characteristics, supporting equitable payment. The finalized pediatric case-mix methodology incorporates modality-specific differences, including the home and self-dialysis training add-on payment adjustment, to further refine payments. Attestation, reporting, and billing requirements under the final policy are specified to ensure transparency and accountability. A comprehensive payment-impact Table 22 details the effects of the TPEAPA expiration, revised pediatric case-mix and outlier factors, LVPA eligibility, combined pediatric impact, and applicable budget-neutrality adjustments to the ESRD PPS base rate, is presented in the following table. CMS has determined that budget neutrality is appropriate under section 1881(b)(14)(D)(iv)(I) of the Act and is finalizing these pediatric payment changes on a budget-neutral basis as proposed, with the final budget-neutrality factor and estimated aggregate effects provided in the rule.

TABLE 22: Combined Pediatric Payment Impacts

Age-group and modality	Facility Size	Pre TPEAPA Adjusters*	Payment Under TPEAPA*	Final CY 2027 Adjusters and LVPA Expansion*	Difference Pre-TPEAPA to CY 2027 Final	Difference TPEAPA to CY 2027 Final
<13 PD	<3k	\$316.26	\$411.14	\$573.88	\$257.62	\$162.74
<13 HD	<3k	\$388.56	\$505.13	\$611.73	\$223.17	\$106.60
13-17 HD	<3k	\$394.81	\$513.25	\$625.16	\$230.35	\$111.91
<13 PD	8k or more	\$316.26	\$411.14	\$419.50	\$103.24	\$8.36
13-17 HD	8k or more	\$394.81	\$513.25	\$456.99	\$62.18	-\$56.26

*Calculations are each based on the final CY 2027 ESRD PPS base rate of 297.52 and a wage index value of 1.000

This table demonstrates that all categories of pediatric ESRD patients see their respective payment increase compared to that before the implementation of TPEAPA, and that only those treated at the large ESRD facilities see a payment decrease between payment under TPEAPA and the final CY 2027 factors. As noted previously, the payment changes to the LVPA are based on our most recent analysis of pediatric renal dialysis services costs which indicates that lower-volume ESRD facilities treating pediatric ESRD patients incur higher costs.

(4) Conforming Edits to § 413.232(g) To Specify Calendar Days

As discussed in the CY 2027 ESRD PPS proposed rule, we proposed to create an exception process for ESRD facilities that are Medicare-certified children's hospitals or that furnish more than 50 percent of treatments to pediatric ESRD patients. In the proposed new paragraph § 413.232(g)(7), we specify a timeline based on "calendar days," rather than "days." We believe that specifying "calendar days" avoids confusion between calendar days, working days, business days, or any other type of day. When we finalized the exceptions for disasters or other emergencies in the CY 2024 ESRD PPS final rule (88 FR 76344), we similarly created a timeline but did not specify the type of "days" despite our intention being calendar days. We proposed edits to § 413.232(g)(5) and (6) to specify that the timeline for the exceptions is based on calendar days, consistent with the proposed language of § 413.232(g)(7). We also proposed an edit to § 413.232(g)(6)(iv) to add the word "of" to the first sentence following "30 calendar days," which was omitted in a typographical error. We solicited comments on these proposed changes, including whether we should finalize such changes even if the exception detailed at the proposed new paragraph (g)(7) is not finalized. We also solicited comments on whether another basis for the timeline, for example business days, would be better for ESRD facilities requesting any of these exceptions.

We did not receive any public comments on these proposals. We are finalizing the proposals as proposed.

10. Home and Self-Dialysis Training Add-On Payment Adjustment

a. Background

Under the ESRD PPS, there are three components to payment for home and self-dialysis training: (1) the base rate, (2) a wage-adjusted home and self-

dialysis³⁸ training add-on payment adjustment, and (3) an allowable number of training treatments. The ESRD PPS includes an add-on payment adjustment for home and self-dialysis training, which is described at § 413.235(c). Hereafter, we refer to the home and self-dialysis training add-on payment adjustment as the training add-on.

CMS makes the same training add-on for both HD and PD. We recognize that the costs for home and self-dialysis training for HD and PD are likely not identical, as supported by our analysis of ESRD facility cost report data discussed later in this section. However, the ESRD PPS is a prospective payment system under section 1881(b)(14)(A)(i) of the Act. As such, payments are not intended to reflect the exact costs incurred by individual facilities, but to provide standardized payments that promote efficiency and access.

When the ESRD PPS was implemented in 2011, we proposed that the cost for all home dialysis services would be included in the bundled payment (74 FR 49930), and therefore, the computation of the base rate included home dialysis training add-on payments made to ESRD facilities as well as all composite rate payments, which account for facility costs associated with equipment, supplies, and staffing. In response to public comments, in the CY 2011 ESRD PPS final rule, we noted that although we were continuing to include training payments in computing the ESRD PPS base rate, we agreed with commenters that we should treat training as an adjustment under the ESRD PPS. Accordingly, we finalized the training add-on amount of \$33.44 per treatment as an additional payment made under the ESRD PPS when one-on-one home dialysis training is furnished by a nurse for either HD or PD training or retraining (75 FR 49063), updated from the previous adjustment amount of \$20. This updated amount of \$33.44 per treatment was based on the national average hourly wage for Registered Nurses (RN) as published by the Occupational Employment Statistics (OES) data compiled by BLS data updated to 2011 (75 FR 49063), and reflected 1 hour of training time by a RN for both HD and PD. This average hourly wage was then inflated to 2011 by the ESRD wages and salaries proxy used in the 2008-based ESRD bundled market basket. In addition, we continued the policy of paying the home dialysis

³⁸ Home dialysis is dialysis performed by a beneficiary or caretaker in their home. Self-dialysis is dialysis performed by a beneficiary in-center.

training add-on payment for 15 training treatments for PD and 25 training treatments for HD.

Section 494.100(a)(2) of the Conditions for Coverage for ESRD Facilities stipulates that the RN must conduct the home or self-dialysis training, and CMS has clarified through interpretive guidance (ESRD Program Interpretive Guidance published October 3, 2008 (<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter09-01.pdf>)) that other members of the clinical dialysis staff may assist in providing the home training. We also elaborated in this guidance that the qualified home training RN is responsible for ensuring that the training is in accordance with the requirements at § 494.100, with oversight from the ESRD facility's interdisciplinary team.

In the CY 2014 ESRD PPS final rule (78 FR 72185), CMS increased this amount from \$33.44 to \$50.16 to reflect 1.5 hours of training time by an RN in response to concerns from interested parties regarding payment adequacy. The \$50.16 training add-on amount was consistent with average costs based on an analysis of pre-PPS cost report data. In the CY 2017 ESRD PPS final rule (81 FR 77856), CMS further updated the home and self-dialysis training add-on to \$95.60 based on 2.66 hours of RN time using BLS wage data.

In 2025, Medicare paid approximately \$7 million in home and self-dialysis training add-on payment adjustment amounts, which remained relatively stable compared to prior years. This relatively flat trend, in conjunction with feedback from interested parties, may indicate that home dialysis and self-dialysis modalities remain underutilized and that payment adequacy for training may be a contributing factor.

b. Analysis of ESRD Cost Report Data

When we last updated the training add-on amount in the CY 2017 ESRD PPS final rule (81 FR 77848 through 77856), we stated that we made changes to the freestanding ESRD facility cost reports to allow for better collection of training data, and that we would evaluate improved cost report data once available. We stated that we intended to compare the average cost per home dialysis training treatment for PD and HD to the proxy value, and to assess the extent to which the training add-on reflects ESRD facility costs for home dialysis training on average.

As discussed in the CY 2027 ESRD PPS proposed rule (91 FR 38831), we

analyzed the data collected on Worksheets B and C on the average home dialysis training cost per training treatment for freestanding ESRD facilities. Specifically, the following analysis is from Worksheets B and C from the freestanding ESRD facility cost report (CMS-265-11) and Worksheets I-2 and I-4 from the hospital-based ESRD facility cost report (CMS-2552-10).³⁹ We used CY 2024 cost report data, which includes cost reporting periods beginning between January 1, 2024, and December 31, 2024. AKI lines were excluded from this analysis since AKI beneficiaries were not eligible for the training add-on for the entirety of the study period.⁴⁰ Data was evaluated at the facility level, and the top and bottom 1 percent of observations were winsorized.⁴¹

We analyzed CY 2024 ESRD cost report data from freestanding and hospital-based ESRD facilities. The median cost-per-training session was approximately \$712 overall, \$381 for HD, and \$797 for PD. The median labor cost-per-training session was approximately \$283 overall, \$164 for HD, and \$314 for PD. As discussed in the proposed rule, CMS believes that these reported ESRD facility costs include resources associated with routine renal dialysis services in addition to training-specific activities. On average, payment per dialysis treatment was approximately \$300 in 2024. As outlined in section II.B.1. of this final rule, the total compensation in the 2024-based ESRDB market basket is 50.9 percent as presented in Table 3. Applying this to the rough per-treatment payment amount of \$300 gives us a payment amount of approximately \$153. To appropriately determine the extent to which training for home dialysis results in increased labor costs, we can subtract this \$153 amount from the median per-training-treatment labor cost of \$283. This results in a per-treatment labor net cost of about \$130 per training treatment

above that which is included in the per-treatment payment.

Because the ESRD PPS is not a cost-based system, and cost report data may not reliably isolate the marginal cost of training, we noted that CMS does not believe it is appropriate to base the training add-on directly on these data. As discussed in further detail in the next section, CMS proposed to continue to rely on a standardized labor-based methodology reflecting RN time, which is more consistent with the design of the ESRD PPS. However, this \$130 net labor per-training treatment cost demonstrates the effectiveness of the methodology, the results of which we discuss in the following section.

c. Proposed Increase to the Home and Self-Dialysis Training Add-On Payment Adjustment

In the CY 2027 ESRD PPS proposed rule, we proposed to increase the training add-on according to the most recently available BLS OEWS, using the same methodology finalized in the CY 2017 ESRD PPS final rule (81 FR 77856), based on 2.66 hours of RN time and updated wage data. CMS proposed to maintain the 2.66-hour basis as cost report data has indicated it is an appropriate basis for the training payment and is administratively simple to calculate. As discussed in the prior section, cost report data shows a net labor cost of approximately \$130 per training treatment for 2024. While we did not propose to base the training amount on this cost report data, we note that it lines up with the result from our established methodology closely. Specifically, applying this 2.66-hour basis to the estimate of RN wages from the May 2024 BLS OEWS, \$47.32, would give us a training adjustment of \$125.87 for 2024, before the application of any wage index. This demonstrates that our longstanding methodology generally accounts for the net labor costs associated with home dialysis training.⁴² We explained that the training add-on is only intended to cover the labor related costs for home and self-dialysis training, as the ESRD PPS base rate includes payment for all other costs associated with furnishing renal dialysis services, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49063).

We stated that this proposed approach would maintain consistency with prior policy while accounting for wage growth over time and aligning with the prospective principles upon which the

ESRD PPS was established. Under the ESRD PPS, and in accordance with section 1881(b)(14)(A)(i) of the Act, CMS implemented a single base rate that applies to all dialysis treatment modalities. CMS did not propose to differentiate payment amounts between PD and HD training. Although cost report data suggest differences, maintaining a single rate is consistent with the ESRD PPS structure as HD and PD are paid the same for adult beneficiaries, and avoids creating financial incentives that could influence modality selection.

We calculated the updated payment amount using the mean hourly wage for RNs (SOC 29-1141) from the May 2025 BLS OEWS (<http://www.bls.gov/oes/tables.htm>) which was \$48.76 in 2025. We then inflated this 2025 mean hourly wage figure to CY 2027 using the growth in the 2024-based ESRDB market basket Wages and Salaries price proxy. We stated that we believe this proposed increase would improve payment adequacy for training while maintaining the integrity of the PPS. This would result in a new RN hourly wage of \$51.96. For the hours, we proposed to continue to use the 2.66 hours as the amount of time for home dialysis training by an RN that is accounted for by the training add-on. This results in a proposed training add-on payment of \$138.22 (2.66 hours × \$51.96 = \$138.22). We proposed to update the RN hourly wage estimate in the final rule with more recent data, such as an updated estimate in the growth of the price proxy, if appropriate.

This proposal would provide for an increase of \$42.62 per training treatment (that is, \$138.22 – \$95.60 = \$42.62). This approach would provide a significant increase in payment for home and self-dialysis training for CY 2027 while maintaining consistent payment for both PD and HD modalities. After evaluating the cost report data presented previously in the proposed rule, we stated that we believe that this amount is an appropriate proxy for the costs of home dialysis training. We proposed to update this training add-on amount with additional data, for example an update in the growth in the 2024-based ESRDB market basket Wages and Salaries price proxy in the final rule, if appropriate.

CMS proposed to implement this increase for the training add-on in a budget neutral manner through an adjustment to the ESRD PPS base rate. We stated that we believe implementing this budget neutral change, similar to the budget neutral training add-on in the CY 2017 ESRD PPS final rule (81 FR 77856), is appropriate because the ESRD

³⁹ Provider training costs from freestanding ESRD facility worksheet B non-AKI lines between Lines 10-13, columns 3-9 and 11-13 and hospital cost report worksheet I-2 non-AKI lines between Lines 4-7, columns 1-8 and 10. Provider training session count freestanding ESRD facility worksheet C non-AKI lines between Lines 10-13, Column 1 and hospital cost report worksheet I-4 non-AKI lines between Lines 3-6, Column 1.

⁴⁰ The training add-on was extended to AKI dialysis payments in the CY 2025 ESRD PPS final rule (89 FR 89168).

⁴¹ Winsorizing is a statistical data transformation technique that limits extreme values-outliers by replacing them with specific, less extreme percentiles. For this analysis we replaced the top 1 percent of values with the 99th percentile value and the bottom 1 percent of values with the 1st percentile value. Unlike trimming, it keeps the total number of data points unchanged while minimizing the influence of outliers on the analysis.

⁴² May 2024 BLS OEWS estimate for category SOC code 29-1141 (Registered Nurses) can be found at <http://www.bls.gov/oes/tables.htm>.

PPS base rate includes certain training costs. For more information on the history of training add-on changes, we refer readers to a discussion in response to comments in the CY 2017 ESRD PPS final rule (81 FR 77853 through 77854). We noted that CMS would estimate aggregate impacts for this proposal using claims and cost report data.

d. Payment for Training During Dialysis Onset

In the CY 2011 ESRD PPS final rule we finalized a payment adjustment for ESRD patients in their first 4 months on renal dialysis (75 FR 49090 through 49094), which we refer to as the onset adjustment. We stated that as home dialysis training costs represent one-on-one staff time to train a patient for home dialysis, we believed we captured staffing costs for training in the onset adjustment. Since we already accounted for training salary costs in the onset adjustment, we believed that applying the training add-on adjustment in addition to the onset adjustment would have the effect of compounding the composite rate costs and would result in an overpayment of nursing staff costs associated with training renal dialysis patients for home dialysis. Therefore, the rule finalized that ESRD facilities would not receive the training add-on adjustment for ESRD patients who are receiving the onset adjustment. In the CY 2011 final rule we stated that we would continue to study the relationship between costs related to the onset of dialysis and home dialysis training for future refinements of the ESRD PPS (75 FR 49094).

At that time, we stated that we believed that the onset adjustment captured additional labor costs for home dialysis training sessions that occur during the onset period, which is the first four months a patient is on renal dialysis (75 FR 49063). The CY 2011 onset adjustment factor was finalized at 1.510 (75 FR 49094). As the training add-on was \$33.44, the onset adjustment factor was generally much larger than the training add-on for any single patient, so it was reasonable to believe that notable additional labor costs associated with home dialysis training were captured by the analysis from which the onset adjustment was derived.

The current onset adjustment factor is 1.327, as finalized in the CY 2016 ESRD PPS final rule (80 FR 68992 through 68993). The current CY 2026 ESRD PPS base rate is \$281.71 so a 1.327 adjustment factor would be an increase of approximately \$92, which is lower than the current training add-on adjustment. As the onset adjustment is

intended to account for more than just home dialysis training, the lower multiplicative onset adjustment factor, combined with the relatively low utilization of home dialysis training during the onset period, led us to reevaluate our longstanding policy of not applying the training add-on during the onset period.

In the CY 2027 ESRD PPS proposed rule, we proposed to allow ESRD facilities to receive the home and self-dialysis training add-on payment adjustment during the onset period (91 FR 38833). We explained that analysis of 2024 claims data indicates that approximately 7.7 percent of onset claims include training. While this is an improvement from the inception of the ESRD PPS, we believe that patient choice would be improved by increased access to home and self-dialysis training during the onset period. Currently, approximately 44 percent of training sessions occurred during the onset period, which demonstrates that most ESRD patients who receive training are not in the onset period. CMS further believes that the training add-on reflects discrete training labor-related resources that are not fully captured by the onset adjustment and therefore would not result in duplicative payment. Home dialysis was included in the data upon which the ESRD PPS base rate was constructed in the 2011 ESRD PPS final rule (75 FR 49084). However, in that rule, we discussed how the ESRD PPS base payment alone does not address home dialysis training costs, so an additional adjustment was warranted (75 FR 49062). In the regression analysis performed for that rule, we stated that we believed the higher costs associated with the onset period were, in part, due to some training labor costs (75 FR 49063). However, based on our analysis of the training labor cost and the onset adjustment for the CY 2027 ESRD PPS proposed rule, we stated that we no longer believe this is the case. There are training costs, primarily equipment supply costs, included in the ESRD PPS base rate (75 FR 49062) which are likely higher during training which would be captured by the analysis from which the onset adjustment was derived. But, as discussed previously, the ESRD PPS base rate does not contain significant monies for labor related to home dialysis training, so we do not believe that allowing both adjustments would be duplicative now, in large part because the onset adjustment factor has decreased since 2011 (which could have reflected some shifting utilization). Similar to how the training add-on accounts for the extra costs not

accounted for by the ESRD PPS base rate, we stated that we believe that most costs associated with home dialysis training are not reflected in the current onset adjustment. Furthermore, our proposal to implement this policy budget neutrally further mitigates the risk of potential duplicative payment. We proposed to base the budget neutrality of this change on the current utilization of home dialysis training during the onset period.

e. Combined Budget Neutrality Implications and Comment Solicitation

The proposed increase to the training add-on and the proposed allowance of the training add-on for ESRD PPS claims during the onset period would result in a budget neutrality adjustment of 0.99884. We solicited comments on these proposed modifications to the home and self-dialysis training adjustment, as well as the proposed budget neutrality of these proposals and the proposed budget neutrality adjustment factor of 0.99884. Additionally, we solicited comments on other ways in which we could improve both home dialysis and self-dialysis utilization. We also solicited comments on the proposal to continue using the calculation established in the CY 2017 ESRD PPS final rule (81 FR 77856), basing the training add-on on 2.66 hours of RN time. As noted previously, we did not propose to base the training add-on on Medicare cost report data, nor did we propose to set different training payment rates for HD and PD but based on comments received in response to the proposed rule, we stated that we may finalize a different policy, if warranted. Such a policy could involve using cost reports to determine the number of hours of nursing time required for home dialysis training or modifying the training add-on for a modality based on the relative cost of that modality reported on cost reports, and we solicited comments on these potential alternative methodologies. We also solicited comments on alternative ways we could budget neutralize this proposal, and specifically whether it would be more appropriate to make the proposal to allow the training add-on during the onset period budget neutral by reducing the onset adjustment factor.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters, including MedPAC, expressed support for CMS's proposed increase to the training add-on amount. Many commenters noted that labor costs have increased since the last time we

updated the training add-on. Some commenters expressed the importance of adequate training add-on payment for access to home dialysis. Many commenters emphasized the importance of home dialysis as an option for ESRD patients for whom it is appropriate and similarly emphasized the importance of high-quality home dialysis training.

Response: We appreciate the commenters' support. We agree that home dialysis is an important modality option for many ESRD patients.

Comment: Several commenters requested more frequent updates to the training add-on. A commenter stated that annual updates were not necessary but recommended we update the training add-on routinely when we rebase the ESRDB market basket. MedPAC recommended annual updates using publicly available BLS OEWS data. A commenter highlighted how large the increase is from the \$95.60 amount set in CY 2017 to the \$138.22 amount proposed for CY 2027.

Response: We appreciate the suggestions and will consider them for potential future rulemaking. We did not propose a routine methodology to update the training add-on amount and are not finalizing any such methodology in this final rule.

Comment: Some commenters noted that there were other costs associated with home dialysis that the training add-on did not cover, for example utility costs or storage costs for home dialysis patients. The commenter stated that CMS should not assume that an increase in payment to ESRD facilities will eliminate all barriers to home dialysis and requested we consider other mechanisms to support home dialysis uptake.

Response: We agree that there are other costs and barriers associated with uptake of home dialysis. In the CY 2027 ESRD PPS proposed rule we issued an RFI requesting detailed information on such costs and barriers (91 FR 38848). We intend to consider the barriers the commenter listed when considering the responses to that RFI for potential future rulemaking.

Comment: MedPAC generally supported the proposed increase to the home dialysis payment but also offered methodological recommendations. Specifically, MedPAC suggested CMS develop a process to empirically derive the share of treatments that are PD vs home HD and the average length of a training session. MedPAC noted that CMS collects "time on machine" data for hemodialysis treatments which could help this purpose.

Response: We appreciate MedPAC's methodological suggestions. The 2.66-

hour training average that we used for this rule was derived from the following values as described in the CY 2017 ESRD PPS final rule (81 FR 77852): (1) that PD represented 67 percent of all home dialysis training treatments, and (2) that PD training took 2 hours whereas HD training took 4 hours. The values for training time were derived from clinical guidelines on treatment times for both modalities. Analysis of ESRD facility cost report data indicates that the share of PD training treatments has decreased slightly, with PD representing 52 percent of training treatments in 2024. Time on machine data from CY 2025 indicates that the median HD training sessions report approximately 180 minutes, or 3 hours, of time on machine; we note that this is slightly lower than the overall median time on machine for in-center HD treatments, which is approximately 210 minutes, or 3.5 hours. The average time on machine for HD training is 235 minutes, or slightly under 4 hours; we believe the median is probably more representative because there were some implausible outliers for time on machine data, with 5 percent of treatments reporting longer than 7 hours of time on machine. We do not collect time on machine data for PD sessions. Using these updated figures, and maintaining the assumption that PD takes 2 hours, we would get an average training time of 2.48 hours ($3 \times 0.48 + 2 \times 0.52$). Basing the calculation instead on the median HD time on machine would yield an average training time of 2.72 hours ($3.5 \times 0.48 + 2 \times 0.52$). We reiterate that these figures were based on median values for HD time on machines, rather than average, because implausibly high reported values would likely skew the average in a way that is inappropriate. However, in doing so, these figures also do not consider real outlier treatment lengths, which we believe would be appropriate. Nevertheless, our longstanding assumption of 2.66 hours falls in between these two alternative estimates based on median values. We believe that this is empirical evidence that our longstanding assumption is reasonable as a proxy for the average home dialysis training treatment time. However, we intend to evaluate why the time on machine for training treatments is lower than other HD treatments, and whether that was partially driven by the amount of the training add-on. We did not propose to modify the methodology to use 2.66 hours of nursing time as the basis for the training add-on amount and we are not finalizing any such changes in this final rule.

Comment: Several commenters requested CMS reevaluate the use of the 2.66-hour figure in the calculation of the training add-on payment. One healthcare organization which operates ESRD facilities stated that their training sessions last anywhere from 3 to 4 hours. Another commenter indicated that training sessions can last 5 to 8 hours. A commenter stated that both HD and PD training sessions can last 5 to 6 hours. A commenter requested we collect actual data on RN time for home dialysis training and use it to determine whether separate payment amounts for PD and HD were appropriate.

Response: We appreciate the commenters' insight on their experience with home dialysis training. We want to note that the 2.66-hour figure used to calculate the training add-on was derived from an assumption of 4 hours of nursing time for HD and 2 hours of nursing time for PD. Those figures were based on Kidney Disease Outcome Quality Initiative (KDOQI) guidelines for HD and PD treatment length (81 FR 77852). While a commenter did not indicate which modality training they performed, we note that the 3 to 4 hours they stated is consistent with the assumed training time for HD. We recognize that some training sessions may last longer than the typical length of treatment for PD and HD, and that some patients may require more nursing time in training than others. Likewise, we acknowledge that the training costs for PD and HD are likely different on average. We believe that a single bundled training payment, adjusted by the ESRD facility's wage index, is most consistent with the principles of a bundled payment system. As noted previously, we evaluated data from ESRD facility cost reports and we believe that our assumptions on the average HD and PD training treatment length on which our training add-on is based are reasonable. However, we will continue to evaluate the appropriateness of the training add-on and will consider the commenters' suggestions for potential future rulemaking, if appropriate.

Comment: A commenter opined that the proposed training add-on amount of \$138.22 was still too low. The commenter noted that the analysis CMS included in the proposed rule stated that the median labor cost-per-training session was \$283 overall, \$164 for HD, and \$314 for PD.

Response: We want to reiterate that the reported figures to which the commenter pointed are not the best comparison alone for the home dialysis training add-on amount as these figures include all labor costs associated with

furnishing the renal dialysis session. The ESRD PPS base rate includes costs associated with the labor for furnishing renal dialysis services. Dialysis treatments which include home dialysis training, also receive the ESRD PPS base rate which covers the more routine aspects of that dialysis session. Although not every renal dialysis service may be identical between routine maintenance dialysis and dialysis that includes home dialysis training, the nature of a bundled payment allows for ESRD facilities to substitute the specific renal dialysis services as appropriate. In the proposed rule, when we referenced these figures, we then removed a portion of the ESRD PPS payment based on the LRS which resulted in a net increased labor cost-per-training session of approximately \$130 for CY 2024 (91 FR 38831). This is consistent with our proposed training add-on of \$138.22 for CY 2027.

Comment: One professional association stated that home dialysis training was more resource intensive for pediatric ESRD patients and recommended that CMS recognize the difference.

Response: We appreciate the insight into home dialysis training costs for pediatric ESRD patients. We are finalizing changes to the case-mix adjustment factors for pediatric ESRD patients and finalizing an extension of the LVPA to payments for pediatric renal dialysis treatments. We note that the cost analysis upon which the updated case-mix adjustments were based included costs associated with home dialysis training. We are confident that the changes to the payment for renal dialysis services furnished for pediatric ESRD patients, including the increase to the training add-on, will continue to support access to home dialysis training for pediatric ESRD patients, including home dialysis performed by a caregiver. Nevertheless, we will consider the commenter's suggestion for potential future rulemaking. We did not propose, and are not finalizing, different training add-on payments for pediatric ESRD patients.

Comment: Most commenters who opined on the proposal to allow the training add-on during the onset period expressed support for the policy. Many commenters expressed support for this proposal alongside support for the increase to the training add-on and listed the same reasonings for both, including the importance of high-quality home dialysis training. A commenter stated that this would improve patient-centered care. Several commenters highlighted the importance

on home dialysis uptake in the initial months of dialysis, with a commenter especially noting the potential impact on those who "crash" into dialysis.

Response: We appreciate the support of commenters on our proposal to allow the training add-on payment during the onset period. We agree that access to home dialysis training is important to facilitate ESRD beneficiaries' ability to choose the modality best for them. We likewise agree that access to home dialysis training is important for those whose transition to ESRD and dialysis is unexpected.

Comment: One coalition of kidney organizations raised concerns with the proposal to allow the training add-on to be applied during the onset period. The commenter was uncertain whether it was methodologically reasonable and indicated a belief that it may have been appropriate for CMS to make corresponding decreases to the onset adjustment factor.

Response: We acknowledge the concerns of commenters regarding the potential overlap between the onset adjustment and training add-on adjustment, should the training add-on be extended during the onset period. When we finalized the training add-on in the CY 2011 ESRD PPS final rule (75 FR 49062) we stated that we believed the onset adjustment accounts for certain higher costs associated with training patients for home dialysis during the first four months of dialysis treatments. In the CY 2027 ESRD PPS proposed rule, we stated that we believed that most costs associated with home dialysis training are not reflected in the current onset adjustment and that we were accounting for the potential for duplicative payments by reducing the ESRD PPS base rate (91 FR 38833). After consideration of the commenters' concerns, we agree that the onset adjustment captures some of the labor costs associated with home dialysis training and that it would be appropriate to reduce the onset factor to account for the overlap. Additionally, we considered the concerns of several other commenters regarding budget neutrality and recognize that a reduction to the onset factor would mitigate the budget neutrality impact on the ESRD PPS base rate. Thus, after considering all of the comments received, we are finalizing a modification to the onset adjustment to account for the overlap in the payments. Specifically, we are scaling down the onset adjustment factor by the estimated training payments during the onset period. This is an option that we discussed as an alternative in the proposed rule and solicited comments

on (91 FR 38833). This will ensure that the expansion of the training payment to the onset period is done in a budget neutral manner and prevent duplicative payments between the onset adjustment and the training add-on. By reducing the onset adjustment by the estimated overlap spending and maintaining budget neutrality we are functionally targeting the onset adjustment funds towards ESRD treatments that include home dialysis training. The reduced onset factor is 1.311, which is a modest reduction from the current factor of 1.327, which we believe is reasonable given the expansion of the training add-on during the onset period will maintain total estimated spending during the onset period. We note that the budget neutrality for this calculation was based on CY 2025 claims data on training sessions during the onset period; we expect that this policy would also result in a shift of training sessions which are currently occurring after the onset period.

Comment: Several commenters raised concerns with the budget neutrality of the proposal and requested it be implemented in a non-budget neutral manner. Some commenters noted that the original training add-on was established in a non-budget neutral manner and stated a belief that future updates should also be non-budget neutral. A commenter noted that, had the establishment of the training add-on been instead a part of the base rate, it would have been updated by the ESRDB market basket and increased over time. A commenter highlighted that large, infrequent updates to the training add-on concentrate the budget neutrality impact in a single year. MedPAC supported implementing this proposal budget neutrally. Some commenters indicated that they believed lowering the payment rate for budget neutrality would be contrary to the stated goal of supporting home dialysis, as the payment rate for home dialysis would decrease.

Response: We understand the concerns raised by commenters regarding the decrease to the ESRD PPS base rate associated with budget neutrality. We also acknowledge commenters' observations regarding the history of the training add-on payment adjustment, including that the original training add-on was established on a non-budget neutral basis and that certain subsequent changes have been implemented budget neutrally.

We proposed this policy budget neutrally because we believe implementing this budget neutral change is appropriate because the ESRD PPS base rate includes certain training

costs, similar to the budget neutral training add-on in the CY 2017 ESRD PPS final rule (81 FR 77856). We included a detailed history of the training add-on changes, including the choices to implement certain changes budget neutrally, in response to comments in the CY 2017 ESRD PPS final rule (81 FR 77853 through 77854). In that rule we characterized the \$95.60 add-on training amount as a temporary measure stated that we would collect and review cost report and claims data to eventually reevaluate the training add-on amount. As noted previously we have since reviewed the available cost report data and believe those data support our longstanding methodology based on 2.66 hours of RN time as an appropriate proxy for the labor costs associated with home dialysis training.

We do not believe it is appropriate at this time to increase overall expenditures under the ESRD PPS as home dialysis training is also accounted for in the base rate. We view this increase to the training add-on as moving dollars to effectively target this modality based on its relative resource use. We recognize that the training add-on was originally implemented non-budget neutrally and that if it had been added to the base rate it would have been increased by the annual ESRDB market basket update. In the CY 2011 ESRD PPS final rule, we acknowledged that there were dollars in the base rate for home dialysis training (75 FR 49062 through 49064) and we established a policy to implement the additional payment for training through an add-on payment, rather than a base rate increase. Regardless of how the training add-on was originally implemented, we are making this change to better allocate the money that is currently in the ESRD PPS, so budget neutrality is most appropriate at this time.

We acknowledge that this is a single budget neutrality factor reflective of changes since CY 2017 and is larger than if it only reflected typical changes in a single year. The budget neutrality factor is based on the estimated payments under the updated factor, the increase to which was based on the most recently available wage data. As noted previously, we will consider more routine updates to the training add-on in potential future rulemaking.

We disagree with the commenters who stated that a budget neutrality decrease would be contrary to our goal of supporting home dialysis uptake. Although a budget neutrality adjustment would decrease the ESRD PPS base rate, it would not decrease total ESRD PPS payments.

As noted previously, we are finalizing this proposal with a slight modification to decrease the onset adjustment factor based on the estimated training add-on spending during the onset period. This change will maintain budget neutrality for the expansion of the training add-on to the onset period, which reduces the impact of the budget neutrality factor for the base rate.

Final rule Action: After consideration of public comments, we are finalizing our proposals to increase the home and self-dialysis training add-on payment adjustment amount and to allow the training add-on during the onset period. The final home dialysis training amount is \$138.00 ($2.66 \times \$51.88 = \138.00), based on an updated hourly RN wage of 51.88, which reflects an updated estimate of the change in labor compensation of the ESRDB market basket from CY 2025 to CY 2027. Additionally, we are finalizing a reduction to the onset add-on amount by a factor to account for the estimated training add-on spending during the onset period, reducing the factor from 1.327 to 1.311. These changes are being finalized budget neutrally with a budget neutrality factor of 0.99964, driven by the payment impact of increasing the training add-on amount. We note that the change in policy to reduce the onset factor has a lessening impact on the budget neutrality factor, which was proposed as 0.99884.

11. Modification to TDAPA and Post-TDAPA Add-On Payment Adjustment Average Sales Price (ASP) Policy

In the CY 2020 ESRD PPS final rule, we finalized a conditional policy for TDAPA payment based on the availability of ASP data (84 FR 60679). In that final rule, we explained that if drug manufacturers were to stop submitting full quarters of ASP data for products that are eligible for the TDAPA, and we had to revert to basing the TDAPA on the wholesale acquisition cost (WAC) or invoice pricing, we believed we would be overpaying for the TDAPA for those products. We stated that we would no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive a full calendar quarter of ASP data within 30 days after the last day of the 3rd calendar quarter after the TDAPA is initiated for the product, or if CMS stops receiving the latest full calendar quarter of ASP data during the applicable TDAPA period specified in § 413.234(c)(1) or (2). We explained that once we determine that the latest full calendar quarter of ASP is not available, we would stop applying the TDAPA for the new renal dialysis

drug or biological product within the next 2-calendar quarters. We adopted this conditional policy to avoid overpaying for the TDAPA on an ongoing basis and to ensure that TDAPA payment is based on the most appropriate data, that is, ASP.

In the CY 2024 ESRD PPS final rule we finalized the post-TDAPA add-on payment adjustment (88 FR 76388 through 76397). When we finalized this payment adjustment, we also finalized a similar conditional ASP policy where if CMS stopped receiving ASP data for a particular drug or biological product, we would no longer apply a post-TDAPA add-on payment adjustment for that drug or biological product.

The CY 2024 ESRD PPS proposed rule (88 FR 42472) discussed that our regulation at § 413.234(c) did not address the application of the TDAPA conditional policy in situations where the manufacturer of the new renal dialysis drug or biological product submitted zero or negative sales ASP data to CMS. Zero or negative sales may occur for a variety of reasons, including no sales, recalls of a product, or repurchases of sold products. In the CY 2012 Physician Fee Schedule (PFS) final rule (76 FR 73296), CMS clarified that zero or negative values are valid for ASP, ASP units, and WAC. Therefore, when such a scenario occurs for separately payable Medicare Part B drugs, we consider the submission of zero or negative sales to fulfill the reporting requirements of manufacturer ASP data to CMS as set forth in sections 1927(b)(3)(A)(iii) and 1847A(f) of the Act.

In the CY 2024 ESRD PPS final rule (88 FR 76410) we clarified that for purposes of the TDAPA conditional policy, in circumstances where a manufacturer submitted zero or negative sales ASP data during the TDAPA period, we consider CMS to have received the latest full calendar quarter of ASP data, and we will not discontinue TDAPA payment under the conditional policy in § 413.234(c). We further indicated that, consistent with the pricing methodologies for separately payable Medicare Part B drugs, in such circumstances, we will set the TDAPA payment amount based on WAC or, if WAC is not available, invoice pricing, for the quarter in which zero or negative sales were reported. Likewise, we finalized that we would also consider ASP reflecting zero or negative sales during the post-TDAPA add-on payment adjustment period as CMS having received the latest full calendar quarter of ASP data and would not discontinue the post-TDAPA add-on payment adjustment. We finalized that we would

use WAC or, if WAC is not available, invoice pricing, for the post-TDAPA add-on payment adjustment calculation (88 FR 76396).

In the CY 2025 PFS final rule (89 FR 97981 through 97982), we specified that for the purposes of calculating a payment limit for Part B drugs, we will consider positive manufacturer's ASP data "available" and negative or zero manufacturer's ASP data "not available." We further specified that the use of the most recent positive ASP data available for a billing and payment code for a drug is most consistent with the payment limit calculations described in section 1847A(b) and (c) of the Act, including section 1847A(c)(5)(B) of the Act. In the CY 2026 PFS final rule (90 FR 49737) we noted that the published payment limit for a drug with negative or zero ASP data reported after January 1, 2025, could be based on a positive amount that is carried forward from a previous quarter in accordance with § 414.904(i).

In the CY 2027 ESRD PPS proposed rule, we proposed modifications to align the TDAPA and post-TDAPA add-on payment adjustment methodologies with pricing methodologies applicable to separately payable Medicare Part B drugs under section 1847A of the Act, including the use of the most recent available positive ASP data (91 FR 38834). This proposed modification would not change the TDAPA payment for a new renal dialysis drug or biological product that is in the first three quarters of the TDAPA payment period for which ASP data has not been reported. Specifically, for any such product, TDAPA payment would continue to be based on 100 percent of WAC and, if WAC is not available, based on the drug manufacturer's invoice price. Consistent with our policy, if CMS does not receive a full calendar quarter of ASP data within 30 days of the last day of the 3rd calendar quarter following the initiation of the TDAPA, CMS will discontinue the TDAPA for that product beginning no later than 2-calendar quarters after CMS determines that such ASP data is not available. We note that, for purposes of this policy, the submission of zero or negative sales ASP data satisfies the manufacturer's ASP reporting requirement under sections 1927(b)(3)(A)(iii) and 1847A(f) of the Act.

Under this proposal, when ASP data are reported as negative or zero for a renal dialysis drug or biological product and CMS has received positive ASP data for the product in a prior calendar quarter, we would no longer base the TDAPA payment amount on WAC or, if

WAC is not available, invoice pricing for that quarter. Instead, consistent with the approach adopted for separately payable Part B drugs in § 414.904(i), we would base the TDAPA payment amount on the most recent prior calendar quarter, with positive ASP data, which we consider the most recent available ASP for purposes of section 1847A of the Act. We proposed to apply a similar modification to the post-TDAPA add-on payment adjustment methodology. Specifically, when the most recent full calendar quarter of ASP data reflects negative or zero sales, and CMS has received positive ASP data for the product in a prior calendar quarter, we would not base the post-TDAPA add-on payment adjustment on WAC, or invoice pricing. Instead, we would base the post-TDAPA add-on payment adjustment on the most recent prior calendar quarter with positive ASP data.

We explained that, as under current policy, in circumstances where a manufacturer submits ASP data reflecting zero or negative sales, CMS considers the manufacturer to have satisfied its ASP reporting obligation, and such submissions do not trigger the discontinuation of the TDAPA under § 413.234(c). However, if a manufacturer ceases submitting ASP data, and CMS determines that the latest full calendar quarter of ASP data is not available, CMS will discontinue the TDAPA for the product within 2 calendar quarters, consistent with § 413.234(c). For purposes of the TDAPA and post-TDAPA add-on payment adjustment, zero or negative ASP data are treated as not usable for purposes of determining the payment amount but are treated as submitted for purposes of the ASP reporting requirement.

We stated that we believe the proposed approach is consistent with section 1847A of the Act because it relies on the most recent available positive ASP data when current quarter ASP data is not usable for purposes of determining a payment amount. We further believe the proposed policy would improve payment accuracy and consistency across Medicare payment systems by avoiding reliance on WAC or invoice pricing when more representative ASP data are available. This is appropriate for the ESRD PPS as it aligns payment with resource use and promotes efficiency, consistent with the principles of the ESRD PPS.

We proposed modifications to § 413.234(c) and (g)(1) to effectuate this change by amending language to state that when the most recently available quarter of ASP data is not usable because it is zero or negative, we would instead use the most recently available

quarter of positive ASP data, and that we would only resort to WAC or invoice pricing if a prior quarter of positive ASP data is not available.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed technical modifications to ASP pricing. Another commenter supported the technical modifications provided CMS confirms their understanding that the policy would apply for products that have previously reported usable ASP data and have a subsequent quarter where ASP is reported as zero or negative, and in this circumstance, CMS would use the most recently available usable quarter of ASP data as the basis for the adjustments. They requested we differentiate between a product that has previously reported ASP and subsequently reports an unusable ASP and a product which has not yet established ASP.

Response: We appreciate the support for the proposed technical modifications to the ASP pricing policy. The commenter's interpretation is correct. This policy only applies if there is a prior quarter for which the drug has a reported ASP data which could be used for the calculation. If a drug has not yet reported ASP data, for example if it is in its first two quarters of the TDAPA period, we would still base payment on WAC, or invoice pricing if WAC is not available. The intent of this policy is to ensure that the TDAPA and post-TDAPA add-on payment adjustment are based on the best available pricing data, which we believe is ASP, unless ASP reflects zero or negative sales. The intent of this policy is not to make any changes to payment before ASP is established or modify the conditional ASP policy in a way that changes what renal dialysis drugs or biological products would be available for an adjustment in a given quarter. We appreciate the commenter's support for this technical pricing change.

Final Rule Action: After consideration of public comments, we are finalizing our policy to use older ASP data, when available, rather than WAC or invoice pricing when the most recent quarter of ASP data is not usable due to zero or negative ASP.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we established the transitional add-on payment adjustment for new and innovative equipment and supplies

(TPNIES) under the ESRD PPS, pursuant to the authority of section 1881(b)(14)(D)(iv) of the Act, to support ESRD facility use and beneficiary access to these new items.

We added § 413.236 to establish the eligibility criteria and payment policies for the TPNIES. Under current § 413.236(b), CMS provides for a TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a complete HCPCS Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for non-drug and non-biological items, supplies, and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular CY; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1); and (6) is not a capital-related asset, except for capital-related assets that are home dialysis machines. For additional background on the TPNIES, we refer readers to the CY 2024 ESRD PPS final rule (88 FR 76410 through 76412).

As indicated in § 413.236(c) CMS includes the summary of each TPNIES application and our analysis of the eligibility criteria for each application in the annual ESRD PPS proposed rule and announces the results in the annual ESRD PPS final rule. Because we did not receive any applications for the TPNIES for CY 2027, we did not include any TPNIES application summaries, CMS analyses, or results in the proposed or final ESRD PPS rules for CY 2027.

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2027

In this section of the final rule, we identify any items previously approved for the TPNIES and for which payment is continuing for CY 2027. Because no new items were approved for the TPNIES for CY 2026 (90 FR 53102), there are no payments continuing in CY 2027.

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2027

In this section of the final rule, we identify any items previously approved for the TDAPA and for which payment is continuing for CY 2027. Under § 413.234(c)(1), a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the TDAPA for 2 years. As described in the CY 2026 ESRD PPS final rule, no new renal dialysis drugs or biological products items were approved for the TDAPA for CY 2026 (90 FR 53102 through 53103). The 2-year TDAPA period for each new renal dialysis drug or biological product previously approved for the TDAPA will conclude on December 31, 2026. As such, there are no items previously approved for the TDAPA for which payment is continuing in CY 2027.

III. CY 2027 Payment for Renal Dialysis Services Furnished to Individuals With AKI

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies to implement subsection (r) of section 1834 of the Act and the amendments to section 1861(s)(2)(F) of the Act, including the payment rate for AKI dialysis furnished by ESRD facilities (81 FR 77866 through 77872 and 77965). We interpret section 1834(r)(1) of the Act as requiring the

amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS as set forth in § 413.220, updated by the ESRDB market basket percentage increase factor reduced by a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965). In the CY 2025 ESRD PPS final rule, we finalized a policy to allow payment for home dialysis for beneficiaries with AKI. Additionally, we extended the payment adjustment for home and self-dialysis training to AKI dialysis payments in a budget neutral manner and calculated a reduction to the AKI dialysis payment rate which rounded to \$0.00 (89 FR 89170).

B. Update of AKI Dialysis Payment

1. CY 2027 AKI Dialysis Payment Rate

The payment rate for AKI dialysis, as set forth in section 1834(r)(1) of the Act, is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual market basket update, geographic wage adjustments, and any other amounts deemed appropriate by the Secretary pursuant to section 1881(b)(14)(D) of the Act, for such year. We note that ESRD facilities could bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis. Accordingly, in the CY 2027 ESRD PPS proposed rule (91 FR 38835), we proposed that the CY 2027 AKI dialysis payment rate would be equal to the proposed CY 2027 ESRD PPS base rate of \$299.55 ($(\$281.71 + \$15.96) \times 1.00267 \times 0.98783 \times 1.016 = \299.55), as outlined in section II.B.4. of the proposed rule. Additionally, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule, we would use such data, if appropriate, to determine the final CY 2027 ESRD PPS base rate. As discussed in section II.B.4. of this final rule, the final CY 2027 ESRD PPS base rate is \$297.52. As outlined in section II.B.1.b. of this final rule, we are rebasing and revising the ESRDB market basket to reflect a 2024 base year. This change would impact the ESRDB market basket update, which would impact the CY 2027 ESRD PPS base rate and therefore the AKI dialysis payment rate. As outlined in section II.B.1.d. of this final rule, the final CY

2027 ESRDB market basket update is based on IGI's third quarter 2026 forecast of the final 2024-based ESRDB market basket.

We received comments from a small regional dialysis chain, an LDO, and an advocacy group regarding the proposed revisions to payment for renal dialysis services furnished to Medicare beneficiaries with AKI. Commenters generally agreed that increasing the payment rate for renal dialysis services furnished to individuals with AKI to \$299.55 and extending the home dialysis and self-dialysis training (the training add-on) payment adjustments to beneficiaries with AKI is appropriate. Commenters did not oppose the proposed changes to the payment for AKI but did request clarification of some points. We summarize these comments and provide our responses in the following section.

Comment: Several comments supported the application of the proposed ESRD PPS base rate of \$299.55 to payment for renal dialysis services furnished to beneficiaries with AKI. A commenter specifically noted the vulnerability of the AKI patient population and highlighted the importance of adequate payment for renal dialysis services for beneficiaries with AKI.

Response: We appreciate the support for our longstanding policy to apply the ESRD PPS base rate for payments for renal dialysis services furnished to beneficiaries with AKI, which represents a payment increase for CY 2027. We agree that adequate payment for AKI dialysis is important and believe that the final AKI dialysis payment rate for CY 2027 will help continue to support high-quality care for beneficiaries with AKI. We note that the final ESRD PPS base rate is \$297.52.

Comment: A commenter urged CMS to clarify how the phosphate binders and other bundled renal dialysis drugs should be provided and paid for in AKI patient care. The commenter stated that since the AKI dialysis payment rate is tied to the ESRD PPS rate, ESRD facilities need guidance on their responsibilities regarding bundled renal dialysis drugs and services and whether the payment method covers associated costs. Specifically, the commenter requested that CMS confirm in the final rule that ESRD facilities must provide phosphate binders to outpatient dialysis patients with AKI starting CY 2027. Further, the commenter stated that guidance should clarify that this responsibility applies only during outpatient renal dialysis services and not to AKI patients who are hospitalized, have not started outpatient

dialysis, or have discontinued dialysis. The commenter noted that these distinctions will help define ESRD facility responsibilities for clinically complex AKI patients. Additionally, this commenter asked CMS to review the outpatient AKI benefit to ensure payment supports proper dialysis care and focuses on kidney recovery.

Response: The AKI dialysis payment rate applies to all renal dialysis services, and ESRD facilities are responsible for furnishing all medically necessary renal dialysis services to beneficiaries with AKI who are receiving renal dialysis services as specified at § 413.374(a). While oral-only renal dialysis drugs and biological products have always met the definition of renal dialysis services, the statutory delays implemented in our regulations at § 413.174(f)(6) postponed their inclusion in the ESRD PPS bundled payment until January 1, 2025. During the TDAPA payment period for phosphate binders, the TDAPA did not apply to renal dialysis services furnished to beneficiaries with AKI and ESRD facilities were not yet responsible for furnishing them for beneficiaries with AKI (89 FR 89172). This is because phosphate binders were not originally included in the ESRD PPS base rate, and therefore were not reflected in the AKI dialysis payment rate that is based on the ESRD PPS base rate. As a result, during the TDAPA period, the AKI dialysis payment rate did not include any amount for phosphate binders, so ESRD facilities had no payment mechanism through which to furnish them to beneficiaries with AKI. Once the payment amount for phosphate binders is established and incorporated directly into the ESRD PPS base rate, that payment is applied for beneficiaries with AKI. Accordingly, the policies finalized in this rule to incorporate the costs of phosphate binders into the ESRD PPS base rate mean that ESRD facilities must furnish phosphate binders to beneficiaries with AKI. The requirement that ESRD facilities furnish all renal dialysis services to beneficiaries with AKI has not changed.

Starting in CY 2027, ESRD facilities must provide medically necessary phosphate binders to beneficiaries with AKI receiving renal dialysis services. Section 1834(r) of the Act only addresses renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished to a beneficiary with AKI by a renal dialysis facility or provider of services. We do not believe that a renal dialysis facility or provider of services would provide renal dialysis services for AKI patients who are hospitalized, have not started outpatient renal dialysis, or have

discontinued renal dialysis services including phosphate binders.

In the CY 2025 ESRD PPS final rule we included a discussion clarifying how the inclusion of oral-only drugs into the ESRD PPS bundled payment impacted MA plans (89 FR 89152). Now that payment is available under part B for furnishing phosphate binders for beneficiaries with AKI, we believe a similar clarification may be helpful to readers. With respect to MA, per section 1852(a)(1) of the Act and its implementation regulations (42 CFR 422.100 and 422.101(a)), Medicare Advantage organizations (MAOs) must cover items and services, including drugs, for which benefits are available under Parts A and B in the Original Medicare program, subject to limited exclusions. We note that phosphate binders are not subject to the limited exclusions at section 1852(a)(1) of the Act and, therefore, must be covered by MAOs. Specifically, in accordance with section 1852(a)(1) if the Act and 42 CFR 422.100 and 422.101(a), MAOs must provide coverage of, by furnishing, arranging for, or making payment for, generally all services that are covered by Part A and Part B of Medicare and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees. In addition, with respect to coverage of Original Medicare benefits such as Part B drugs, MAOs must comply with applicable Medicare statutes, regulations, national coverage determinations (NCDs) and local coverage determinations (LCDs) of Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan (42 CFR 422.101(b)). In general, an MA plan that offers Part D benefits (MA-PD) must determine whether payment for the drug is allocated under Parts B or D, consistent with Original Medicare and Part D program drug coverage policies (see Appendix C, Attachment II, Question 5 of Chapter 6⁴³ Medicare Prescription Drug Benefit Manual for additional detail). Concerning how Part D sponsors will determine whether a drug is covered under Part B, in most cases Part B drug coverage should not impact payment decisions by Part D sponsors since Part B coverage is generally in a provider setting or physician's office rather than for drugs dispensed at a pharmacy. A Part D sponsor cannot deny payment for a particular drug on

⁴³ <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf>.

the basis that it is covered under Part B in some instances and Part D in others unless there is Part B coverage as the drug is prescribed and dispensed or administered in that particular instance. The fact that a claim is received for a drug that is sometimes covered by Part B is not a basis for denial since the Part D sponsor would have to determine whether the drug is being prescribed and dispensed or administered on the basis under which Part B coverage is available. This will generally involve interaction between the Part D sponsor and the Medicare Part B contractor with jurisdiction in that geographic area for that drug. Regarding new drugs, as decisions are made nationally or by individual A/B MAC contractors, this information will be available on the CMS and contractor websites. MA-PD coordinated care plans must coordinate all benefits administered by the plan with respect to drugs for which payment as so prescribed and dispensed or administered to an individual may be available under Part A or Part B, or under Part D (42 CFR 422.112(b)(7)). As a result of the rules and regulations described here, MAOs must cover oral-only ESRD drugs, including phosphate binders, under their plans for beneficiaries with AKI receiving outpatient renal dialysis services, as these are drugs under Part B and are not subject to the limited exclusions under section 1852(a)(1) of the Act.

Regarding the commenter's suggestion on renal function recovery monitoring, because the ESRD facility Conditions for Coverage (CfCs) apply uniformly across the certified facility's patient population, the same monitoring expectations apply to AKI patients. In addition, any individualized needs specific to a patient's AKI status should be identified through the required patient assessment and reflected in that patient's individualized plan of care, consistent with existing CfC requirements. Facilities should also address these AKI-specific considerations in their facility policies and procedures to ensure staff consistently apply appropriate safeguards for this patient population in accordance with national standards of care.

We will continue to consider comments on dialysis adequacy and kidney recovery and may potentially address these concerns in future rulemaking.

Comment: A commenter requested that CMS ensure AKI patients using home dialysis receive the same safety protections as ESRD beneficiaries, including comprehensive training and access to in-center back-up care. The

commenter stated that sending patients to the hospital or requiring them to find another provider is not acceptable as back-up.

Response: We appreciate the commenters' recommendations regarding patient safety protections for individuals with AKI receiving dialysis in the home. We agree that appropriate patient training, access to necessary support, and monitoring for renal function recovery are important components of furnishing renal dialysis services to patients with AKI. We also agree that sending an AKI home dialysis patient to the hospital or emergency room or discharging the patient and requiring them to find a new ESRD facility or health care provider, does not satisfy the facility's obligation to provide back-up renal dialysis support services. The ESRD Facility CfCs at 42 CFR part 494 apply equally to all patients treated in a Medicare-certified ESRD facility, regardless of whether the patient's underlying diagnosis is ESRD or AKI. Because AKI patients receiving renal dialysis in a Medicare-certified facility are treated under that same facility's conditions for coverage, the existing home dialysis requirements, including comprehensive training on the home modality, and access to back-up renal dialysis support services already apply equally to AKI patients using home modalities. The CfCs do not distinguish between ESRD and AKI patients with respect to these protections; a Medicare certified facility must furnish the same standard of care, training, and support structures to any patient it treats, including AKI patients dialyzing at home.

Final Rule Action: After consideration of public comments, CMS is finalizing the CY 2027 AKI dialysis payment rate of \$297.52, which is equal to the CY 2027 ESRD PPS base rate.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRDB market basket percentage increase and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we proposed to apply the same wage index under § 413.231 that is used under the ESRD PPS. As outlined in section II.B.2.a. of this final rule, the ESRD PPS wage index is based on mean hourly wage data from the BLS OEWS weighted by FTE data from freestanding

ESRD facility cost reports. We finalized the methodology for determining the wage index value for an ESRD facility in the CY 2025 ESRD PPS final rule (89 FR 89097 through 89116), and we proposed to continue to apply this methodology to AKI dialysis payments. Consistent with this approach, we proposed to apply the same wage index under § 413.231 that is used under the ESRD PPS to the AKI dialysis payment. We proposed to continue using this methodology when adjusting AKI dialysis payments to ESRD facilities, consistent with our historical practice. We stated that we believe this approach is appropriate because ESRD facilities utilize substantially similar staff, resources, and cost structures in furnishing renal dialysis services to beneficiaries with AKI and ESRD, and therefore the ESRD PPS wage index reasonably reflects geographic variation in labor costs for both populations. The AKI dialysis payment rate would be adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate would be adjusted by the wage index for that ESRD facility (81 FR 77868). Specifically, we would apply the wage index to the LRS of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. As outlined in section II.B.1.c. of this final rule, we proposed to update the LRS of the ESRD PPS from 55.2 percent to 63.5 percent based on the labor-related cost share weights of the proposed 2024-based ESRDB market basket. We also proposed to continue applying the wage index policies regarding the 0.600 wage index floor (87 FR 67161 through 67166) and the 5 percent cap on wage index decreases (87 FR 67159 through 67161) to AKI dialysis payments to ESRD facilities. ESRD facilities would utilize the same staff to provide renal dialysis services to and educate beneficiaries with AKI as those beneficiaries with ESRD. Therefore, utilizing the same wage index methodology would be appropriate in accordance with § 413.372, which addresses the payment rate for AKI dialysis and refers to § 413.231 for the wage adjustment. Accordingly, we proposed a CY 2027 AKI dialysis payment rate of \$299.55, adjusted by the ESRD facility's wage index. As outlined in section II.B.2.c. of the proposed rule, we proposed that, if more recent data became available after the publication of the proposed rule and before the publication of this final rule, we would use such data, if appropriate, to update the CY 2027 ESRD PPS wage

index, and we would describe any such changes in this final rule.

We did not receive any substantive comments on our longstanding policy to apply the ESRD PPS wage index value to payment for renal dialysis services furnished to beneficiaries with AKI, although some commenters acknowledged our AKI wage index policy and the underlying statute. We discuss comments on the ESRD PPS wage index more generally in section II.B.2.c. of this final rule.

Final Rule Action: We are finalizing our proposal to continue to apply the ESRD PPS wage index to dialysis payments for beneficiaries with AKI. We note that the CY 2027 ESRD PPS wage index is based on the most recently available data which is the May 2025 BLS OEWS and the most recent available CY 2025 cost report data.

3. Other Adjustments to the AKI Dialysis Payment Rate

Section 1834(r)(1) of the Act also provides that the payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act. As discussed in the CY 2025 ESRD PPS final rule, we extended the home and self-dialysis training add-on payment adjustment under the ESRD PPS to AKI dialysis payments in a budget neutral way (89 FR 89170). Under § 413.373(a), CMS applies the wage-adjusted add-on per-treatment adjustment for home and self-dialysis training as set forth at § 413.235(c) to payments for AKI dialysis claims that include such training. Section 413.235(c) provides for a training add-on payment adjustment for home and self-dialysis modalities, which is wage-adjusted and paid on a per-treatment basis. Therefore, we proposed that any revisions to the ESRD PPS training add-on payment adjustment would be reflected in payments for AKI dialysis. That is, the proposed ESRD PPS training add-on amount of \$138.22 would be applicable to beneficiaries with AKI during the training period. Beneficiaries with AKI do not receive the onset payment adjustment, so they would not be impacted by the proposal to allow training during the onset period. However, we noted that for beneficiaries with AKI that progress to ESRD the proposal to allow training payments during the onset period would allow for

continued access to the training add-on during the onset period for ESRD. We stated that, currently, there are no other adjustments that apply to AKI dialysis payments.

We received a comment specifically on the impact to beneficiaries with AKI of the proposals to modify the training add-on. The following is our summary of the comment and our response.

Comment: The commenter supported extending the home and self-care training add-on to AKI patients, noting that access to home dialysis training is important for patient safety and success. The commenter requested that CMS clarify in the CY 2027 ESRD PPS final rule that the AKI budget-neutrality adjustment for the add-on will remain at zero. The commenter stated that any increase could negatively impact payment rates for AKI patients.

Response: CMS noted in the CY 2025 ESRD PPS final rule when we extended home dialysis and home dialysis training to beneficiaries with AKI (89 FR 89163 through 89167) that incorporation of an adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act into AKI dialysis payments must be done on a budget neutral basis for payments under section 1834(r) of the Act. Therefore, we stated that establishing a training add-on payment adjustment for training for home and self-care dialysis could have an impact on the AKI base rate (89 FR 89166). The expansion of the training add-on to dialysis payments for beneficiaries with AKI has already been implemented in a budget neutral manner. As noted in section II.B.10. of this final rule, we are finalizing the modification to the training add-on adjustment in a budget neutral manner. We did not propose, and are not finalizing, a separate budget neutrality factor for the impact of the increase in the training add-on amount for beneficiaries with AKI as the expansion of the training add-on to dialysis payments for the AKI population has already been budget neutralized.

We recognize the commenter's concerns regarding the impact budget neutrality could have on the AKI dialysis payment rate. We reiterate that section 1834(r)(1) of the Act requires the application of any adjustment factor established under section 1881(b)(14)(D) to AKI dialysis payments be budget neutral.

Final Rule Action: As noted in section II.B.10. of this final rule, the final home

and self-dialysis training add-on payment adjustment amount is \$138.00. This reflects a more recent estimate of the change in the ESRDB compensation growth from CY 2025 to CY 2027. We are finalizing our proposal to continue to apply the training add-on to dialysis payments for beneficiaries with AKI at this new amount in a budget neutral manner.

IV. Updates to the End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the citations provided at IV.A. of the CY 2024 ESRD PPS final rule (88 FR 76433). We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Updates to Requirements Beginning With the PY 2029 ESRD QIP

1. PY 2029 ESRD QIP Measure Set

In the CY 2027 ESRD PPS proposed rule (91 FR 38836), we proposed to replace the Hypercalcemia reporting measure with the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients clinical measure, update the National Healthcare Safety Network Bloodstream Infection clinical measure, and remove both the Medication Reconciliation reporting measure and the COVID-19 Vaccination Coverage Among Healthcare Personnel reporting measure beginning with the PY 2029 measure set. Table 19 of the proposed rule summarized the previously finalized measures, proposed new measures, and proposed updated measures that we would include in the PY 2029 ESRD QIP measure set (91 FR 38837). As discussed in sections IV.B.2. through IV.B.5. of this final rule, we are finalizing these updates as proposed. We describe the finalized PY 2029 ESRD QIP measure set in Table 23. Details on the technical specifications for current measures that will remain in the measure set for PY 2029 can be found in the CMS ESRD Measures Manual for the 2026 Performance Period.⁴⁴

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⁴⁴ Centers for Medicare & Medicaid Services (April 2026). CMS ESRD Measures Manual for the 2026 Performance Period: Final Version 11.2.

TABLE 23: Finalized Measures for the PY 2029 ESRD QIP Measure Set

Consensus-Based Entity (CBE) #	Measure Title and Description	Policy Status
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple survey questions.	Previously finalized
5110*	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.	Previously finalized
Based on CBE #2979	Standardized Transfusion Ratio (STrR), a clinical measure Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.	Previously finalized
Based on CBE #0323, # 0318**, #1423, and #2706	(Kt/V) Dialysis Adequacy Measure Topic, a clinical measure topic Four measures of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. The individual Kt/V measures are adult hemodialysis (HD) Kt/V, adult peritoneal dialysis (PD) Kt/V, pediatric HD Kt/V, and pediatric PD Kt/V.	Previously finalized
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.	Previously finalized
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.	Previously finalized
Based on CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure Facility reports in ESRD Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during the performance period.	Previously finalized
Based on CBE #1460***	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.	Updated
N/A*****	Percentage of Prevalent Patients Waitlisted for Kidney Transplant (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.	Previously finalized
CBE #4650****	Hyperphosphatemia, a clinical measure Percentage of adult dialysis patients with a 6-month rolling average phosphorus value greater than or equal to 6.5 mg/dL.	New

* We note that this measure was endorsed under CBE #5110 in the Spring 2026 endorsement cycle.

** We note that the prior CBE number listed for this measure in last year's rule (#0321) was incorrect.

*** We are finalizing our proposal to update the NHSN BSI clinical measure beginning with PY 2029, as discussed in section IV.B.3. of this final rule.

**** We are finalizing our proposal to adopt the Hyperphosphatemia clinical measure, beginning with PY 2029, as discussed in section IV.B.2. of this final rule.

***** We note that the Percentage of Prevalent Patients Waitlisted clinical measure name was updated to the Percentage of Prevalent Patients Waitlisted for Kidney Transplant clinical measure in May 2025. For more information on the updated measure specifications please refer to <https://www.cms.gov/files/document/esrd-qip-cy2026-final-technical-specifications.pdf>.

***** We are finalizing our proposal to remove the Hypercalcemia reporting measure, MedRec reporting measure and the COVID-19 Vaccination Coverage Among HCP reporting measure beginning with PY 2029, as discussed in sections IV.B.2.a., IV.B.4.a., and IV.B.4.b. of this final rule.

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2. Replacement of the Hypercalcemia Reporting Measure With the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients Clinical Measure

a. Removal of the Hypercalcemia Reporting Measure

Abnormalities of mineral and bone metabolism are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced chronic kidney disease (CKD). Studies have associated disorders of mineral and bone metabolism with mortality, fractures, cardiovascular disease, and other comorbidities.^{45 46} Section 1881(h)(2)(A)(iv)(II) of the Act states that the measures specified for the ESRD QIP shall include other measures as the Secretary specifies, including, to the extent feasible, measures of mineral and bone metabolism. Therefore, in the CY 2014 ESRD PPS final rule (78 FR 72200 through 72203), we adopted the Hypercalcemia clinical measure as part of the ESRD QIP measure set, which encouraged adequate management of mineral and bone disease in patients with ESRD by monitoring elevated serum calcium levels. In the CY 2023 ESRD PPS final rule, we converted the Hypercalcemia clinical measure to a reporting measure in light of concerns that the measure was close to being topped out and that small differences in measure performance may disproportionately impact a facility's score on the measure (87 FR 67250 through 67251). Given the statutory requirement to include measures of mineral and bone metabolism to the extent feasible, we noted that we would retain the Hypercalcemia reporting measure while we explored possible replacement measures that would be more clinically meaningful for purposes of quality improvement.

Beginning with the PY 2029 ESRD QIP, we proposed to remove the Hypercalcemia reporting measure under measure removal factor 5, a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available (§ 413.178(c)(5)(i)(E)), and replace it

with the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients (Hyperphosphatemia) clinical measure. Both calcium and phosphorus are important in mineral and bone metabolism. The Hypercalcemia reporting measure only requires reporting of the calcium value⁴⁷ while the Hyperphosphatemia clinical measure will encourage facilities to identify patients with chronically elevated phosphorus levels who would benefit from additional intervention, a meaningful clinical practice more strongly associated with desired patient outcomes. Studies have demonstrated a consistent association between chronic hyperphosphatemia and adverse outcomes, including cardiovascular complications, bone fractures, and increased mortality.^{48 49} Prospective studies have also reported lower mortality among patients with improved phosphorus control, including treatment with phosphate-binding medications.^{50 51} The Hyperphosphatemia clinical measure will help drive decreases in cardiovascular complications, hospitalizations, and overall mortality by incentivizing additional interventions such as nutritional counseling, phosphorus binding medications, and adjustment of dialysis prescription.^{52 53 54 55} Compared to the

Hypercalcemia reporting measure, the Hyperphosphatemia clinical measure will more directly assess patient-focused clinical outcomes.

b. Adoption of the Hyperphosphatemia Clinical Measure

(1) Measure Overview

The Hyperphosphatemia clinical measure is an outcome measure developed by CMS to assess long-term phosphorus control across the dialysis population by measuring the percentage of adult dialysis patients with a 6-month rolling average serum phosphorus value greater than or equal to 6.5 mg/dL.⁵⁶ The cohort for the Hyperphosphatemia clinical measure will consist of adult patients, aged 18 years and older, with ESRD who are receiving in-center hemodialysis, home hemodialysis, hemodiafiltration, or peritoneal dialysis and have been under the care of the same dialysis facility for the entire reporting month. Eligible patients must have had ESRD for more than 90 days and sufficient laboratory data to calculate a 6-month rolling average serum phosphorus level.⁵⁷

For more information about the testing, feasibility, scientific acceptability, meaningfulness, and validity of the Hyperphosphatemia clinical measure, we refer readers to <https://p4qm.org/prmr-measures/muc2025-064>.

(2025). Oral phosphate binders and incident osteoporotic fracture in patients on dialysis. *Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association—European Renal Association*, 40(2), 329–340. <https://doi.org/10.1093/ndt/gfae139>.

⁵³ Rivara, M. B., Ravel, V., Kalantar-Zadeh, K., Streja, E., Lau, W. L., Nissenson, A. R., Kestenbaum, B., de Boer, I. H., Himmelfarb, J., & Mehrotra, R. (2015). Uncorrected and Albumin-Corrected Calcium, Phosphorus, and Mortality in Patients Undergoing Maintenance Dialysis. *Journal of the American Society of Nephrology: JASN*, 26(7), 1671–1681. <https://doi.org/10.1681/ASN.2014050472>.

⁵⁴ Floege J. Phosphate binders in chronic kidney disease: an updated narrative review of recent data. *J Nephrol*. 2020;33(3):497–508. <https://pubmed.ncbi.nlm.nih.gov/31865608>.

⁵⁵ Hall, R., Platt, A., Wilson, J., Ephraim, P. L., Hwang, A. S., Chen, A., Weiner, D. E., Boulware, L. E., Pendergast, J., Scialla, J. J., & Comparative Effectiveness Studies in Dialysis Patients Group (2020). Trends in Mineral Metabolism Treatment Strategies in Patients Receiving Hemodialysis in the United States. *Clinical journal of the American Society of Nephrology: CJASN*, 15(11), 1603–1613. <https://doi.org/10.2215/CJN.04350420>.

⁵⁶ Partnership for Quality Measurement. Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients. Available at <https://p4qm.org/prmr-measures/muc2025-064>.

⁵⁷ Further details on the proposed Hyperphosphatemia clinical measure are available at <https://p4qm.org/measures/4650>.

⁴⁷ Centers for Medicare & Medicaid Services. (2025). Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Calendar Year (CY) 2026 Measure Technical Specifications. Available at <https://www.cms.gov/files/document/esrd-qip-cy2026-final-technical-specifications.pdf>.

⁴⁸ Kim, J. E., Park, J., Jang, Y., Kang, E., Kim, Y. C., Kim, D. K., Joo, K. W., Kim, Y. S., & Lee, H. (2025). Oral phosphate binders and incident osteoporotic fracture in patients on dialysis. *Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association—European Renal Association*, 40(2), 329–340. <https://doi.org/10.1093/ndt/gfae139>.

⁴⁹ Rivara, M. B., Ravel, V., Kalantar-Zadeh, K., Streja, E., Lau, W. L., Nissenson, A. R., Kestenbaum, B., de Boer, I. H., Himmelfarb, J., & Mehrotra, R. (2015). Uncorrected and Albumin-Corrected Calcium, Phosphorus, and Mortality in Patients Undergoing Maintenance Dialysis. *Journal of the American Society of Nephrology: JASN*, 26(7), 1671–1681. <https://doi.org/10.1681/ASN.2014050472>.

⁵⁰ Floege J. Phosphate binders in chronic kidney disease: an updated narrative review of recent data. *J Nephrol*. 2020;33(3):497–508. <https://pubmed.ncbi.nlm.nih.gov/31865608>.

⁵¹ Hall, R., Platt, A., Wilson, J., Ephraim, P. L., Hwang, A. S., Chen, A., Weiner, D. E., Boulware, L. E., Pendergast, J., Scialla, J. J., & Comparative Effectiveness Studies in Dialysis Patients Group (2020). Trends in Mineral Metabolism Treatment Strategies in Patients Receiving Hemodialysis in the United States. *Clinical journal of the American Society of Nephrology: CJASN*, 15(11), 1603–1613. <https://doi.org/10.2215/CJN.04350420>.

⁵² Kim, J. E., Park, J., Jang, Y., Kang, E., Kim, Y. C., Kim, D. K., Joo, K. W., Kim, Y. S., & Lee, H.

⁴⁵ Salera, D., Merkel, N., Bellasi, A., & de Borst, M. H. (2025). Pathophysiology of chronic kidney disease-mineral bone disorder (CKD-MBD): from adaptive to maladaptive mineral homeostasis. *Clinical kidney journal*, 18(Suppl 1), i3–i14. <https://doi.org/10.1093/ckj/sfae431>.

⁴⁶ Dempster, D. W., Evenepoel, P., Nickolas, T. L., Massy, Z. A., Mazzaferro, S., Harvey, N. C., Miller, P. D., & Pazianas, M. (2026). Osteoporosis and CKD-metabolic bone disease under the same umbrella: Insights from a joint scientific symposium. *Kidney International Reports*. <https://doi.org/10.1016/j.ekir.2026.106362>.

(2) Measure Calculation

The numerator of this measure includes patient reporting months with a 6-month rolling average phosphorus value of 6.5 mg/dL or greater. The number of patient reporting months with a phosphorus average of 6.5 mg/dL or greater will then be divided by the total number of eligible patient reporting months for the facility and multiplied by 100 to calculate the percentage of patient reporting months with hyperphosphatemia. Patient reporting months will be excluded if the patient had a 6-month rolling average albumin level of less than 3.5 g/dL or a body mass index (BMI) of less than 18.5. The measure will be calculated only for facilities with more than 10 eligible patients during the reporting period.

(3) Recommendation From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement for details on the Pre-Rulemaking Measure Review process convened by the CBE, including the voting procedures used to reach consensus on measure recommendations.^{58 59} The Pre-Rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available “2025 Measures Under Consideration List,” including the Hyperphosphatemia clinical measure (MUC2025–064).⁶⁰

The voting results of the Recommendation Group for the proposed inclusion of the Hyperphosphatemia clinical measure in the ESRD QIP were: 16 members (76 percent) recommended adopting the measure into the ESRD QIP and 5 members (24 percent) voted not to

recommend the measure for adoption.⁶¹ With 76 percent of the votes for recommend, consensus was reached, as the majority of the Recommendation Group expressed support for use of the measure in the ESRD QIP. In expressing support for use of the Hyperphosphatemia clinical measure in the ESRD QIP, Recommendation Group members emphasized its importance given evidence linking chronic hyperphosphatemia to adverse outcomes, including increased mortality, hospitalizations, cardiovascular events, vascular calcification, and bone fractures.⁶² The minority of Recommendation Group members who voted not to recommend the measure for inclusion in the ESRD QIP provided the following rationales: (1) the evidence base does not justify use as a performance measure; (2) the protein restrictions required to achieve the goals of this measure may lead to unintended adverse outcomes; (3) phosphorus control is influenced by multiple clinical and patient-level factors that are not fully captured by this measure; and (4) the measure should undergo additional development before implementation.⁶³

Regarding concerns about the sufficiency of the evidence base supporting use of the Hyperphosphatemia clinical measure, we note that studies have demonstrated a consistent association between chronic hyperphosphatemia and adverse outcomes, including cardiovascular complications, bone fractures, and increased mortality.^{64 65}

Prospective studies have also reported lower mortality among patients with improved phosphorus control, including treatment with phosphate-binding medications.^{66 67} The Hyperphosphatemia clinical measure will incentivize and assess additional interventions such as nutritional counseling, phosphorus binding medications, and adjustment of dialysis prescription.

Regarding concerns about the need for additional measure development, we note that the Hyperphosphatemia clinical measure was developed and refined with input from a technical expert panel (TEP) and underwent extensive feasibility, reliability, and validity testing. The TEP consisted of interested parties, clinicians, subject matter experts, and consumer representatives, including patient advocates who contributed their input through the Hyperphosphatemia clinical measure design process.⁶⁸ There were no concerns regarding feasibility because phosphorus levels are routinely measured as part of standard clinical care in dialysis facilities. Testing demonstrated strong validity at the facility level, with higher rates of hyperphosphatemia associated with increased mortality and hospitalization, consistent with expected clinical relationships. In addition, testing demonstrated high reliability, and the measure was endorsed by the CBE in the Fall 2024 cycle for use in the ESRD QIP.⁶⁹ Please refer to section IV.B.2.b.(4) of this final rule for more information on endorsement of the measure.

Regarding concerns about the potential for unintended adverse outcomes associated with dietary protein restrictions, we note the measure includes exclusions intended to mitigate potential unintended

⁵⁸ Partnership for Quality Measurement. Pre-Rulemaking Measure Review webpage. Available at <https://p4qm.org/prmr/about>.

⁵⁹ In 2025, the CBE updated the Pre-Rulemaking Measure Review voting process such that Recommendation Group members will vote to either “recommend” or “do not recommend” that a measure be added to the intended CMS program(s), thus, removing the “recommend with conditions” voting option. The threshold to reach consensus on a given measure continues to be a minimum of 75 percent agreement among members. Recommendation Group members can provide considerations for CMS to review prior to implementation.

⁶⁰ Centers for Medicare & Medicaid Services. (2025). 2025 Measures Under Consideration List. Available at <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

⁶¹ Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendations Group Final Meeting Summary: Hospital Committee. Available at <https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf>.

⁶² Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendations Group Final Meeting Summary: Hospital Committee. Available at <https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf>.

⁶³ Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Final Recommendations Report. Available at <https://p4qm.org/sites/default/files/2026-02/Final-2025-2026-MUC-Recommendations-Report-508.pdf>.

⁶⁴ Kim, J.E., Park, J., Jang, Y., Kang, E., Kim, Y.C., Kim, D.K., Joo, K.W., Kim, Y.S., & Lee, H. (2025). Oral phosphate binders and incident osteoporotic fracture in patients on dialysis. *Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association—European Renal Association*, 40(2), 329–340. <https://doi.org/10.1093/ndt/gfae139>.

⁶⁵ Rivara, M.B., Ravel, V., Kalantar-Zadeh, K., Streja, E., Lau, W.L., Nissenon, A.R., Kestenbaum, B., de Boer, I. H., Himmelfarb, J., & Mehrotra, R. (2015). Uncorrected and Albumin-Corrected Calcium, Phosphorus, and Mortality in Patients Undergoing Maintenance Dialysis. *Journal of the*

American Society of Nephrology: JASN, 26(7), 1671–1681. <https://doi.org/10.1681/ASN.2014050472>.

⁶⁶ Floege J. Phosphate binders in chronic kidney disease: an updated narrative review of recent data. *J Nephrol*. 2020;33(3):497–508. <https://pubmed.ncbi.nlm.nih.gov/31865608>.

⁶⁷ Hall, R., Platt, A., Wilson, J., Ephraim, P.L., Hwang, A.S., Chen, A., Weiner, D.E., Boulware, L.E., Pendergast, J., Scialla, J.J., & Comparative Effectiveness Studies in Dialysis Patients Group (2020). Trends in Mineral Metabolism Treatment Strategies in Patients Receiving Hemodialysis in the United States. *Clinical Journal of the American Society of Nephrology: CJASN*, 15(11), 1603–1613. <https://doi.org/10.2215/CJN.04350420>.

⁶⁸ Centers for Medicare & Medicaid Services. (May 2024). ESRD Mineral and Bone Disorder Measure Development Technical Expert Panel. Available at <https://mmshub.cms.gov/sites/default/files/ESRD-MBD-TEP-Summary-Report.pdf>.

⁶⁹ Partnership for Quality Measurement. Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients. Available at <https://p4qm.org/prmr-measures/muc2025-064>.

consequences, including patients with indicators of poor nutritional status, such as a 6-month rolling average albumin of less than 3.5 g/dL and a BMI under 18.5. We also note that as part of routine measure maintenance we conduct ongoing monitoring and evaluation to identify and act upon any unintended consequences.

Regarding concerns that phosphorus control is influenced by multiple clinical and patient-level factors not fully captured by the measure, we note that phosphorus management is addressed through the interdisciplinary care team of a facility, including the prescribing physician and dietitian, who work together with ESRD patients through clinical care, dietary counseling, and treatment decisions. The Hyperphosphatemia clinical measure will capture the extent to which facilities are able to address these multi-layered factors.

(4) Measure Endorsement

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria.⁷⁰ Section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act. The Hyperphosphatemia clinical measure was submitted to the CBE for endorsement review in the Fall 2024 cycle (CBE #4650), and the CBE endorsed the measure, without conditions, for use in the ESRD QIP on February 12, 2025.⁷¹

(5) Data Submission and Reporting

We proposed to require facilities to submit data needed to calculate the Hyperphosphatemia clinical measure using EQRS beginning with the performance period for PY 2029. Facilities will report the required data through EQRS in accordance with the existing monthly data submission processes used for other ESRD QIP clinical measures. Because the measure

uses a 6-month rolling average of serum phosphorus values, we proposed that facilities will need to submit phosphorus data for the five months preceding the start of the performance period to allow calculation of rolling averages for the first months of the performance year. For example, the rolling average for January 2027 would be calculated using phosphorus values from August 2026 through January 2027. We proposed that data used to calculate the Hyperphosphatemia clinical measure will be based on a 12-month performance period, with data submission consistent with current reporting deadlines for other ESRD QIP measures. For example, for PY 2029, facilities will report the required data through EQRS on a monthly basis during CY 2027, with final data submission due by the end of the December 2027 data reporting month.

Table 26 describes the performance standards we are finalizing for the Hyperphosphatemia clinical measure. Facilities will be required to follow the existing submission and reporting requirements for web-based measures under the ESRD QIP, as described on the QualityNet website at <https://qualitynet.cms.gov/esrd>.

We welcomed public comment on our proposals to remove the Hypercalcemia reporting measure and adopt the Hyperphosphatemia clinical measure beginning with PY 2029.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to replace the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure, stating that phosphorus management is a clinically meaningful component of dialysis care and that the Hyperphosphatemia measure would more meaningfully assess bone and mineral metabolism management and patient outcomes than the existing Hypercalcemia reporting measure. A few commenters noted that the measure could incentivize and facilitate timely, coordinated interventions such as nutrition counseling, dialysis prescription adjustments, and appropriate use of phosphorus-binding medications rather than simply documenting phosphorus management. A commenter acknowledged that managing phosphorus can be challenging due to the variability associated with diet, dialysis efficiency, residual kidney function, and other factors, but stated that the measure accounts for this variability, focuses on patients at greatest clinical risk, is

consistent with clinical guidelines, actionable, and supported by robust long-term data. A few commenters stated that facilities may be accountable for phosphorus outcomes and for timely, continuous, and equitable access to clinically appropriate care.

Response: We thank the commenters for their support.

Comment: Many commenters did not support the proposal to replace the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure, raising concerns that serum phosphorus is influenced by factors outside a facility's direct control, including patient dietary choices and medication adherence, food insecurity, access to phosphate binders and affordable low-phosphorus foods, pill burden, socioeconomic circumstances, phosphorus additives in processed foods, and the lack of phosphorus content information on food labels. Several commenters expressed concern about holding facilities accountable for phosphorus outcomes when facilities have provided education and support but cannot ensure adherence to dietary recommendations or phosphate binders. A commenter recommended that CMS evaluate the measure threshold, risk adjustment, and potential unintended consequences to avoid penalizing facilities for factors outside of their control or creating inappropriate pressure for patients or additional burden. A few commenters recommended retaining the Hypercalcemia measure, which they stated is more directly manageable by ESRD facilities.

Response: We acknowledge commenters' concerns that phosphorus control may be influenced by multiple clinical and patient-level factors. However, dialysis facilities and their interdisciplinary care teams, including the prescribing physician and dietitian, play an important role in phosphorus management through patient support, clinical care, dietary counseling, treatment decisions, and adjustment of dialysis prescriptions. The Hyperphosphatemia clinical measure would capture the extent to which facilities are able to address these multi-layered factors. We note that the measure includes exclusions intended to mitigate potential unintended consequences for patients with indicators of poor nutritional status, including a 6-month rolling average albumin of less than 3.5 g/dL and a BMI under 18.5. Given the prominent role of phosphorus management as part of ESRD treatment, we continue to believe that the Hyperphosphatemia clinical measure more directly and meaningfully

⁷⁰ Partnership for Quality Management. Pre-Rulemaking Measure Review webpage. Available at <https://p4qm.org/prmr/about>.

⁷¹ Partnership for Quality Measurement. (April 2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report: Management of Acute Events and Chronic Conditions. Available at <https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events%2C%20Chronic%20Disease%2C%20Surgery%2C%20and%20Behavioral%20Health/material/EM-Fall-2024-Management-Final-Project-Report.pdf>.

assesses patient outcomes than the Hypercalcemia reporting measure. We also note that the Hyperphosphatemia clinical measure underwent feasibility, reliability, and validity testing and was endorsed by the CBE in the Fall 2024 endorsement cycle.⁷² Additionally, as part of routine measure maintenance, we conduct ongoing monitoring and evaluation to identify and act upon any unintended consequences.

Comment: A few commenters expressed support for the proposal to replace the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure but recommended initially implementing the Hyperphosphatemia measure as a reporting measure before using it for payment scoring. The commenters stated that a reporting period would allow CMS to establish appropriate data and quality benchmarks, validate data, address initial measurement and technical submission issues, and clarify measure specifications before payment consequences apply. A few commenters that did not support the proposal recommended that CMS withdraw the proposal or, at a minimum, initially implement the measure as a nonpayment reporting or feedback measure while CMS validates the threshold, establishes transparent performance standards, and addresses patient-level factors outside facility control.

Response: We appreciate commenters' recommendations to initially implement the Hyperphosphatemia measure as a reporting measure. However, we believe the measure is sufficiently developed for use as a clinical measure in the ESRD QIP. The measure was developed and refined with input from a TEP and underwent extensive feasibility, reliability, and validity testing. Testing demonstrated strong validity at the facility level and high reliability, and the measure was endorsed by the CBE.⁷³ We also note that the proposed performance standards for the

Hyperphosphatemia clinical measure were published in the CY 2027 ESRD PPS proposed rule (91 FR 38837), providing facilities with information on how performance would be assessed before payment consequences apply. Therefore, we do not believe that initially implementing the measure as a reporting measure is necessary.

Comment: A few commenters questioned or opposed the proposed 6.5 mg/dL threshold. A few commenters stated that there is insufficient evidence supporting a specific biochemical target as a facility-level accountability standard. A commenter stated that the Measures Assessment Tool used as a regulatory compliance guide for CMS surveyors identifies a phosphorus level of 5.5 mg/dL and requested clarification regarding why the proposed measure uses a 6.5 mg/dL threshold. The commenter further recommended that, if CMS adopts the measure, CMS use the exclusion criteria established in the Measures Assessment Tool. A commenter supporting the proposal similarly expressed concern that the proposed threshold is higher than phosphorus targets reflected in other CMS materials and requested clarification regarding how the threshold was selected. Another commenter recommended using a lower threshold, such as 4.4 mg/dL.

A commenter recommended that the 6.5 mg/dL threshold remain a facility-level performance threshold rather than an individual treatment target and that CMS continue to evaluate the threshold, exclusions, case mix, disparities, and unintended consequences. The commenter cautioned that favorable aggregate laboratory results should not mask avoidable delays, interruptions, non-clinical changes in care, excessive treatment burden, or barriers to individualized care plans.

Response: We appreciate commenters' concerns regarding the evidence supporting the proposed 6.5 mg/dL threshold. We wish to clarify that the threshold is not intended to establish a clinical treatment target for individual patients. The threshold was selected for purposes of the facility-level performance measure to identify patients with significant sustained elevations in phosphorus who are at greatest risk of adverse outcomes rather than month-to-month fluctuations. While facilities typically aim for phosphorus below 5.5 mg/dL as part of clinical management, evidence indicates that a 6-month average above 6.5 mg/dL is associated with the highest

cardiovascular risk.⁷⁴ The measure also underwent extensive feasibility, reliability, and validity testing. Testing demonstrated strong validity at the facility level, with higher rates of hyperphosphatemia associated with increased mortality and hospitalization, and high reliability. Regarding the commenter's recommendation to use the exclusion criteria established in the Measures Assessment Tool, we note that the Hyperphosphatemia clinical measure includes exclusion criteria that was established through the measure development process with input from a technical expert panel and underwent extensive testing. We believe the exclusion criteria established are appropriate for purposes of the ESRD QIP.

Regarding commenters' recommendations, we note that the 6.5 mg/dL threshold is intended as a facility-level performance threshold that confers the highest risk of adverse outcomes designed to assess long-term phosphorus control across the dialysis population rather than an individual treatment target. We also note that as part of routine measure maintenance, we conduct ongoing monitoring and evaluation of measure performance and potential unintended consequences. We agree with the commenter that high performance on the measure does not replace the need for individualized clinical assessment and appropriate patient-centered care.

Comment: Several commenters stated that tying facility performance or reimbursement to phosphorus outcomes could disproportionately penalize facilities serving medically complex, low-income, rural, or otherwise underserved patients. A few commenters expressed concern that facilities could be disincentivized from accepting medically complex or otherwise high-need patients. Commenters recommended that CMS account for differences among patients, ensure sufficient risk adjustment for medically and socially complex populations, and monitor for disparities and other unintended consequences. A commenter supporting the proposal similarly recommended that CMS finalize the measure within a balanced accountability framework that holds facilities responsible for outcomes while monitoring patient risk and disparities.

Response: We appreciate commenters' concerns regarding differences among patients and the potential for

⁷² Partnership for Quality Measurement. (April 2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report: Management of Acute Events and Chronic Conditions. Available at <https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events%2C%20Chronic%20Disease%2C%20Surgery%2C%20and%20Behavioral%20Health/material/EM-Fall-2024-Management-Final-Project-Report.pdf>.

⁷³ Partnership for Quality Measurement. (April 2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report: Management of Acute Events and Chronic Conditions. Available at <https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events%2C%20Chronic%20Disease%2C%20Surgery%2C%20and%20Behavioral%20Health/material/EM-Fall-2024-Management-Final-Project-Report.pdf>.

⁷⁴ Partnership for Quality Management. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Final Recommendations Report. Available at <https://p4qm.org/sites/default/files/2026-02/Final-2025-2026-MUC-Recommendations-Report-508.pdf>.

unintended consequences. During measure development, comorbidities and other factors for potential risk adjustment were evaluated and found that expected factors, such as access to healthy nutrition, did not significantly impact outcomes.⁷⁵ We also acknowledge commenters' concerns regarding potential effects on facilities serving medically or socially complex populations. We do not anticipate unintended consequences with the adoption of the Hyperphosphatemia clinical measure, and we note as part of routine measure maintenance, we conduct ongoing monitoring and evaluation to identify and act upon any unintended consequences and will continue to evaluate measure performance as the measure is implemented.

Comment: A few commenters raised concerns regarding the exclusion for patients with a BMI under 18.5 at ESRD incidence, stating that limiting the exclusion to BMI at ESRD incidence may not align with the CBE-endorsed measure specification, may become inaccurate over time, and may not be known to facilities when patients initiated dialysis elsewhere. The commenters recommended using a more current BMI and suggested that CMS automatically calculate BMI using the height and estimated dry weight information already available in EQRS to avoid duplicative data entry. The commenters recommended changing the exclusion from "BMI at ESRD Incidence" to "Current BMI" or simply "Patients with BMI under 18.5."

Response: We appreciate the commenters' concerns and recommendations regarding the BMI exclusion. We note that, while the CBE-endorsed measure specification identifies the exclusion as "BMI under 18.5" without specifying "at ESRD incidence," the measure documentation indicates that height and weight from the Medical Evidence Form (CMS Form-2728) are used to calculate BMI, which is completed at ESRD incidence. We are currently evaluating the height and weight data available in EQRS to determine if there is acceptable reliability for calculating current BMI rather than relying on the BMI that is calculated from the Medical Evidence Form (CMS Form-2728). If the height

and weight fields in EQRS are found to be sufficiently complete and reliable, we could incorporate this change as part of the annual measure maintenance process.

Comment: A few commenters recommended that CMS consider whether patients may have at least 90 days of dialysis vintage and sufficient time at the facility before being included in the measure so that facilities have a reasonable opportunity to manage the patient's phosphorus.

Response: We appreciate commenters' recommendations. We note that the Hyperphosphatemia clinical measure excludes patients who have been receiving ESRD treatment for fewer than 91 days. In addition, patients are included in a facility's measure calculation only if they remain at the same facility for the full reporting month and the preceding 5 months.⁷⁶

Comment: A few commenters requested clarification regarding which laboratory result would be used for measure calculation, including whether CMS would use a pre-dialysis phosphorus value and whether the first, last, or average phosphorus result during the month would be used. A few commenters noted that the timing of laboratory collection could affect phosphorus results because levels obtained following the two-day interdialytic interval may differ from levels obtained following a one-day interval. A commenter recommended allowing repeat phosphorus measurements following a documented clinical intervention or otherwise recognizing improvement over time rather than relying solely on the initial monthly value. Another commenter recommended using the last phosphorus measurement of the month because an elevated result earlier in the month may prompt initiation or adjustment of phosphate binder therapy and a later result may better reflect the patient's response to treatment.

Response: We appreciate commenters' recommendations. We wish to clarify that the Hyperphosphatemia clinical measure uses phosphorus values that are collected pre-dialysis. Regarding the phosphorus laboratory value used to calculate the measure, the 6-month rolling average is calculated using the first reported pre-dialysis phosphorus value from the current month and up to 5 prior consecutive calendar months. If more than one phosphorus value is collected for a patient during a calendar

month, facilities are expected to report the first phosphorus value of the month. The TEP that informed development of the measure specifically recommended using the first value of the month to avoid potential unintended consequences, such as facilities obtaining multiple repeat measurements during the month for purposes of measure calculation.

Because the Hyperphosphatemia clinical measure assesses long-term phosphorus control using a 6-month rolling average, changes in phosphorus following clinical intervention would be reflected in subsequent monthly values included in the rolling average. We also note that while the phosphorus value obtained after the two-day interdialytic interval may be somewhat higher than values obtained later in the week, the Hyperphosphatemia clinical measure was developed to identify patients with long-term, significantly elevated phosphorus levels that would benefit from further intervention.

Comment: A commenter stated that phosphorus and serum albumin distributions differ between hemodialysis and peritoneal dialysis patients and expressed concern that use of a single threshold could classify a disproportionately higher share of PD patients as having hyperphosphatemia. The commenter also stated that the hypoalbuminemia-related exclusion could exclude a disproportionately higher share of PD patients and potentially destabilize measure performance in PD-only facilities. The commenter recommended that CMS consider differences between HD and PD populations. The commenter also requested clarification regarding which phosphorus laboratory value would apply when a patient changes dialysis modality during a month.

Response: We appreciate the commenter's concerns regarding potential differences in phosphorus and serum albumin distributions between HD and PD patients. The adverse cardiovascular and mortality associations of chronically elevated phosphorus have been reported in both hemodialysis and peritoneal dialysis populations. Differences in phosphate clearance associated with dialysis modality may require individualized management, including nutritional counseling, phosphate binder management, or adjustment of the dialysis prescription. Although albumin values tend to be somewhat lower among patients receiving peritoneal dialysis, the TEP did not recommend a different hypoalbuminemia threshold for PD patients given concerns that doing so could result in unintended

⁷⁵ Partnership for Quality Measurement. (April 2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report: Management of Acute Events and Chronic Conditions. Available at <https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events%2C%20Chronic%20Disease%2C%20Surgery%2C%20and%20Behavioral%20Health/material/EM-Fall-2024-Management-Final-Project-Report.pdf>.

⁷⁶ CMS. (July 2026). ESRD QIP CY 2027 Measure Technical Specifications ESRD PPS Proposed Rule. Available at <https://www.cms.gov/files/document/cy-2027-proposed-rule-technical-measure-specifications-072026.pdf>.

consequences, such as excessive nutritional restriction among patients at risk for malnutrition. Therefore, no adjustment in the hypoalbuminemia threshold was recommended for peritoneal dialysis patients. Regarding commenters' request for clarification regarding modality changes, we wish to clarify that the first reported phosphorus value of the month is used for the measure calculation, even if a patient changes modality during the calendar month.

Comment: A few commenters expressed concern about implementing the Hyperphosphatemia measure in conjunction with the incorporation of oral phosphate binders into the ESRD PPS bundled payment, stating that facilities would assume financial responsibility for phosphate binders while also being held accountable under the ESRD QIP for a laboratory outcome affected by patient-level circumstances. A few commenters specifically cited concerns with the timing of the proposal, noting that facilities would be adjusting to the new bundled-payment policy during the measure performance period and that some performance data would reflect a period before phosphate binders were incorporated into the base rate or before facilities had notice that the data could affect QIP payment reductions. Commenters stated these timing issues could affect the establishment of appropriate data and quality benchmarks.

A commenter recommended that CMS monitor whether incorporation of phosphate binders into the ESRD PPS bundle influences prescribing patterns and stated that treatment decisions may reflect individual clinical needs and patient preferences rather than acquisition costs. Another commenter recommended excluding patients who are not eligible for bundled phosphate binders, citing insurance denials, limited insurance-covered medication options, high out-of-pocket costs, and other barriers to obtaining prescribed therapies. A commenter also recommended expanding public reporting on use of oral-only phosphate-lowering therapies to provide additional context for facility performance on the Hyperphosphatemia measure. A commenter stated that CMS policies favoring calcitriol for PTH management may contribute to higher phosphorus levels.

Response: We acknowledge commenters' concerns regarding implementation of the Hyperphosphatemia clinical measure in conjunction with the incorporation of oral phosphate binders into the ESRD PPS bundled payment. The shift in

responsibility for providing phosphate binders to dialysis facilities could improve access to phosphate binders and control of phosphorus levels, and we will monitor trends closely. We also acknowledge commenters' concerns regarding the timing of the measure in relation to the incorporation of phosphate binders into the ESRD PPS and the PY 2029 payment implications. We note that the performance period for the PY 2029 ESRD QIP is CY 2027. We also recognize commenters' concerns regarding the establishment of appropriate performance standards. Consistent with our general methodology, the performance standards, including the benchmark and achievement threshold, for PY 2029 are based on CY 2025 data. This methodology also applies to the Hyperphosphatemia clinical measure. Because the ESRD QIP does not currently calculate this measure, we are using facility-level CY 2025 data to establish the applicable performance standards. The data necessary to calculate this measure have been required elements within EQRS for several years; therefore, we do not anticipate data availability to pose a barrier to implementation. Facilities will continue to report the data needed to calculate the Hyperphosphatemia clinical measure through the existing EQRS submission process. Accordingly, implementation of the measure does not require facilities to establish a new reporting process or submit new data elements. We have published the measure specifications in the CY 2027 Proposed Technical Measure Specifications available at <https://www.cms.gov/medicare/quality/end-stage-renal-disease-esrd-quality-incentive-program/technical-specifications-esrd-qip-measures>, which provides facilities several months to review the specifications before the start of the performance period. Given these considerations, we are finalizing the measure as proposed.

We agree that treatment decisions must continue to be based on the individual patient's clinical needs and circumstances. Regarding the recommendation to exclude patients who experience barriers to obtaining prescribed phosphate-lowering therapies, we note that the shift in responsibility for the provision of phosphate binders may improve access. We also acknowledge commenters' concerns regarding the potential effects of payment, coverage, or other CMS policies on phosphorus management, including access to phosphate-lowering therapies and prescribing patterns. As

part of routine measure maintenance, we conduct ongoing monitoring and evaluation to identify and act upon any unintended consequences. We appreciate the commenter's recommendation to expand public reporting on the use of oral-only phosphate-lowering therapies. However, the Hyperphosphatemia clinical measure is intended to assess phosphorus management at the facility level, rather than the use of a particular therapy at the individual level. Treatment decisions may vary based on individual patients' clinical needs, and we therefore do not believe that additional therapy-specific public reporting is necessary for purposes of this measure.

Comment: A few commenters recommended that CMS consider a non-punitive process measure focused on actions within the facility's control, such as phosphorus review, dietary education, medication reconciliation, assessment of phosphate binder access, and shared decision-making. A few commenters recommended pairing the Hyperphosphatemia measure with a requirement that facilities document individualized responses to persistently elevated phosphorus, including sustained education, medication review, barrier resolution, individualized nutrition education, and evaluation of the dialysis prescription. A commenter recommended that CMS require education and patient engagement as part of the measure, and another recommended encouraging coordination across interdisciplinary teams to optimize measure performance.

A commenter stated that facilities must not use phosphorus levels to blame patients. Another commenter expressed concern that patients may experience being blamed for their phosphorus levels.

Response: We appreciate commenters' recommendations regarding use of a process measure and documentation of specific facility actions in response to elevated phosphorus. We believe the Hyperphosphatemia clinical measure appropriately encourages facilities to evaluate and respond to persistently elevated phosphorus through the interdisciplinary care team, including through dietary counseling, medication management, patient education, and adjustment of the dialysis prescription. The measure is intended to directly assess and provide useful information regarding facility-level patient outcomes and phosphorus control, allowing for flexibility for facilities to determine the appropriate combination of interventions based on individual patient circumstances. We agree that

patient engagement and individualized care are important components of phosphorus management and do not intend for the measure to be used to attribute elevated phosphorus solely to patient behavior. In fact, the TEP placed a significant focus on patient engagement and non-patient blaming during measure development which drove support for the 6-month rolling average.

Comment: A few commenters recommended that CMS work with other Federal agencies, including the FDA, to improve phosphorus labeling on foods before implementing the measure. A few commenters similarly recommended adding phosphorus content to food labels to help patients better manage dietary phosphorus intake.

Response: We appreciate commenters' recommendations regarding phosphorus content information on food labels and recognize that dietary choices can affect phosphorus levels and management. We agree that access to information about phosphorus content in food may assist patients and clinicians in dietary management and note that dietary counseling and phosphorus education is one of several interventions that facilities may use to address phosphorus management.

Comment: A commenter recommended that CMS assess the pediatric implications of the proposal because the Hyperphosphatemia measure would apply only to adult dialysis patients.

Response: We thank the commenter for this recommendation. The Hyperphosphatemia clinical measure proposed for the ESRD QIP is currently specified for adult dialysis patients age 18 years and older. We note that CMS has subsequently developed an all-patient version of the measure, Percentage of Chronic Hyperphosphatemia in Dialysis Patients, that includes pediatric dialysis patients and was endorsed by the CBE in the Fall 2025 cycle.⁷⁷ We will take the commenter's recommendation into consideration as we evaluate future updates to the ESRD QIP measure set.

Comment: A commenter stated that conventional dialysis treatments do not meaningfully affect phosphorus levels compared with longer or more frequent dialysis treatments.

Response: We appreciate the commenter's concern and recognize that phosphorus management may be influenced by dialysis duration and

frequency which remains an individualized, clinical treatment decision. The Hyperphosphatemia clinical measure uses a 6-month rolling average of phosphorus values, which reflects phosphorus control over time rather than an isolated laboratory result. Phosphorus management may involve multiple interventions, including nutritional counseling, phosphorus-binding medications, and adjustment of the dialysis prescription.

After consideration of public comments, we are finalizing our proposal to remove the Hypercalcemia reporting measure and replace it with the Hyperphosphatemia clinical measure beginning with PY 2029.

3. Update to the National Healthcare Safety Network Bloodstream Infection in Hemodialysis Patients Clinical Measure

In the CY 2014 ESRD PPS final rule, we adopted the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients (hereafter referred to as the NHSN BSI) clinical measure into the ESRD QIP to assess BSIs among patients receiving hemodialysis at outpatient hemodialysis centers (78 FR 72204 through 72207). The NHSN BSI clinical measure is based on infection surveillance data reported by facilities to the Centers for Disease Control and Prevention (CDC) through the NHSN Dialysis Event Surveillance system.⁷⁸ The current measure uses a standardized infection ratio (SIR), which compares the number of observed BSIs to the number of predicted BSIs among facilities. The predicted number of BSIs represents the number expected if a facility had a BSI rate equal to the national rate derived from 2014 NHSN surveillance data. The predicted number is estimated using pooled national BSI rates by patient access type, which are multiplied by facility-level patient-months for each access type.⁷⁹

We proposed to update the baseline and risk adjustment used to calculate the SIR for the NHSN BSI clinical measure beginning with PY 2029 to ensure that national benchmarks better reflect current healthcare practices, surveillance protocols, and infection prevention efforts. To estimate the expected number of BSIs, we proposed

to update the national baseline from 2014 data to 2023 data and revise the risk adjustment model to incorporate additional patient and facility-level characteristics, including vascular access type, facility hospital affiliation, and number of dialysis stations, which were identified as significant predictors of BSI risk among the data reported to NHSN.⁸⁰ Additionally, these factors may reflect differences that are not fully within a facility's direct control. The predicted number of BSIs will be estimated using a regression model developed from the 2023 national baseline data. This model uses parameter estimates associated with the identified risk factors to calculate predicted BSIs for each facility-access type combination and then multiplies these estimates by facility patient-months to determine the predicted number of BSIs. Additionally, this updated risk adjustment model will better account for differences in facility characteristics associated with BSI risk. The proposed 2023 national baseline updates will not change the underlying SIR calculation formula but will instead be used to calculate revised denominators for the SIR by estimating the number of predicted BSIs for a given facility based on the 2023 national baseline data.⁸¹

The proposed 2023 national baseline updates will allow facilities to compare their performance to more recent national data, improve the accuracy of benchmark comparisons, and serve as a new national reference point for measuring progress in BSI prevention. Because the updated 2023 national baseline reflects more recent national data, facilities may observe changes in their SIR values compared to their SIR values calculated using the 2014 national baseline. These changes may reflect differences in national baseline rates rather than changes in facility performance. The number of predicted infections may increase or decrease depending on multiple factors, including vascular access type, location, and number of stations in a facility. The SIRs calculated under the 2014 national baseline will not be directly comparable to the SIRs calculated under the 2023 national baseline because each baseline

⁷⁸ Centers for Medicare & Medicaid Services. (April 2026). CMS ESRD Measures Manual for the 2026 Performance Period: Final Version 11.2. Available at <https://www.cms.gov/files/document/esrd-measures-manual-v11-2.pdf>.

⁷⁹ Centers for Disease Control and Prevention. Guide to the NHSN Dialysis Event Surveillance Bloodstream Infection (BSI) Standardized Infection Ratio (SIR) Measure. Available at <https://www.cdc.gov/nhsn/pdfs/dialysis/understanding-the-de-bsi-sir.pdf>.

⁸⁰ Centers for Disease Control and Prevention. (April 2026). NHSN 2023 Dialysis BSI SIR Rebaseline Guide. Available at <https://www.cdc.gov/nhsn/pdfs/rebaseline/New-SIR-Guide.pdf>.

⁸¹ Centers for Disease Control and Prevention. (2023). Charter the Course: 2023 Dialysis BSI Rebaseline. Available at <https://www.cdc.gov/nhsn/pdfs/rebaseline/22-Rebaseline-FAQs-Final-Version.pdf>.

⁷⁷ PQM. Percentage of Chronic Hyperphosphatemia in Dialysis Patients. Available at <https://p4qm.org/measures/5320>.

relies on a distinct national reference dataset and risk adjustment model.

For additional information on the 2023 BSI national baseline process, please refer to the CDC NHSN website at <https://www.cdc.gov/nhsn/bsirebaseline/bsi.html/>.

We welcomed public comment on our proposal to update the NHSN BSI clinical measure beginning with PY 2029.⁸²

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to update the NHSN Bloodstream Infection in Hemodialysis Patients clinical measure to use a more recent 2023 national baseline and revised risk adjustment. Commenters stated that the updates would provide a more current, accurate, and fair assessment of facility performance. A few commenters specifically supported the proposed updates to the revised risk adjustment, noting that incorporating additional facility-level characteristics, including patient access type, hospital affiliation and number of dialysis stations, would help account for factors associated with infection risk that are outside a facility's control. A commenter stated that accounting for these factors could reduce the potential for facilities serving higher-risk patient populations to be unfairly disadvantaged. A few commenters also emphasized that infection prevention remains an important component of high-quality dialysis care and patient safety.

Response: We thank the commenters for their support.

Comment: A few commenters supported the proposed updates, but raised continuing concerns regarding the validity and reliability of NHSN BSI data, including potential under-reporting, facilities' reliance on hospitals to report infections, and whether the measure appropriately attributes infections to dialysis facilities. Commenters recommended that CMS continue evaluating measure validity and ensure that differences in facility performance reflect differences in infection prevention rather than differences in reporting practices. A commenter specifically expressed concern that infections originating from non-dialysis sources may be attributed to facilities and recommended limiting

the measure to vascular access-related bloodstream infections or excluding infections with a documented non-dialysis source.

Response: We appreciate commenters' concerns, and agree that accurate and reliable reporting is important to ensure that the measure reflects differences in infection prevention rather than differences in reporting practices. We note that NHSN data validation activities are intended to support the accuracy and completeness of data used for the ESRD QIP. The proposed update to the national baseline and risk adjustment is part of ongoing measure maintenance intended to provide a more current national comparison and account for additional factors associated with BSI risk that are outside a facility's direct control. We will continue to monitor measure performance and consider commenters' concerns regarding validity and reliability.

Regarding the commenter's concern about attribution, facilities are required to report qualifying positive blood cultures regardless of whether a true infection is suspected or whether the infection is thought to be related to hemodialysis. Facilities separately report the suspected source of the positive blood culture, including whether the source is vascular access, another source, contamination, or uncertain. The NHSN Dialysis Event Surveillance Protocol defines a BSI as any positive blood culture event, while an access-related BSI is separately defined as a positive blood culture for which the suspected source is the vascular access or is uncertain.⁸³

Consistent with these definitions, the ESRD QIP NHSN BSI clinical measure numerator includes new positive blood culture events based on blood cultures drawn as an outpatient or within one calendar day after hospital admission and does not limit the numerator to vascular access-related infections. This enables a standardized approach to collect data for BSIs with a high probability that the infection is associated with hemodialysis. We also note that using a standardized performance measure such as the SIR helps account for possible under- and over-reporting.

Comment: A few commenters requested greater transparency before the revised methodology affects ESRD QIP scoring. Commenters recommended that CMS publish updated technical specifications and the revised risk-

adjustment model, provide facilities an opportunity to preview the changes, and provide sufficient advance notice and baseline performance information to understand how the revised methodology would affect facility performance.

Response: We appreciate commenters' requests for additional transparency regarding the revised methodology. We note that the NHSN has provided email communications and virtual office hours for registered NHSN users regarding updates, trainings, and resources. Additionally, we refer readers to the updated SIR guide, FAQs, and 2023 re-baseline website available at <https://www.cdc.gov/nhsn/pdfs/rebaseline/New-SIR-Guide.pdf>, <https://www.cdc.gov/nhsn/pdfs/rebaseline/22-Rebaseline-FAQs-Final-Version.pdf>, and <https://www.cdc.gov/nhsn/bsirebaseline/bsi.html>. The ESRD QIP CY 2027 Measure Technical Specifications are also available at <https://www.cms.gov/files/document/cy-2027-proposed-rule-technical-measure-specifications-072026.pdf> for more details.

Comment: A commenter supporting the proposed updates also expressed concern that low event counts or reporting errors may disproportionately affect small facilities and recommended that CMS evaluate measure reliability for these facilities and establish a transparent and timely process for correcting NHSN data-entry errors before the data are used for ESRD QIP scoring. If these refinements cannot be implemented for PY 2029, the commenter recommended delaying payment consequences and initially using the revised methodology for feedback and further testing.

Response: We acknowledge the commenter's concerns regarding measure reliability for small facilities and the potential effect of data entry errors on facility performance. We note that facilities treating fewer than 11 in-center HD patients during the performance period are excluded from the NHSN BSI clinical measure, and facilities treating 11 to 25 in-center HD patients receive the small facility adjustment (SFA).

Regarding data accuracy, facilities are responsible for reporting complete and accurate data and are expected to review their reported data and analysis reports regularly, including at least once before the QIP reporting deadline.⁸⁴ If additional information becomes

⁸² In the proposed rule we stated that this proposed change would be a technical update to the measure specifications, rather than a substantive change. However, we were interested in feedback on this technical update and therefore proposed it in the proposed rule to facilitate public comment.

⁸³ CDC National Healthcare Safety Network. (January 2026). NHSN Dialysis Event Surveillance Protocol. Available at <https://www.cdc.gov/nhsn/pdfs/pscmanual/8pscdialysiseventcurrent.pdf>.

⁸⁴ CDC National Healthcare Safety Network. (January 2026). NHSN Dialysis Event Surveillance Protocol. Available at <https://www.cdc.gov/nhsn/pdfs/pscmanual/8pscdialysiseventcurrent.pdf>.

available, facilities are expected to report the information retrospectively, which may include reporting additional dialysis events or correcting existing event data. Facilities must submit relevant measure data by the applicable quarterly reporting deadlines and once a reporting deadline has passed, a frozen data file is created for calculating final ESRD QIP scores. Only data reported before the applicable quarterly reporting deadline are used to calculate ESRD QIP scores.

We do not believe that delaying implementation of the revised methodology is necessary. The proposed update would not change the underlying SIR calculation formula, but would update the national baseline from 2014 to 2023 data and revise the risk-adjustment model to provide a more current national baseline and better account for facility characteristics associated with BSI risk that are outside a facility's direct control.

After consideration of public comments, we are finalizing the updates to the NHSN BSI clinical measure beginning with PY 2029.

4. Removal of Two Measures From the ESRD QIP Measure Set

We have undertaken efforts to review the existing ESRD QIP measure set to ensure continued clinical impact and effectiveness of the measures on facility performance. Based on that analysis and our evaluation of the ESRD QIP measure set, we proposed to remove the Medication Reconciliation reporting measure and the COVID-19 Vaccination Coverage Among Healthcare Personnel reporting measure, beginning with PY 2029.

a. Removal of the Medication Reconciliation Reporting Measure

To ensure continued impact and effectiveness of our measure set on facility performance, we proposed to remove the Medication Reconciliation (MedRec) reporting measure beginning with PY 2029. When we first adopted the MedRec reporting measure in the CY 2019 ESRD PPS final rule (83 FR 57008 through 57010), we stated that inclusion of the measure in the ESRD QIP measure set would align with national goals for patient safety and the reduction of harm caused by care delivery. The MedRec reporting measure assesses whether a facility has appropriately evaluated a patient's medications, an important safety concern for the ESRD patient population because those patients typically see multiple providers and may require numerous medications.

Our proposal to remove the MedRec reporting measure is consistent with

evolving the ESRD QIP to focus on a measure set of high-value, impactful measures that have been developed to drive care improvements for a broader set of ESRD patients. As such, we proposed to remove this measure from the ESRD QIP measure set under measure removal factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program (§ 413.178(c)(5)(i)(H)).

Although recent annual measure analyses have indicated that the MedRec reporting measure may not be fully topped out based on the statistical criteria that we adopted in the CY 2015 ESRD PPS final rule (79 FR 66171 through 66174), available data show consistently high performance and limited variation across facilities. For example, the mean MedRec reporting measure performance in CY 2024 was 97.3 percent and the median MedRec reporting measure score was 10 points, which indicates more than 50 percent of providers achieved perfect scores for the measure. These results suggest that the programmatic benefit of retaining the measure is limited.

One of the goals of the ESRD QIP is to advance the program in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. Our priority is a continued focus on measurable clinical outcomes to incentivize the improvement of dialysis care quality and health outcomes for all patients through measurement and transparency. In light of consistently high performance on the MedRec reporting measure, leaving limited opportunity for further distinctions or improvements in facility performance, and the burden facilities incur in collecting, documenting, and reporting data for the measure, the costs associated with the measure outweigh the benefit of its continued use in the ESRD QIP. Our proposal to remove the MedRec reporting measure from the ESRD QIP is consistent with these priorities.

We welcomed public comment on our proposal to remove the MedRec reporting measure from the ESRD QIP measure set, beginning with PY 2029.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to remove the MedRec reporting measure from the ESRD QIP. A few commenters agreed that performance on the measure is consistently high with limited variation

among facilities, reducing its usefulness for distinguishing differences in facility quality. A few commenters also stated that the administrative burden associated with continued reporting is no longer justified by the measure's value, and supported focusing the ESRD QIP measure set on measures that more meaningfully assess patient outcomes and facility performance.

Response: We thank the commenters for their support.

Comment: A few commenters expressed support for the proposed measure removal, and emphasized that medication reconciliation remains an important component of high-quality dialysis care and patient safety, particularly for patients with complex medication regimens or who receive medications from multiple providers. A few commenters encouraged CMS to continue working with interested parties to identify ways to account for appropriate medication reconciliation for patients with ESRD. A commenter also recommended replacing the measure with other meaningful and actionable reporting measures.

Response: We agree with commenters that medication reconciliation remains important, particularly for patients with ESRD who receive multiple medications from multiple providers with the potential for medication interactions and dialysis treatment impacts. We thank the commenters for their recommendations and will take these into consideration for future measure development and quality reporting activities in the ESRD QIP.

Comment: A commenter did not support removing the MedRec reporting measure, stating that medication reconciliation can reduce medication discrepancies, improve clinical outcomes, reduce hospital readmissions, and improve quality of life and that continued monitoring is particularly important for patients with ESRD because of the complexity of their medication regimens. The commenter recommended that CMS reconsider the proposed removal despite high current facility performance. Another commenter characterized the measure as topped out, but recommended that CMS continue monitoring whether its removal affects facility medication reconciliation practices and ensure that patients continue to have access to medication safety supports.

Response: We agree with commenters regarding the continued importance of medication reconciliation for patients with ESRD, and note that the removal of the measure is consistent with our goal of evolving the ESRD QIP measure set toward high-value, impactful measures

that more meaningfully drive improvements in care for patients with ESRD. Given the consistently high performance across facilities, the MedRec reporting measure leaves limited opportunity for further distinctions or improvements in facility performance, such that the costs associated with the measure outweigh the benefit of its continued use in the ESRD QIP. Additionally, as part of our usual monitoring and evaluation activities, we monitor for any unintended consequences associated with changes to the ESRD QIP measure set.

After consideration of public comments, we are finalizing our proposal to remove the MedRec reporting measure beginning with PY 2029.

b. Removal of the COVID-19 Vaccination Coverage Among Healthcare Personnel Reporting Measure

We refer readers to the CY 2023 ESRD PPS final rule where we adopted the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure (hereafter referred to as COVID-19 HCP Vaccination measure) into the ESRD QIP (87 FR 67244 through 67248) and the CY 2024 ESRD PPS final rule where we modified the COVID-19 HCP Vaccination measure to account for updated COVID-19 vaccine guidance (88 FR 76446 through 76451). The COVID-19 HCP Vaccination measure requires dialysis facilities to report the COVID-19 vaccination status of HCP through the CDC NHSN. Facilities must collect current vaccination status for all employees, licensed independent practitioners, adult trainees, students, and volunteers, as well as certain contract personnel one week out of each month and report these data on a quarterly basis (88 FR 76448 through 76449).

We proposed to remove the COVID-19 HCP Vaccination measure beginning with the PY 2029 ESRD QIP under removal factor 3, a measure no longer aligns with current clinical guidelines or practice (§ 413.178(c)(5)(i)(C)). When we originally adopted this measure, the United States was in the midst of a Public Health Emergency (PHE) with millions of COVID-19 cases and over 965,000 COVID-19 deaths (87 FR 67244). In April 2023, the last full month of the PHE, the weekly number of deaths due to COVID-19 averaged around 1,300.⁸⁵ While preventing the

spread of COVID-19 remains a public health goal, the PHE ended on May 11, 2023,⁸⁶ and the COVID-19 death rate has continued to decrease. The weekly number of deaths attributed to COVID-19 during a recent 6-month period (weeks ending 8/2/25 through 1/31/26) ranged from 188 to 498.⁸⁷

With the end of the PHE, the continued costs and burden to providers of reporting on this measure outweighed the benefit of continued information collection on COVID-19 HCP Vaccination in several settings. We likewise removed this measure from several program measure sets: the Hospital Inpatient Quality Reporting Program (90 FR 37010 through 37012), the Inpatient Psychiatric Facility Quality Reporting Program (90 FR 37657 through 37658), the Inpatient Rehabilitation Facility Quality Reporting Program (90 FR 37701 through 37702), the Ambulatory Surgical Center Quality Reporting Program (90 FR 53917 through 53919), and the Hospital Outpatient Quality Reporting Program (90 FR 53917 through 53919). We did not initially remove this measure from other settings, including ESRD facilities, due to the continuing benefit to higher risk patient populations.

Since the end of the PHE, the CDC's clinical recommendations for COVID-19 vaccination have changed. In December 2020, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should receive a complete vaccination course.⁸⁸ At the time the COVID-19 HCP Vaccination reporting measure was adopted, vaccination was a critical part of the nation's strategy to effectively counter the spread of COVID-19.⁸⁹ There were well-defined parameters for receiving the COVID-19 vaccination intended to capture routine, catch-up, and risk-based immunization recommendations.

Available at <https://www.cdc.gov/covid/php/surveillance/index.html>.

⁸⁶ U.S. Department of Health and Human Services. (2023). COVID-19 Public Health Emergency. Available at <https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html>.

⁸⁷ Centers for Disease Control and Prevention. Provisional COVID-19 Mortality Surveillance. Available at <https://www.cdc.gov/nchs/nvss/vsrr/covid19/>.

⁸⁸ Dooling, K, McClung, M, et al. "The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID-19 Vaccine—United States, 2020." *Morb. Mortal Wkly Rep.* 2020; 69(49): 1857–1859.

⁸⁹ Centers for Disease Control and Prevention. (2020). COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed March 6, 2026 at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

However, these parameters no longer apply, due to evolving circumstances. The latest CDC COVID-19 vaccination recommendations for the 2025 through 2026 season are now based on shared clinical decision-making.⁹⁰ For shared clinical decision-making, there is not a default decision to vaccinate for a defined population.⁹¹ Given that there is no single default recommendation to vaccinate a defined population, both receipt and non-receipt of vaccination may reflect the guidance of shared clinical decision-making. This differs from the guidance in place when this measure was finalized.

On this basis, we proposed removing the measure from the ESRD QIP measure set under removal factor 3, a measure does not align with current clinical guidelines or practice.

We stated that, if finalized, facilities would not be required to report COVID-19 HCP Vaccination reporting measure data beginning with the performance period for PY 2029. Any COVID-19 HCP vaccination data received by CMS beginning with the performance period for PY 2029 would not be used for ESRD QIP public reporting.

We welcomed public comment on our proposal to remove the COVID-19 Vaccination Coverage Among Healthcare Personnel measure from the ESRD QIP beginning with PY 2029.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to remove the COVID-19 HCP Vaccination measure from the ESRD QIP. A few commenters stated that the measure no longer aligns with current clinical recommendations and practice. A few commenters also cited consistently high performance, limited value in distinguishing differences in facility quality, reporting burden, and alignment with removal of the measure from other Medicare quality programs. Commenters supported focusing the ESRD QIP measure set on measures that more meaningfully assess patient outcomes and facility performance. A commenter stated that public reporting of COVID-19 healthcare personnel vaccination rates is not an appropriate tool to assess dialysis facility quality.

⁹⁰ Centers for Disease Control and Prevention. (2025). 2025–2026 COVID-19 Vaccination Guidance. Available at <https://www.cdc.gov/covid/hcp/vaccine-considerations/routine-guidance.html>.

⁹¹ Centers for Disease Control and Prevention. (January 2025). ACIP Shared Clinical Decision-Making Recommendations. Available at <https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html>.

⁸⁵ Centers for Disease Control and Prevention. (September 2025). Surveillance and Data Analytics.

Response: We thank the commenters for their support.

Comment: A few commenters supporting removal emphasized that vaccination and infection prevention remain important for patients with ESRD because of their heightened vulnerability to infectious disease. A commenter stated that healthcare personnel may continue to follow current immunization recommendations. A commenter recommended that CMS promptly remove COVID–19 vaccination performance information from Dialysis Facility Compare following removal of the measure to avoid confusion regarding the continued relevance of the information. Another commenter recommended replacing the measure with other meaningful and actionable reporting measures.

Response: We appreciate commenters' feedback on the importance of vaccination and infection prevention for patients with ESRD. We agree that preventing the spread of infectious disease and protecting vulnerable patients remain important goals. We note that removal of the measure is not a reflection of the effectiveness or importance of COVID–19 vaccination.

We also appreciate commenters' recommendations regarding public reporting and future quality measures. As discussed in the proposed rule, COVID–19 HCP vaccination data received beginning with the PY 2029 performance period would no longer be used for ESRD QIP public reporting (91 FR 38842). We will take recommendations regarding future meaningful and actionable measures into consideration as we continue to evaluate the ESRD QIP measure set.

Comment: A commenter did not support removing the COVID–19 HCP Vaccination measure, expressing concern that patients with ESRD remain particularly vulnerable to infectious disease and face repeated exposure in shared dialysis settings. The commenter expressed concern that removing the measure could signal that healthcare personnel vaccination is no longer a priority, potentially reducing vaccination coverage among staff. The commenter recommended that CMS instead update the measure to reflect current vaccination recommendations, align reporting requirements across healthcare settings to reduce burden, and use the measure for monitoring and quality improvement, including identifying facilities with low vaccination rates to target technical assistance.

Another commenter recommended that CMS monitor whether removal of the measure affects facility practices and ensure that patients continue to have access to appropriate vaccination and infection prevention supports.

Response: We acknowledge commenters' concerns regarding the continued importance of vaccination and infection prevention for patients with ESRD and agree that protecting vulnerable patients from COVID–19 remains an important goal. However, removal of the COVID–19 HCP Vaccination measure is based on changes in current clinical guidance and practice, not as a reflection of the effectiveness or importance of COVID–19 vaccination. As discussed in the proposed rule, current COVID–19 vaccination recommendations have shifted toward shared clinical decision-making, for which there is no single default recommendation to vaccinate a defined population (91 FR 38842). Both receipt and non-receipt of vaccination may therefore be consistent with current guidance. Therefore, we continue to believe that removal of the measure is appropriate and consistent with our goal of focusing the ESRD QIP measure set on high-value, impactful measures.

Regarding the commenter's recommendations to update the measure, align reporting requirements across healthcare settings, and use vaccination data for monitoring and quality improvement, we note that we will continue to monitor for unintended consequences associated with changes to the ESRD QIP measure set.

After consideration of public comments, we are finalizing our proposal to remove the COVID–19 HCP Vaccination measure beginning with PY 2029.

5. Updates To Measure Domains and to the Domain and Measure Weights Used To Calculate the Total Performance Score

In the CY 2019 ESRD PPS final rule (83 FR 56991 through 56992), we finalized revisions to the ESRD QIP measure domains. Specifically, in that rule we eliminated the Reporting Domain and reorganized the Clinical Domain into three distinct domains: Patient & Family Engagement Domain, Care Coordination Domain, and Clinical Care Domain. We finalized our proposal to eliminate the Reporting Measure Domain from the ESRD QIP measure set, beginning in PY 2021, because there would no longer be any measures in that domain.

In the CY 2023 ESRD PPS final rule, we finalized our proposal to create a

new Reporting Measure Domain (87 FR 67251 through 67254), which would include the six individual reporting measures in the ESRD QIP measure set at that time. In the CY 2023 ESRD PPS final rule, we stated that a separate Reporting Measure Domain was necessary to increase incentives for improving performance by increasing the weights on measures where there is the most room for improvement, especially on patient clinical outcomes.

Currently, ESRD QIP measures are weighted and distributed across five measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, Safety, and Reporting. As discussed in section IV.B.2. of the proposed rule, we proposed to replace the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure beginning with the PY 2029 ESRD QIP. In sections IV.B.4.a. and IV.B.4.b. of the proposed rule, we also proposed to remove the COVID–19 Vaccination Coverage among HCP reporting measure and the MedRec reporting measure from the ESRD QIP measure set beginning with the PY 2029 ESRD QIP (91 FR 38841 through 38842). We stated that, if these proposals are finalized as proposed, the ESRD QIP measure set would not include any measures under the Reporting Measure Domain. Therefore, we proposed to remove the Reporting Measure Domain and to update the domain weights and individual measure weights in the Care Coordination Domain and the Clinical Care Domain accordingly to reflect the proposed updates to the ESRD QIP measure set. As the ESRD QIP measure set has evolved over the years, we believe that removing the Reporting Measure Domain and updating the Care Coordination Domain and the Clinical Care Domain, both of which contain multiple measures, would help to address concerns regarding the impact of individual measure performance on a facility's Total Performance Score (TPS), while also further incentivizing improvement on clinical measures. Although we proposed to remove the Reporting Measure Domain beginning with PY 2029 because the ESRD QIP measure set would no longer include any reporting measures, we note that in future rulemaking, reporting measures may be proposed for inclusion in the ESRD QIP measure set under the remaining measure domains. For a comparison of current and finalized measure domains and weighting, see Tables 24 and 25.

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TABLE 24: Current ESRD QIP Measure Domains and Weights

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	15.00
ICH CAHPS measure	15.00
Care Coordination Measure Domain	30.00
SHR clinical measure	7.50
SRR clinical measure	7.50
PPPW measure	7.50
Clinical Depression Screening and Follow-Up measure	7.50
Clinical Care Measure Domain	35.00
Kt/V Dialysis Adequacy Measure Topic	11.00
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	10.00
NHSN BSI clinical measure*	10.00
Reporting Measure Domain	10.00
Hypercalcemia reporting measure**	3.33
MedRec reporting measure**	3.33
COVID-19 HCP Vaccination reporting measure**	3.33

*We are finalizing our proposal to update the NHSN BSI clinical measure beginning with PY 2029, as discussed in section IV.B.3. of this final rule.

**We are finalizing our proposal to remove the Hypercalcemia reporting measure, the MedRec reporting measure, and the COVID-19 Vaccination Coverage Among HCP reporting measure beginning with PY 2029, as discussed in sections IV.B.2.a., IV.B.4.a., and IV.B.4.b. of this final rule.

TABLE 25: Finalized ESRD QIP Measure Domains and Weights beginning with PY 2029

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	15.00
ICH CAHPS measure	15.00
Care Coordination Measure Domain	35.00
SHR clinical measure	9.00
SRR clinical measure	9.00
PPPW measure	10.00
Clinical Depression Screening and Follow-Up measure	7.00
Clinical Care Measure Domain	40.00
Hyperphosphatemia clinical measure*	7.00
Kt/V Dialysis Adequacy Measure Topic	11.00
Long-Term Catheter Rate clinical measure	11.00
STrR clinical measure	11.00
Safety Measure Domain	10.00
NHSN BSI clinical measure**	10.00

*We are finalizing our proposal to adopt the Hyperphosphatemia clinical measure, beginning with PY 2029, as discussed in section IV.B.2. of this final rule.

**We are finalizing our proposal to update the NHSN BSI clinical measure beginning with PY 2029, as discussed in section IV.B.3. of this final rule.

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We welcomed public comment on our proposal to remove the Reporting Measure Domain and to update the existing domains and measure weights used to calculate the TPS, beginning with PY 2029.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported removing the Reporting Measure Domain if no reporting

measures remain in the ESRD QIP. A commenter specifically supported the proposed changes to the remaining domains and measure weights.

Response: We thank the commenters for their support.

Comment: A few commenters supporting the updates emphasized that eliminating the Reporting Measure Domain should not preclude future use of reporting measures. Commenters stated that reporting measures may remain useful for data collection, feasibility and reliability testing, baseline development, and evaluation of emerging quality concepts. A commenter also recommended monitoring whether redistribution of the domain weight creates unintended consequences for facilities serving medically complex, high-need, or socially at-risk populations.

Response: We appreciate commenters' recommendations regarding the future use of reporting measures. As discussed in the proposed rule, although we would remove the Reporting Measure Domain beginning with PY 2029 because no reporting measures would remain in the measure set, reporting measures may be proposed for inclusion in the ESRD QIP in future rulemaking under the remaining measure domains (91 FR 38842). We also note that the proposed changes to the Care Coordination and Clinical Care Domain weights are intended to address concerns regarding the impact of individual measure performance on a facility's Total Performance Score while further incentivizing improvement on clinical measures. As part of our usual monitoring and evaluation activities, we monitor for unintended consequences associated with the ESRD QIP measure set.

Comment: A commenter opposed removing the Reporting Measure Domain and recommended replacing the measures proposed for removal with meaningful and actionable reporting measures rather than eliminating the domain. The commenter recommended that future reporting measures address areas such as patient education and treatment support.

Response: We thank the commenter for their recommendations. As discussed in the proposed rule, although we would remove the Reporting Measure Domain beginning with PY 2029 because no reporting measures would remain in the measure set, reporting measures may be proposed for inclusion in the ESRD QIP in future rulemaking under the remaining measure domains (91 FR 38842). Regarding the recommendation to address patient education and treatment support, we will take these recommendations into consideration as we continue to evaluate the ESRD QIP measure set.

Comment: A few commenters recommended assigning the full 10 percentage points to the Clinical Care Domain rather than redistributing the Reporting Measure Domain weight as proposed.

Response: Regarding redistribution of the Reporting Measure Domain weight, we intend to redistribute 5 percentage points to the Care Coordination Domain and 5 percentage points to the Clinical Care Domain to address concerns regarding the impact of individual measure performance on a facility's Total Performance Score while further incentivizing improvement on clinical measures. We determined that the proposed weights better reflect the priorities of the ESRD QIP by maintaining a balanced allocation across domains while placing greater emphasis on measures focused on meaningful clinical outcomes and other priority areas of care. For example, within the Care Coordination Domain, the proposed weights place greater emphasis on the PPPW measure to support our priority of increasing transplantation and on the SHR and SRR clinical measures relative to the Clinical Depression Screening and Follow-Up measure to emphasize patient outcomes. We believe the proposed redistribution appropriately balances the impact of individual measures on a facility's TPS while advancing the ESRD QIP's priorities for meaningful clinical measures.

Comment: A few commenters also requested greater transparency regarding the reweighting methodology, including publication of the methodology, examples of effects on facility-level scores, and modeled impacts for different facility types.

Response: The weighting methodology, including the current and updated domain and individual measure weights, is described in Tables 24 and 25 of this final rule. We note that we publish the ESRD QIP scoring methodology in this final rule and also include examples in the ESRD Measures Manual. We also make facility-level ESRD QIP data available to support transparency and allow interested parties to reproduce program calculations. The domain and measure weights reflect CMS priorities and the clinical importance of the measures, including the extent to which measures are associated with meaningful clinical outcomes.

Comment: A commenter recommended retaining the Reporting Measure Domain if the Hyperphosphatemia measure is initially implemented as a reporting measure

and otherwise supported removing the domain if no reporting measures remain. The commenter also requested CMS to ensure that removal of the domain would not preclude use of reporting measures in future years.

Response: We note that the Hyperphosphatemia measure would be implemented as a clinical measure rather than a reporting measure and, therefore, continue to believe it is appropriate to remove the Reporting Measure Domain as no measures would remain in the domain for the proposed PY 2029 measure set. As discussed in the proposed rule, removal of the Reporting Measure Domain would not preclude reporting measures from being proposed for inclusion in the ESRD QIP in future rulemaking under the remaining measure domains (91 FR 38842).

After consideration of public comments, we are finalizing our proposal to update the measure domains and the domain and measure weights used to calculate the Total Performance Score beginning with PY 2029.

6. Performance Standards for the PY 2029 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by sections 1881(h)(4)(B) and (C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (77 FR 67500 through 67502), as well as § 413.178(a)(1), (3), (7), and (12), for further information related to performance standards.

We continue to believe that our current policy of 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. Under this policy, we are finalizing CY 2027 as the performance period and CY 2025 as the baseline period for the PY 2029 ESRD QIP. In the proposed rule, we estimated the performance standards for the PY 2029 clinical measures in Table 22 using data from CY 2024, which were the most recent data available (91 FR 38844). In this final rule, we are updating these performance standards for all measures, using the most recently available data from CY 2025, in Table 26.

TABLE 26: Updated Performance Standards for the ESRD QIP Clinical Measures for PY 2029

Measure	Achievement Threshold (15 th Percentile of National Performance)	Median (50 th Percentile of National Performance)	Benchmark (90 th Percentile of National Performance)
VAT Long-Term Catheter Rate	18.35%*	11.04%*	4.69%*
Kt/V Dialysis Adequacy Measure Topic			
Adult Hemodialysis (HD) Kt/V	96.08%*	98.52%*	99.73%*
Pediatric Hemodialysis (HD) Kt/V	81.25%*	98.29%*	100.00%*
Adult Peritoneal Dialysis (PD) Kt/V	87.37%*	95.20%*	99.04%*
Pediatric Peritoneal Dialysis (PD) Kt/V	66.49%*	85.65%	98.91%*
Hyperphosphatemia	34.30%	24.42%	12.94%
Standardized Readmission Ratio ^a	34.27*	26.50*	16.18*
NHSN BSI	2.064	0.688	0.000
Standardized Hospitalization Ratio ^b	166.60*	129.14*	87.98*
Standardized Transfusion Ratio ^b	48.29*	26.19*	8.07*
Percentage of Prevalent Patients Waitlisted for Kidney Transplant	8.12%*	16.73%*	33.90%*
Clinical Depression Screening and Follow-up	93.26%	98.31%	100.00%*
ICH CAHPS: Quality of Dialysis Center Care and Operations	55.82%*	64.90%*	76.18%*
ICH CAHPS: Providing Information to Patients	71.87%	78.53%	85.77%
ICH CAHPS: Overall Rating of Dialysis Center Staff	56.33%	68.77%	82.70%
ICH CAHPS: Overall Rating of the Dialysis Facility	57.42%	70.70%	84.16%

*Values are the same final performance standards for those measures for PY 2028. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2029 because they are higher standards than the PY 2029 numerical values for those measures.

^aRate calculated as a percentage of hospital discharges

^bRate per 100 patient-years

Data sources: VAT measure: 2025 EQRS; SRR, SHR, STTrR: 2025 Medicare claims; Kt/V: 2025 EQRS and 2025 Medicare claims; Hyperphosphatemia measure: 2025 EQRS; NHSN: 2025 CDC; ICH CAHPS: CMS 2025; PPPW: 2025 EQRS and 2025 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2025 EQRS.

7. Eligibility Requirements for the PY 2029 ESRD QIP

In the proposed rule, we proposed to update eligibility requirements as part

of our proposal to replace the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure beginning with PY 2029 (91 FR

38845). Our finalized eligibility requirements are described in Table 27.

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TABLE 27: Finalized Eligibility Requirements for Scoring on ESRD QIP Measures Beginning with PY 2029

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Dialysis Adequacy Measure Topic: Adult HD Kt/V (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Pediatric HD Kt/V (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Adult PD Kt/V (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Pediatric PD Kt/V (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hyperphosphatemia (Clinical)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	11-25 qualifying patients
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Clinical Depression Screening and Follow-Up (Clinical)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	11-25 qualifying patients
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients

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8. Payment Reduction Scale for the PY 2029 ESRD QIP

Under our current policy, a facility does not receive a payment reduction for a payment year in connection with

its performance under the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined

the mTPS in our regulations at § 413.178(a)(8).

Under § 413.177(a), we implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that a facility's TPS falls below the mTPS, up to a maximum reduction of 2 percent. In the proposed

rule, for PY 2029, we estimated using available data that a facility must meet or exceed an mTPS of 54 to avoid a payment reduction (91 FR 38846). In the proposed rule, we estimated the mTPS based on data from CY 2024 instead of the PY 2029 baseline period (CY 2025) because CY 2025 data were not yet

available. In this final rule, we are updating the mTPS and associated payment reduction ranges for PY 2029 using the most recently available data, CY 2025. The estimated payment reduction scale for PY 2029 based on the most recently available data is described in Table 28.

TABLE 28: Updated Payment Reduction Scale for PY 2029 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-54	0.0%
53-44	0.5%
43-34	1.0%
33-24	1.5%
23-0	2.0%

C. Request for Information on the Inclusion of the Dialysis Facility Discussion of Patient Life Goals Patient-Reported Outcome Performance Measure in the ESRD QIP

1. Background

We sought feedback related to the potential inclusion of the Dialysis Facility Discussion of Patient Life Goals (D-PaLS) Patient-reported Outcome Performance Measure (PRO-PM) in the ESRD QIP. For people on chronic dialysis, regular discussion of patient life goals with their dialysis facility care team can lead to better understanding by facilities and providers of those life goals, and how patients' goals can be considered as part of initial and ongoing treatment planning and decision-making.^{92 93} Evidence suggests that discussions to identify and incorporate patient life goals into modality and treatment decisions do not consistently

occur in practice among ESRD patients.^{94 95 96} Individuals with ESRD report that they often do not receive adequate information about treatment options or do not regard themselves as the primary decision-maker in their care.⁹⁷ This suggests discussion of life goals as part of treatment planning and

decisions is desired by patients and is not always happening.

Discussions of patient life goals are consistent with the patient plan of care requirements under § 494.90 and the patient rights provisions under § 494.70(a) and with clinical practice guidelines that emphasize integrating patient life goals into kidney replacement therapy decision-making and care planning as established under the ESRD Conditions for Coverage finalized in 2008 (73 FR 20370).⁹⁸ The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative guidelines underscore a longitudinal, patient-centered approach to kidney replacement therapy planning that incorporates a patient's medical circumstances, life goals, individual preferences, and social support across the continuum of CKD and end-stage kidney disease (ESKD) care.⁹⁹

⁹² Dahlerus, C., Carlozzi, N. E., Price, K., Miner, J. A., Hirth, R. A., Gremel, G., Han, P., Zhang, W., Sardone, J., Roach, J., Agbenyikey, W., Clark, S. L., Horton, G., Yaldo, A., & Messana, J. M. (2025). Preliminary Testing of the Discussion of Patient Life Goals Patient-Reported Outcome Measure for Dialysis Facilities. *Kidney medicine*, 7(4), 100972. <https://doi.org/10.1016/j.xkme.2025.100972>.

⁹³ Dahlerus, C., Carlozzi, N. E., Hirth, R. A., Price, K., Sardone, J., Miner, J. A., Segal, J. H., Andress, J., Roach, J., Balovlenkov, E., Clark, S., & Messana, J. M. (2025). Conceptual Development Informing the Kidney Failure Patient Life Goals Survey. *Kidney medicine*, 8(2), 101203. <https://doi.org/10.1016/j.xkme.2025.101203>.

⁹⁴ Dahlerus, C., Carlozzi, N. E., Price, K., Miner, J. A., Hirth, R. A., Gremel, G., Han, P., Zhang, W., Sardone, J., Roach, J., Agbenyikey, W., Clark, S. L., Horton, G., Yaldo, A., & Messana, J. M. (2025). Preliminary Testing of the Discussion of Patient Life Goals Patient-Reported Outcome Measure for Dialysis Facilities. *Kidney medicine*, 7(4), 100972. <https://doi.org/10.1016/j.xkme.2025.100972>.

⁹⁵ Dahlerus, C., Carlozzi, N. E., Hirth, R. A., Price, K., Sardone, J., Miner, J. A., Segal, J. H., Andress, J., Roach, J., Balovlenkov, E., Clark, S., & Messana, J. M. (2025). Conceptual Development Informing the Kidney Failure Patient Life Goals Survey. *Kidney medicine*, 8(2), 101203. <https://doi.org/10.1016/j.xkme.2025.101203>.

⁹⁶ Ladin, K., Lin, N., Hahn, E., Zhang, G., Koch-Weser, S., & Weiner, D. E. (2017). Engagement in decision-making and patient satisfaction: a qualitative study of older patients' perceptions of dialysis initiation and modality decisions. *Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association—European Renal Association*, 32(8), 1394–1401. Available at <https://doi.org/10.1093/ndt/gfw307>.

⁹⁷ Ladin, K., Lin, N., Hahn, E., Zhang, G., Koch-Weser, S., & Weiner, D. E. (2017). Engagement in decision-making and patient satisfaction: a qualitative study of older patients' perceptions of dialysis initiation and modality decisions. *Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association—European Renal Association*, 32(8), 1394–1401. Available at <https://doi.org/10.1093/ndt/gfw307>.

⁹⁸ Chan, C. T., Blankestijn, P. J., Dember, L. M., Gallieni, M., Harris, D. C. H., Lok, C. E., Mehrotra, R., Stevens, P. E., Wang, A. Y., Cheung, M., Wheeler, D. C., Winkelmayer, W. C., Pollock, C. A., & Conference Participants (2019). Dialysis initiation, modality choice, access, and prescription: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. *Kidney international*, 96(1), 37–47. Available at <https://doi.org/10.1016/j.kint.2019.01.017>.

⁹⁹ Lok, C. E., Huber, T. S., Lee, T., Shenoy, S., Yevzlin, A. S., Abreo, K., Allon, M., Asif, A., Astor, B. C., Glickman, M. H., Graham, J., Moist, L. M., Rajan, D. K., Roberts, C., Vachharajani, T. J., Valentini, R. P., & National Kidney Foundation

Incorporating patient life goals into care planning also aligns with current CMS and HHS priorities to empower beneficiaries, strengthen shared decision-making, and improve health outcomes through person-centered approaches to care delivery.^{100 101}

2. Measure Overview

The D-PaLS PRO-PM assesses patients' satisfaction with whether and how their care team discusses life goals as part of treatment planning.¹⁰² The D-PaLS PRO-PM self-report survey captures patient-reported experiences and allows for facility-level comparison of facility engagement in patient life goals discussions.¹⁰³ The D-PaLS PRO-PM survey contains a total of eight items and takes approximately 2 minutes to complete.¹⁰⁴ The survey includes example life goals that patients may consider when reflecting on their own life goals; however, the list of goals is not intended to be exhaustive and is included only as examples. Selecting or completing these goals is optional as they are not scored or evaluated. There are six Likert-type items¹⁰⁵, including: (1) whether at least one member of the dialysis care team knows about the patient's life goals; (2) whether the patient believes it is important that a

member of the care team discuss life goals with them; (3) whether the patient's treatment plan is consistent with their life goals; (4) whether a member of the care team talks with the patient about their life goals; (5) whether the patient is comfortable discussing changes in life goals with a member of the care team; and (6) whether a member of the care team helps the patient meet their life goals. These six Likert-type items are used to generate a patient-level "quality of facility care team discussion" quality score as described later in this rule. These six items form the quality score, while the final survey item is not scored and is included to provide additional contextual information regarding dialysis care team members with whom the patient reports discussing their life goals. For further information regarding the full survey instrument, including the specific Likert-type items, please refer to <https://p4qm.org/measures/3742>.

The population for this measure is patients on chronic dialysis in the U.S. who are at least 18 years old at the time of the survey and includes all payer types. The survey tool is available to dialysis patients in both U.S. English and in Spanish. Scoring for the D-PaLS PRO-PM is based on responses to the six individual Likert-type items that are used to generate a patient-level t-score. Response options for each item are scored from 1 to 5, with higher scores indicating greater patient agreement that the dialysis care team engages in discussions about the patient's life goals and treatment planning. For each patient at a given facility, the t-score represents a patient's perceptions of their satisfaction with their dialysis care team discussions about life goals, with t-scores greater than 40 indicating average or above average satisfaction with those discussions. The overall D-PaLS PRO-PM is calculated as the percentage of patients at a facility with a t-score greater than 40 (the facility level quality score).

The D-PaLS PRO-PM is not designed to evaluate individual life goals or whether patients achieve those goals; rather, the measure reflects the percentage of patients at a facility who report at least average satisfaction with discussions about life goals with their dialysis care team and the incorporation of those discussions into treatment planning. The intent of the D-PaLS PRO-PM is for the survey tool to be offered to patients for self-administration, with de-identified results and feedback provided to dialysis facilities. For additional details on the measure specifications, please

refer to <https://p4qm.org/prmr-measures/muc2025-011>.

3. Solicitation for Public Comment

We sought public comment on the potential inclusion of the D-PaLS PRO-PM in the ESRD QIP and on the following considerations:

- Would inclusion of the D-PaLS PRO-PM provide valuable information on the extent to which facilities are asking about life goals and incorporating those discussions into treatment planning?
- What concrete approaches could dialysis facilities use to operationalize life-goal discussions on a regular basis into care planning, addressing barriers to care, modality selection including kidney transplantation, vascular access decisions, and other ESRD treatment decisions?
- To what extent can survey burden be minimized for patients while maintaining meaningful patient-reported outcomes around patient life goals discussions?
- What factors may affect patient participation or survey completion rates, and what strategies could CMS consider to encourage meaningful participation and high response rates across patients?

• What strategies could mitigate potential barriers to regular discussions of patient life goals (such as resource constraints, workflow integration, patient engagement and education) and support meaningful integration of these discussions into treatment planning?

• In addition to electronic delivery via email/text directly to patients, are there additional methods of delivery CMS should consider, for example for patients who may not access a computer or cell phone?

• What strategies could CMS use to capture information on patients who may be cognitively impaired or need a proxy to complete the survey?

We received public comments on this RFI. The following is a summary of the comments we received and our responses.

Comment: Many commenters provided feedback in response to our request for public comment on the potential inclusion of the D-PaLS PRO-PM in the ESRD QIP.

Many commenters supported the potential inclusion or continued development of the D-PaLS PRO-PM, emphasizing the importance of incorporating patients' life goals, preferences, and priorities into dialysis care and treatment planning. Commenters stated that the measure should assess meaningful engagement and whether patient priorities are

(2020). KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update. American journal of kidney diseases: the official journal of the National Kidney Foundation, 75(4 Suppl 2), S1–S164. Available at <https://doi.org/10.1053/j.ajkd.2019.12.001>.

¹⁰⁰ Centers for Medicare & Medicaid Services. (2025). Strategic Direction: CMS Innovation Center 2025 Strategy to Make America Healthy Again. Available at <https://www.cms.gov/priorities/innovation/about/strategic-direction>.

¹⁰¹ U.S. Department of Health and Human Services. (2025). HHS Priorities. Available at <https://www.hhs.gov/about/priorities/index.html>.

¹⁰² The D-PaLS PRO-PM was included in the 2023 and 2024 Measures Under Consideration (MUC) lists (MUC2023–138 and MUC2025–011, respectively) for inclusion in the ESRD QIP. The 2023 MUC list is available at <https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx>. The 2025 MUC list is available at <https://mmshub.cms.gov/sites/default/files/2025-MUC-List.xlsx>.

¹⁰³ For additional information on the ESRD QIP measure domains and domain weights please refer to section IV.B.5. of this final rule.

¹⁰⁴ Dahlerus, C., Carlozzi, N. E., Price, K., Miner, J. A., Hirth, R. A., Gremel, G., Han, P., Zhang, W., Sardone, J., Roach, J., Agbeniyeky, W., Clark, S. L., Horton, G., Yaldo, A., & Messana, J. M. (2025). Preliminary Testing of the Discussion of Patient Life Goals Patient-Reported Outcome Measure for Dialysis Facilities. *Kidney medicine*, 7(4), 100972. <https://doi.org/10.1016/j.xkme.2025.100972>.

¹⁰⁵ "Likert-type items" refer to individual survey questions with ordered categorical response options that capture gradations of opinion or experience, such as "strongly disagree," "disagree," "neither agree nor disagree," "agree," and "strongly agree." For further information regarding the full survey instrument, including the specific Likert-type items, please refer to <https://p4qm.org/measures/3742>.

incorporated into care rather than whether a discussion was simply documented. A few commenters emphasized that life-goal discussions should consider patients as whole individuals and may include priorities such as work, family responsibilities, independence, travel, quality of life, treatment burden, and other goals that matter to the patient.

Commenters supporting the measure also recommended that implementation support continuous shared decision-making and meaningful interdisciplinary follow-up on patient-identified goals and barriers. Several commenters recommended minimizing survey burden, providing accessible and non-digital administration options, accommodating language and accessibility needs, involving family members or caregivers when requested, and continuing to involve patients and caregivers in measure testing. A few commenters recommended additional testing and evaluation of feasibility, validity, representative response rates, meaningful use of results, and response disparities before linking payment to the measure.

Many commenters raised concerns about including the D-PaLS PRO-PM in the ESRD QIP at this time. Commenters cited insufficient evidence regarding facility-level validity and reliability, patient and administrative burden, patient readiness, factors outside facilities' control, and uncertainty about whether measure results would be actionable or improve care. Several commenters recommended additional testing and evidence that the measure leads to meaningful improvements in care before considering it for the ESRD QIP. A commenter also stated that the underlying measure previously failed the required evidence criterion during consensus-based review, and that the current version has not been endorsed by a CBE.

A few commenters opposing the measure also noted that patient goals and preferences are already addressed through individualized care planning under the ESRD Conditions for Coverage and questioned the added value of a separate payment-linked measure. A commenter recommended focusing measurement on actionable factors within facility control, such as treatment modality, frequency, scheduling, and time on treatment. A few commenters expressed concern about asking patients to identify goals or barriers that facilities may lack the resources or ability to address and emphasized the importance of patient readiness and flexibility in when and how life-goal discussions occur. A

commenter recommended beginning the patient-reported assessment 45 to 60 days after dialysis initiation to account for patient readiness.

Other commenters offered additional considerations for future measure development. A commenter recommended minimizing administrative burden and preserving flexibility for clinicians so that a scored survey does not make life-goal discussions more rigid or unnecessarily lengthy or take time away from direct patient care. Another commenter supported incorporating patient-defined goals into quality assessment but cautioned that the measure should not influence end-of-life decision-making or use life-expectancy or quality-of-life considerations to affect access to ESRD care.

Response: We appreciate all of the comments and recommendations on this topic. While we are not responding to specific comments submitted in response to this RFI in this final rule, we believe that this input is valuable and will continue to take commenters' concerns, recommendations, and suggestions into account as we consider future implementation of the D-PaLS PRO-PM and development of other patient-centered measure concepts for the ESRD QIP.

V. Requests for Information on Advancing Alternative Dialysis Care in Accordance With Executive Order 13879

A. Background and Overview

On July 10, 2019, President Trump issued Executive Order (E.O.) 13879, *Advancing American Kidney Health*, directing Federal agencies to advance policies that increase patient choice through affordable alternative treatments for ESRD. Despite having a wide range of individual needs and preferences, most dialysis patients in the United States continue to receive their care three times per week in an outpatient renal dialysis facility. E.O. 13879 specifically identifies that greater rates of home dialysis will improve quality of life and care for patients with ESRD.

The ESRD PPS, implemented on January 1, 2011, established a bundled per-treatment payment for outpatient renal dialysis services furnished by ESRD facilities. While this system has served as the foundation of Medicare's ESRD payment framework for over a decade, the landscape of ESRD care delivery has evolved considerably. Advances in clinical practice, such as home dialysis technology, increased attention to the needs of beneficiaries

approaching end-of-life, and growing clinical evidence supporting more flexible dialysis schedules, create opportunities to consider fundamental changes to Medicare's payment and coverage frameworks for ESRD and AKI care that could better support high-quality, patient-centered care across all dialysis modalities, settings, and patient populations.

In this section, we solicited public comment on several interrelated areas where potential payment and coverage policy changes could better align the ESRD PPS and AKI payment frameworks with the goals of E.O. 13879 and the evolving needs of ESRD beneficiaries. Specifically, we sought input on the following: (1) policies to promote greater use of home dialysis among Medicare beneficiaries; (2) approaches to strengthen care continuity and expand beneficiary choice of renal dialysis services that could be considered palliative in nature for beneficiaries approaching end-of-life; and (3) changes to the ESRD PPS to support greater flexibility for patients and nephrologists to use alternative dialysis schedules.

In the CY 2027 ESRD PPS proposed rule, we noted that these RFIs are intended solely to gather information and are not proposals for specific regulatory changes (91 FR 38848). Information received in response to these RFIs will be considered as CMS develops future rulemaking and policy initiatives in furtherance of E.O. 13879 and CMS's broader strategic priorities of aligning payment with value and advancing patient-centered care for Medicare beneficiaries with kidney disease. We noted that the proposals in other sections of the proposed rule are not final policy, and responders may not consider them as such when responding to the RFIs in this section.

B. Request for Information on Increasing Home Dialysis Uptake

1. Background

CMS has statutory authority under section 1881(b)(14) of the Act to implement a PPS for renal dialysis services furnished to individuals with ESRD. Under this authority, CMS established the ESRD PPS, which provides a bundled, per-treatment payment to ESRD facilities for renal dialysis services, as defined at § 413.171, furnished in outpatient settings.

The ESRD PPS base rate is adjusted to account for patient-level characteristics through case-mix adjustments, as well as for geographic differences in area wage levels through the wage index.

The payment system also includes additional adjustments and policies, such as outlier payments for high-cost cases and a training add-on payment under § 413.235(c) for home dialysis modalities. CMS's implementing regulations for the ESRD PPS are codified at 42 CFR part 413, subpart H.

Home dialysis modalities, including PD and home HD, furnish clinically appropriate beneficiaries with the opportunity to receive renal replacement therapy in the home setting. The ESRD Conditions for Coverage at 42 CFR part 494 include requirements related to modality education and patient rights.

According to the most recent United States Renal Data System (USRDS) Annual Data Report, approximately 14 to 15 percent of prevalent (all people currently on renal dialysis in the U.S., not just new starters) dialysis patients nationally are treated with home modalities, with PD accounting for most home treatments and home HD comprising a smaller proportion. CMS ESRD PPS claims and dashboard data for Medicare Fee-For-Service (FFS) beneficiaries reflect similar utilization rates among the FFS population.

Although home dialysis utilization increased between 2019 and 2021, more recent data indicate that growth has moderated. Technique failure, modality switching, workforce constraints, geographic variation, and beneficiary-level factors (lack of education, limited caregiver support, fear of treatment complexity, housing constraints, and insufficient transitional support following hospitalization) may contribute to the observed plateau in prevalence rates. Based on recent Medicare FFS data, approximately 14.5 percent of prevalent FFS dialysis beneficiaries receive dialysis via home modalities. Interested parties have emphasized that increasing home dialysis requires more than provider-facing financial incentives and must address patient experience, education, support systems, operational barriers and infrastructure. They have stated that absent additional policy changes, current growth trends would not significantly increase.

Accordingly, we solicited comment on potential approaches, consistent with our statutory authority under section 1881 of the Act and implementing regulations at 42 CFR part 413, subpart H, that could increase home dialysis utilization among Medicare FFS ESRD beneficiaries. We sought public comment on policy, payment, operational, and regulatory changes within the ESRD PPS, and in coordination with other Medicare

payment systems, when relevant, that could increase the percentage of incident, non-pediatric, non-MA ESRD beneficiaries initiating dialysis on a home modality and remaining on that modality. For purposes of this RFI, we use the term "incident ESRD beneficiaries" to refer to OM beneficiaries who newly initiate maintenance dialysis for ESRD during a given period, consistent with CMS ESRD PPS and United States Renal Data System (USRDS) conventions.

For purposes of this RFI, we considered measuring home dialysis uptake among Medicare FFS ESRD beneficiaries defined as those initiating home dialysis and remaining on that modality for at least 60 days, excluding pediatric ESRD patients, as defined in § 413.171. This continuation threshold is intended to ensure sustained modality selection and prevent short-term initiation from inflating performance measurements.

We note that increasing overall home dialysis prevalence depends largely on influencing modality selection at initiation. Therefore, we were particularly interested in policies that would affect modality choice at or before the start of dialysis.

We did not propose a specific numeric benchmark for the share of Medicare FFS ESRD beneficiaries who receive home dialysis. Instead, we sought comment on actionable policy changes that could measurably increase the number of incidences ESRD PPS beneficiaries select and sustain home dialysis. The RFI noted that commenters may wish to address how incremental increases in initiation rates would translate into additional incident ESRD beneficiaries selecting home modalities annually.

CMS emphasized that modality selection must remain clinically appropriate and consistent with patient choice protections under § 494.70.

2. Medicare FFS Baseline and Illustrative Modeling Framework

For purposes of informing public comment, CMS provided the following illustrative Medicare FFS baseline:

Approximately 220,000 chronic ESRD patients captured under the ESRD PPS receive renal dialysis services annually. At a home dialysis prevalence rate of approximately 14.5 percent, roughly 31,900 Medicare FFS beneficiaries with ESRD currently receive home dialysis.

We sought comment on the feasibility of achieving a significant increase in utilization of the home dialysis modality for ESRD PPS patients.

3. Request for Information

In the CY 2027 ESRD PPS proposed rule we issued an RFI on increasing home dialysis uptake. Topics upon which we asked questions included barriers to home dialysis, kidney disease education (KDE), home dialysis training, staff-assisted home dialysis, payment for home dialysis, home dialysis machine installation, in-center self-dialysis, improving access to home dialysis, and interactions with other payment systems and sites of care. For a full list of questions included in the RFI we invite readers to see the proposed rule (91 FR 38849).

We received 50 comments in response to the RFI on home dialysis uptake. Commenters included ESRD patients and caregivers; patient and consumer advocacy organizations; ESRD facilities and dialysis organizations, including large dialysis organizations and regional chains; SNF providers and interested parties; professional and trade associations; health systems; device manufacturers; MedPAC; and other parties and experts interested in kidney care. Commenters generally supported efforts to increase appropriate access to and sustained use of home dialysis, while emphasizing that policies must support informed beneficiary choice, clinical appropriateness, and the services needed to initiate and sustain home modalities rather than focus primarily on numerical utilization targets. Commenters frequent recommendations included that CMS: (1) strengthen kidney disease and modality education through earlier, repeated, individualized, unbiased, and culturally and linguistically appropriate education, including opportunities for beneficiaries who initiate dialysis emergently to reconsider home modalities; (2) establish payment or coverage for temporary or ongoing staff-assisted home dialysis, respite and backup support, retraining, and enhanced clinical or technical support to help beneficiaries initiate and remain on home dialysis when health, function, or caregiver availability changes; (3) address financial and practical barriers, including utility and broadband costs, home modifications, housing and storage constraints, supply delivery and disposal, transportation, equipment usability, and caregiver burden; (4) strengthen home dialysis training and workforce capacity and align payment with competency-based training and retraining, qualified staffing, care coordination, practitioner involvement, remote monitoring, and program infrastructure; and (5) align payment, regulatory, and quality policies to

support home dialysis capacity, access, and retention, including appropriate access in SNFs and transitional settings, while preserving modality neutrality and beneficiary choice.

Commenters also raised recurring concerns about policies intended to increase home dialysis utilization. These include concerns related to: (1) numerical targets or incentives tied primarily to home dialysis uptake could steer ESRD beneficiaries toward a modality that is not clinically appropriate or preferred and could disadvantage ESRD facilities serving medically or socially complex patients; (2) expansion without adequate support could shift treatment, financial, technical, and caregiving burdens to ESRD beneficiaries and unpaid caregivers; (3) workforce flexibility that weakens qualification, competency, or supervision standards could create patient-safety risks, with several commenters emphasizing continued qualified nephrology RN oversight; (4) budget-neutral financing or redistribution within the ESRD PPS could reduce resources for existing renal dialysis services or weaken investment in home dialysis capacity; and (5) staff-assisted home dialysis and other new supports could create cost, workforce, safety, duplicative-payment, or overutilization risks without clear eligibility criteria, clinical safeguards, accountability, and evaluation.

We thank the commenters for their thoughtful responses to our RFI on increasing home dialysis uptake and will consider them when developing any potential future policy. Any change in policy would be proposed in future notice and comment rulemaking.

C. Request for Information To Advance Palliative Care for Dialysis Patients

1. Background

a. Statutory and Regulatory Framework

Section 1881 of the Act establishes Medicare coverage and payment for renal dialysis services furnished to individuals with ESRD. CMS implemented the ESRD PPS beginning January 1, 2011 (75 FR 49030), which provides a bundled, per-treatment payment for renal dialysis services, including certain drugs, biologicals, laboratory services, and supplies.

The hospice benefit, established under section 1814(i) of the Act, provides a per diem payment to hospice providers for all items and services related to the palliation and management of the terminal illness and related conditions. Under current policy, services related to the terminal

condition are not separately payable outside the hospice benefit.

b. ESRD PPS and Current Payment Policy

Under the ESRD PPS, Medicare pays a single bundled amount for dialysis treatments furnished in-center or at home. This payment is intended to cover all renal dialysis services as defined in regulation at § 413.171.

Dialysis is life-sustaining but not curative. While it may be furnished consistent with palliative goals of care, current Medicare policy does not distinguish between maintenance dialysis and dialysis furnished in a comfort-focused context. As a result, payment policy does not explicitly account for palliative care objectives within ESRD treatment.

c. Interaction With the Hospice Benefit

When ESRD is the terminal condition, hospice providers are responsible for furnishing dialysis services within the hospice per diem payment. Because dialysis is a high-cost service, it is rarely furnished under the hospice benefit in practice.¹⁰⁶ As a result, beneficiaries with ESRD often delay or forgo hospice services to continue receiving renal dialysis services under the ESRD PPS.

MedPAC reported relatively low rates of hospice utilization among ESRD beneficiaries and noted that dialysis costs may represent a substantial share of hospice payments if furnished within the hospice benefit.¹⁰⁷ MedPAC also highlighted the potential for improved care coordination and reduced end-of-life spending when ESRD beneficiaries receive hospice services.

d. Home Dialysis and Structural Barriers

Current policy requires that home dialysis be performed independently by the ESRD beneficiary or with the assistance of an unpaid caregiver. Medicare does not routinely pay for ongoing staff assistance in the home for dialysis treatments. This may create access barriers for beneficiaries with functional impairments, frailty, or lack of caregiver support.

These barriers may be particularly relevant for ESRD beneficiaries with palliative care goals who may benefit from receiving renal dialysis services in a home-based, lower-burden setting.

¹⁰⁶ Schell JO, Johnson DS. Challenges with Providing Hospice Care for Patients Undergoing Long-Term Dialysis. *Clin J Am Soc Nephrol*. 2021 Mar 8;16(3):473–475. doi: 10.2215/CJN.10710720. Epub 2020 Oct 9. PMID: 33037019; PMCID: PMC8011021.

¹⁰⁷ <https://www.medpac.gov/wp-content/uploads/2025/09/Tab-F-Hospice-ESRD-cancer-Sept-2025-SEC.pdf>.

e. Policy Considerations and Prior Rulemaking Context

In prior ESRD PPS rulemaking (see, for example, 84 FR 60648 through 60652), CMS emphasized goals of promoting home dialysis, improving patient experience, and supporting high-quality, patient-centered care. CMS also sought to maintain the integrity of prospective payment systems and avoid duplicative payment.

Consistent with these goals, CMS is exploring whether refinements to payment policy could improve access to palliative dialysis while maintaining the following: ESRD PPS bundled payment integrity; Hospice per diem integrity; and appropriate safeguards against duplicative payment and program integrity risks.

3. Request for Information

In the CY 2027 ESRD PPS proposed rule we issued an RFI to advance palliative care for dialysis patients. Topics upon which we asked questions included the definition of palliative dialysis, eligibility, care delivery, payment considerations, program integrity, and potential policy approaches. For a full list of questions included in the RFI we invite readers to see the proposed rule (91 FR 38852).

CMS received 29 comments on the RFI on palliative care for dialysis patients. Commenters included patient advocates, hospice and palliative-care organizations, professional associations, dialysis organizations, health systems, MedPAC, and other interested parties. Commenters generally supported improving access to goal-concordant dialysis, that is, dialysis provided in a way that reflects the patient's needs, goals, and wishes, including goals related to comfort and quality of life, and reducing barriers to hospice, but differed on eligibility, treatment limits, payment, and terminology.

Areas of greatest agreement were an intent-based definition, shared decision-making and documented goals, clear provider roles, payment that does not place the full cost of dialysis on the hospice per diem, and quality policies aligned with palliative goals. Key areas of disagreement were terminology, prognosis and eligibility thresholds, treatment or time limits, payment methodology, and whether policy should proceed through demonstrations or broader national changes.

Some of the specific recommendations we received included: (1) that CMS should define palliative dialysis by treatment intent and patient goals as commenters generally favored a definition centered on symptom relief,

comfort, quality of life, function, treatment burden, and documented goals rather than modality, frequency, or duration; (2) that CMS should permit concurrent hospice and renal dialysis services without requiring hospices to absorb dialysis costs as many commenters identified the hospice per diem as the primary access barrier when ESRD is the terminal condition and favored separate or direct payment to the ESRD facility; (3) that CMS should base eligibility and safeguards on shared decision-making and a documented care plan focusing on documenting patient goals, expected benefits and burdens, provider roles, and reassessment, with clinical, functional, frailty, and prognostic factors generally serving as screening tools; (4) that commenters generally favored ESRD facilities retaining dialysis-specific responsibilities and hospices retaining responsibility for the hospice plan of care, supported by shared care plans, designated contacts, information exchange, and cross-provider education; (5) that maintenance-dialysis measures and payment incentives may conflict with individualized palliative care and recommended protections or measures focused on symptoms, treatment burden, goal concordance, patient experience, and avoidable acute care.

Commenters also noted several concerns, which include: (1) that ESRD beneficiaries may postpone or decline hospice to preserve access to renal dialysis services, resulting in shorter hospice stays and potentially greater distress and acute-care use; (2) that the hospice per diem generally cannot absorb dialysis costs, while emphasizing the need for clear payment boundaries across the ESRD, hospice, and home health benefits; (3) differing opinions on the appropriate role of hospice eligibility, prognosis, frailty, and functional decline, with many cautioning against criteria that are either too restrictive or too broad; (4) that there were several barriers including separate care plans and records, contracting, transportation, scheduling, vascular-access management, medication responsibility, and differing regulatory requirements; and (5) that maintenance-oriented quality measures may discourage palliative treatment changes, while some payment models could create undertreatment risk.

We thank the commenters for their thoughtful responses to our RFI on palliative care for dialysis patients and will consider them when developing any potential future policy. Any change in policy would be proposed in future notice and comment rulemaking.

D. Requests for Information on Potential Payment Changes To Support Alternative Dialysis Schedules

1. Background

Section 1881(b)(14)(C) of the Social Security Act (the Act) authorizes payment under the ESRD PPS based on renal dialysis services furnished during a week, or month, or such other appropriate unit of payment as the Secretary specifies. When we implemented the ESRD PPS beginning January 1, 2011, we established payment on a per-treatment basis (75 FR 49064). In developing that policy, we considered other units of payment, including a monthly ESRD PPS, which would provide ESRD facilities more flexibility in alternative treatment requirements, such as increased frequency nocturnal dialysis, home HD using compact portable dialysis machines, and shorter but more frequent dialysis services. However, given the difficulties of implementing a monthly ESRD PPS during the transition period in which a per-treatment methodology applied, we chose to continue the per-treatment payment methodology that had been in effect under the composite rate system prior to the ESRD PPS (75 FR 49064). That transition period concluded on December 31, 2013.

In the CY 2011 ESRD PPS final rule, we noted that MedPAC recommended that we reconsider the unit of payment once a strengthened dialysis quality monitoring system is implemented, to ensure that quality of care does not decline (75 FR 49064). In its comments on the CY 2011 ESRD PPS proposed rule, MedPAC noted that a larger unit of payment would be consistent with several aspects of dialysis care, pointing out that a weekly unit of payment corresponds to the typical weekly interval for PD. MedPAC also noted that Medicare pays nephrologists a monthly capitated payment for caring for dialysis beneficiaries (75 FR 49064). Since that time, the ESRD Quality Incentive Program (QIP) and the Five-Star Quality Rating System for ESRD facilities have been established and are well-functioning, addressing the quality monitoring concern MedPAC identified.

2. Current ESRD PPS Payment Methodology and Considerations for Potential Changes to the ESRD PPS Unit of Payment

Although the ESRD PPS unit of payment is a treatment, renal dialysis services are billed monthly. In addition, the ESRD PPS currently makes a daily rate payment, which is effectively a prorated monthly payment, for certain renal dialysis services. Specifically,

home Continuous Ambulatory PD (CAPD) and Continuous Cycling PD (CCPD) are paid daily for the number of PD days billed in the month, following the payment approach for this modality that has been in place since the inception of the composite rate payment system in 1983. For home ESRD patients undergoing PD, the number of days of PD, regardless of the number of dialysate exchanges performed each day, is converted to home HD-equivalent sessions by dividing the number of PD days by 7 and multiplying the result by 3 (see Medicare Benefit Policy Manual, Chapter 11). For example, a patient receiving 30 days of home CAPD would be paid an amount equal to 12.857 home HD-equivalent treatments ($30 \div 7 \times 3 = 12.857$). This approach creates a per-treatment amount that is paid for each day of PD treatment and that complies with the monthly treatment payment limit of 13 treatments in a 30-day month and 14 treatments in a 31-day month (81 FR 42809).

This existing methodology demonstrates that a daily rate structure is operationally feasible within the current ESRD PPS framework and has been successfully administered by MACs for over 4 decades. When considering alternative units of payment for the ESRD PPS, a daily payment rate is effectively the same as a prorated monthly payment rate, which functions identically to a monthly payment rate in the case that an ESRD facility bills for a full month, but also offers additional flexibility. Importantly, the daily rate payment allows for more flexible payment for renal dialysis services during service interruptions such as hospitalizations. A daily rate payment could also provide flexibility when a patient temporarily receives renal dialysis services at a different ESRD facility than their usual ESRD facility.

In recent public comments, interested parties have further noted that some renal dialysis services do not directly correspond to a dialysis treatment. For example, oral phosphate binders, which were incorporated into the ESRD PPS bundled payment beginning January 1, 2025, through the TDAPA, and which we are including in the ESRD PPS base rate beginning in CY 2027, are typically taken daily with meals and often follow irregular dosing schedules. Other oral drugs, as well as clinical interventions such as patient education, access management, and nutrition management, may occur outside the boundaries of a dialysis session. Furthermore, alternative treatment options—such as in-center self-dialysis, nocturnal dialysis, and more frequent

home HD, or more conservative approaches for renal care which may not focus on dialysis—may involve treatment schedules that align more naturally with a monthly unit of payment than with the current per-treatment payment structure.

These considerations lead us to examine whether a change to the unit of payment for the ESRD PPS could more appropriately recognize patient-specific needs and better align payment with overall resource use, while continuing to advance the principles of prospective payment and the goals of Executive Order 13879, *Advancing American Kidney Health*. A monthly (or daily rate) unit of payment could offer meaningful administrative simplification for ESRD facilities. Under the current system, facilities must obtain and document additional medical justification when an ESRD patient's clinical needs require more than 3 treatments per week. These requirements impose administrative burden on ESRD facilities of all sizes, and may be particularly challenging for smaller, independent ESRD providers with limited billing infrastructure. A daily rate structure would eliminate the need for the $\frac{3}{7}$ conversion, reduce the complexity of tracking monthly treatment limits (13 or 14 per month depending on month length), and simplify billing for ESRD patients who receive care at multiple ESRD facilities or experience service interruptions. ESRD facilities would bill for actual days of service provided, creating a more direct and transparent relationship between care delivery and payment.

Beyond administrative simplification, a daily rate structure could better support patient-centered care by reducing financial disincentives associated with alternative dialysis schedules. Under the current per-treatment payment structure, the ESRD PPS was designed around a conventional thrice-weekly home HD schedule. As noted in the CY 2011 ESRD PPS final rule, CMS recognized that a monthly unit of payment would provide ESRD facilities with more flexibility in alternative treatment requirements, such as increased frequency nocturnal dialysis, home HD using compact portable dialysis machines, and shorter but more frequent dialysis services (75 FR 49064). A daily rate structure could reduce the rigidity of the current payment framework and better support individualized treatment plans developed collaboratively by patients and their nephrologists, without creating financial incentives to adhere to a fixed treatment schedule when a patient's clinical needs call for a different approach. For patients who

would benefit from more frequent renal dialysis services—such as those with fluid management challenges, cardiovascular comorbidities, or a preference for shorter, more frequent sessions—a daily payment structure could remove a structural barrier to accessing those options.

At the same time, we recognize that such a change would represent a significant operational shift for ESRD facilities, MACs, and CMS systems, and would require careful consideration of how to maintain budget neutrality, preserve payment equity across modalities, protect beneficiary access to care, and ensure that payment incentives continue to support high-quality, appropriate care. We are mindful that any change to the unit of payment must be designed to ensure that patients receive all medically necessary services and that ESRD providers are not inadvertently incentivized to reduce the frequency or intensity of care. We sought public input on how a daily payment structure could be designed and monitored to achieve these goals.

4. Request for Information

In the CY 2027 ESRD PPS proposed rule we issued an RFI on potential payment changes to support alternative dialysis schedules. Topics upon which we asked questions included the appropriateness and calibration of a daily payment rate, administrative burden and operational impacts on facilities, safeguards to prevent underutilization of medically necessary care, and how a new payment structure could affect billing, budget neutrality, and outlier policy. For a full list of questions included in the RFI we invite readers to see the proposed rule (91 FR 38854).

CMS received 16 comments on the RFI on potential payment changes to support alternative dialysis schedules. Commenters expressed a wide range of views in response to this RFI. Some commenters wrote that they did not support the change at all, arguing that a monthly system could lead facilities to reduce services to the minimum necessary to receive full payment, and that it would introduce new complications, such as accounting for partial months of service in the event of travel or hospitalization. Other commenters questioned whether the change was necessary in the first place, writing that it was not clear how modifying the payment cadence would meaningfully improve patient outcomes or support innovation, and separately noted that revising the payment structure to address a comparatively

small group of ESRD patients who need less-frequent renal dialysis services could risk health outcomes for the larger population that requires thrice-weekly treatment.

Other commenters took a more conditional stance. Some wrote in support of exploring payment approaches that could better accommodate individualized and alternative dialysis schedules, while stipulating that any change must include explicit safeguards ensuring ESRD patients retain timely access to medically necessary extra in-center treatments. A commenter stated that a per-treatment unit may be a reasonable fit for conventional, episodic dialysis care but could become a less natural fit for future therapies prescribed for longer, more frequent, nocturnal, portable, or continuous use. This commenter suggested that Medicare evaluate future authorized therapies based on their prescribed use, safety, outcomes, and total cost of care rather than requiring them to conform to a facility-based billing schedule. Another commenter wrote that, since medical justification is already required for a facility to receive payment for additional treatments, changing to a daily rate calculated as three-sevenths of the per-treatment base rate would have limited practical impact, and separately observed that the current per-treatment system already discourages clinically appropriate twice-weekly dialysis schedules due to lost revenue on unfilled treatment slots and potential risk of penalties under the IPFQR program. A commenter noted that nephrologists often set thrice-weekly dialysis as an early expectation for patients, in part to avoid the more difficult conversation of persuading patients to increase treatment frequency later as residual kidney function declines.

A subset of commenters called for more extensive analysis, such as a Technical Expert Panel or a similar formal review process before any further action, citing the methodological complexity and significance of a potential change to the payment unit.

We thank the commenters for their thoughtful responses to our RFI on potential payment changes to support alternative dialysis schedules. We will take these comments into consideration when developing any potential future policy through notice and comment rulemaking.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we

are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ESRD QIP—Wage Estimates

We refer readers to the CY 2026 ESRD PPS final rule for information regarding previously used wage estimates and resulting information collection burden calculations used in this final rule (90 FR 53121 through 53122). To derive wage estimates, we used data from the United States Bureau of Labor Statistics' May 2025 National Occupational Employment and Wage Estimates for Medical Records Specialists, who are responsible for organizing and managing health information data, and are tasked with submitting measure data to the ESRD Quality Reporting System (EQRS) (formerly, CROWNWeb) and the Centers for Disease Control and Prevention's (CDC's) NHSN, as well as compiling and submitting patient records for the purpose of data validation. When this analysis was conducted, the most recently available median hourly wage of a Medical Records Specialist (SOC 29–2072) was \$24.59 per hour.¹⁰⁸ We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance

on estimating the cost of fringe benefits and overhead. Using these assumptions, we estimated an hourly labor cost of \$49.18 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this wage estimate, along with updated facility and patient counts, to update our estimates for the total information collection burden in the ESRD QIP for PY 2029. We provide the re-estimated information collection burden to reflect updated facility and patient counts in this final rule.

B. Estimated Burden Associated With the Data Validation Requirements for PY 2029

We refer readers to the CY 2026 ESRD PPS final rule for information regarding the estimated burden associated with data validation requirements for PY 2028 (90 FR 53122).

1. Estimated Burden Associated With EQRS Data Validation Requirements for PY 2029

In this final rule, using the most recently available data, we estimate that the aggregate cost of the EQRS data validation for PY 2029 will be approximately \$36,885 (750 hours × \$49.18), or an annual total of approximately \$122.95 (\$36,885/300 facilities) per facility in the sample. We include the updated aggregate cost of EQRS data validation to reflect updated wage estimates in this final rule. The burden cost increase associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1289).

2. Estimated Burden Associated With NHSN Data Validation Requirements for PY 2029

In this final rule, we estimate that the aggregate cost of the NHSN data validation for PY 2029 will be approximately \$73,770 (1,500 hours × \$49.18), or a total of approximately \$245.90 (\$73,770/300 facilities) per facility in the sample. We included the updated aggregate cost of NHSN data validation to reflect updated wage estimates in this final rule. The burden cost updates associated with these requirements will be submitted to OMB as a revision of the information collection request currently approved under OMB control number 0938–1340.

C. Estimated EQRS Reporting Requirements for PY 2029

To estimate the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility will be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2026 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2028 ESRD QIP was approximately \$125 million for approximately 2,588,770 total burden hours (90 FR 53122).

We are finalizing measure updates in this final rule that will affect the burden associated with EQRS reporting requirements beginning with PY 2029. We are finalizing two measure removals and one measure adoption that will affect the burden associated with EQRS reporting requirements beginning with PY 2029. We provide the burden estimate for PY 2029 in this final rule to reflect the impact of these policies and include the updated information collection burden to reflect updated facility and patient counts in this final rule. In this final rule, we estimate that the amount of time required to submit measure data to EQRS will be 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. There are 109 data elements for 512,458 patients across 7,551 facilities, for a total of 55,857,922 elements across all patients (109 data elements × 512,458 patients). At 2.5 minutes per element, the changes will yield approximately 308 hours per facility for a total PY 2029 burden of 2,327,413 hours. Using the Medical Records Specialist wage estimates available at this time, we estimate that the PY 2029 total burden cost will be approximately \$114.5 million (2,327,413 hours × \$49.18). The estimated reduction in burden associated with the measure updates is described in Table 29.

¹⁰⁸ Bureau of Labor Statistics. (May 2026). U.S. Department of Labor, Occupational Outlook Handbook, Medical Records Specialists. Available at <https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.

**TABLE 29: Updated Estimated Reduction in Burden Associated with Measure Updates
Beginning with the PY 2029 ESRD QIP**

Requirement	Per Facility		All Facilities	
	Change in annual burden hours	Change in annual cost	Change in annual burden hours	Change in annual cost
Adoption of the Hyperphosphatemia Clinical Measure	135.73	\$6,675.32	1,024,916	\$50,405,369
Removal of the Hypercalcemia Reporting Measure	-67.87	-\$3,337.66	-512,458	-\$25,202,684
Removal of the MedRec Reporting Measure	-101.80	-\$5,006.49	-768,687	-\$37,804,027
Total Change in Information Collection Burden Hours: -256,229				
Total Cost Estimate: Updated Hourly Wage (\$49.18) x Change in Burden Hours (-256,229) = - \$12,601,342				

The information collection request currently approved under the OMB control number 0938-1289 will be revised and submitted to OMB for approval.

VII. Regulatory Impact Analysis

A. Statement of Need

1. ESRD PPS

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA (Pub. L. 110-275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Affordable Care Act (Pub. L. 111-148), established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRDB market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule finalizes routine updates to the payment rate for renal dialysis services furnished by ESRD facilities and rebases and revises the ESRDB market basket and labor-related share. This rule also finalizes policy changes to the ESRD PPS for CY 2027, including updates to our ESRD PPS wage index, outlier threshold, TPNIES offset amount, and post-TDAPA add-on payment adjustment amounts to reflect the latest available data for Korsuva®, DefenCath®, and Vafseo®. We are also finalizing changes to increase the ESRD PPS base rate to account for the addition of phosphate binders into the ESRD PPS bundled payment, changes to payment for pediatric ESRD patients, changes to the LVPA, changes to the home and self-dialysis training add-on, and changes to

our ASP policy for the TDAPA and post-TDAPA payment adjustment. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2027 for renal dialysis services furnished to ESRD beneficiaries.

2. AKI

This rule finalizes updates to the payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2027 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

3. ESRD QIP

Section 1881(h)(1) of the Act requires CMS to reduce the payments otherwise made to a facility under the ESRD PPS for a year by up to 2 percent if the facility does not satisfy the requirements of the ESRD QIP for that year. This rule finalizes updates for the ESRD QIP, which will replace the Hypercalcemia reporting measure with the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients clinical measure. This rule also finalizes updates to the NHSN BSI clinical measure. Additionally, this rule finalizes the removal of the MedRec reporting measure and the COVID-19 Vaccination Coverage Among HCP reporting measure from the ESRD QIP measure set beginning with PY 2029.

B. Overall Impact Analysis

We have examined the impacts of this rule as required by Executive Order 12866, “Regulatory Planning and Review”; Executive Order 13132, “Federalism,” Executive Order 13563,

“Improving Regulation and Regulatory Review”; Executive Order 14192, “Unleashing Prosperity Through Deregulation”; the Regulatory Flexibility Act (RFA) (Pub. L. 96-354); section 1102(b) of the Act; section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4); and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President’s priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of Executive Order 12866. Based on our analysis, OMB’s Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant pursuant to section 3(f)(1) of

Executive Order 12866. Accordingly, we have prepared a Regulatory Impact Analysis that presents, to the best of our ability, the estimated costs and benefits associated with this rulemaking.

1. ESRD PPS

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately \$190 million in ESRD PPS payments to ESRD facilities in CY 2027. This includes the estimated impact of the final ESRD PPS market basket update of 1.9 percent (\$170 million), as well as the estimated changes in payments associated with several changes that are expected between CYs 2026 and 2027. The net effect of the offsetting increases and decreases to payments, as discussed in the following paragraph, results in the estimated \$240 million overall increase in ESRD PPS payments to ESRD facilities in CY 2027.

First, as discussed in section II.B.3.b. of this final rule, we estimate that outlier payments in CY 2026 will be approximately 2.6 percent of total ESRD PPS payments. Accordingly, the final increases to the FDL and MAP amounts for CY 2027 are projected to reduce ESRD PPS payments by approximately 1.6 percent (\$140 million). At the same time, we estimate that approximately \$413 million will be paid through the TDAPA for DefenCath®, Vafseo®, and phosphate binders in CY 2026. The end of the TDAPA periods for these drugs is projected to result in a corresponding decrease to CY 2027 payments of 4.6 percent, which is offset by the final 4.4 percent increase to the ESRD PPS base rate for phosphate binders for a net decrease of \$40 million, and further offset by the estimated 2.9 percent increase in payments under the post-TDAPA add-on payment adjustment in CY 2027 (\$260 million). The net difference between estimated CY 2026 TDAPA payments and estimated CY 2027 payments under the post-TDAPA add-on payment adjustment and the ESRD PPS base rate, including the final incorporation of phosphate binders, is therefore a 2.5 percent increase in payments to ESRD facilities ($1.044 \times 1.029 \times 0.954 = 1.025$) which equals approximately \$220 million (\$260 million – \$40 million = \$220 million). In addition, this amount includes, but is not impacted by, any budget neutral changes for CY 2027 such as the routine updates to the ESRD PPS wage index, labor-related share, and the changes to the LVPA. In addition, for public awareness, we estimate that the updated CY 2027 post-TDAPA add-on payment adjustments will total approximately \$290 million, an increase from around

\$34 million in CY 2026. These amounts are included in the estimated \$240 million overall increase in ESRD PPS payments for CY 2027, because as we previously noted the net effect of the offsetting increases and decreases to payments, as discussed in the prior paragraph, results in the estimated \$240 million overall increase in ESRD PPS payments to ESRD facilities in CY 2027.

2. AKI

We estimate that the final updates to the AKI dialysis payment rate will result in an increase of approximately \$5 million in Medicare payments to ESRD facilities in CY 2027.

3. ESRD QIP

We estimate that, as a result of our previously finalized policies and the policies we are finalizing in this final rule, the updated ESRD QIP will result in \$18.7 million in estimated payment reductions across all facilities for PY 2029.

4. Summary of Impacts

We estimate that the combined impact of the policies finalized in this rule on payments for CY 2027 is approximately \$245 million based on the combined estimates of the updated ESRD PPS and the AKI dialysis payment rates.¹⁰⁹ We estimate the impacts of the ESRD QIP for PY 2029 to be \$114.5 million in information collection burden and \$18.7 million in estimated payment reductions across all facilities.

C. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this final rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this final rule.

1. Benefits

Under the final CY 2027 ESRD PPS and AKI dialysis payment, ESRD facilities will continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective Medicare payments to ESRD facilities will enhance the efficiency of the Medicare program. Additionally, we expect that updating the Medicare ESRD PPS base rate and rate for AKI dialysis treatments furnished by ESRD facilities by 5.6 percent based on the final CY 2027 ESRDB market basket percentage increase of 2.9 percent reduced by the

¹⁰⁹ Note: The combined estimated payment increase for the rule may not align with the sum of ESRD PPS and AKI payment estimates due to rounding.

final CY 2027 productivity adjustment of 1.0 percentage point, as well as the final increase to the ESRD PPS base rate from the inclusion of phosphate binders into the base rate, will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services. We estimate that overall payments under the ESRD PPS will increase by 2.7 percent and payments under the AKI payment system will increase by 5.3 percent because of the final policies in this rule.

2. Costs

a. ESRD PPS and AKI

We do not anticipate the provisions of this final rule regarding ESRD PPS and AKI rate-setting will create additional costs or burden to ESRD facilities.

b. ESRD QIP

We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for EQRS data validation (previously known as the CROWNWeb validation study) or NHSN data validation. Although we do not anticipate that the updates in this final rule regarding ESRD QIP will create additional cost or burden to ESRD facilities for PY 2029, we have included the updated estimated costs associated with the information collection requirements under the ESRD QIP in this final rule, with updated estimates of the total number of ESRD facilities, the total number of patients nationally, and a refined estimate of the number of hours needed to complete data entry for EQRS reporting.

3. Transfers

We estimate that the updates to the ESRD PPS and AKI dialysis payment rates will result in a total increase of approximately \$245 million in Medicare payments to ESRD facilities in CY 2027, which includes the amount associated with the final inclusion of phosphate binders to the base rate, the final updates to the outlier threshold amounts, and final updates to the ESRD wage index. This estimate includes an increase of approximately \$5 million in Medicare payments to ESRD facilities in CY 2027 due to the final updates to the AKI dialysis payment rate, of which approximately 20 percent is increased beneficiary coinsurance payments. We estimate approximately \$195 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately \$50 million in transfers from beneficiaries to ESRD facilities due

to increased beneficiary coinsurance payments because of this final rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this ESRD PPS final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the ESRD PPS final rule, we assume that the total number of unique commenters on this year's ESRD PPS proposed rule, which was 171 for the CY 2027 ESRD PPS proposed rule, is equal to the number of individual reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters will review this year's final rule in detail, and it is also possible that some reviewers chose not to comment on the CY 2027 ESRD PPS proposed rule. For these reasons, we determined that the number of past commenters will be a fair estimate of the number of reviewers of this final rule. We used a similar methodology for calculating the regulatory review costs in the CY 2027 ESRD PPS proposed rule. We solicited comments on this approach.

We also recognized that different types of entities are in many cases

affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assumed that each reviewer reads approximately 50 percent of this final rule. We sought comments on this assumption.

We did not receive public comments on this provision, and therefore, we are using our established methodology for estimating the regulatory review costs of this rule.

Using the BLS OEWS May 2025 National, cross-industry median hourly wage information for medical and health service managers (SOC 11–9111), we estimate that the cost of reviewing this rule is \$119.10 (\$59.55 * 2) per hour, including overhead and fringe benefits¹¹⁰ (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed of 250 words per minute, we estimate that it will take approximately 240 minutes (4 hours) for the staff to review half of this final rule, which has a total of approximately 120,000 words. For each entity that reviews the rule, the estimated cost is \$476.40 (4 hours × \$119.10). Therefore, we estimate that the total cost of reviewing this regulation is \$81,464.40 (\$476.40 × 171 reviewers).

¹¹⁰ Calculated by multiplying the mean hourly wage for medical and health service managers (SOC 11–9111) by 2 to account for overhead and fringe benefits.

5. Impact Statement and Table

a. CY 2027 End-Stage Renal Disease Prospective Payment System

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting Medicare payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2026 to estimated payments in CY 2027. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of Medicare payments in CY 2026 and CY 2027 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this final rule, we use CY 2025 data from the Medicare Part A and Part B Common Working Files as of July 31, 2026, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2025 claims to 2026 and 2027 using various updates. The final updates to the ESRD PPS base rate are described in section II.B.4. of this final rule. Table 30 shows the impact of the estimated CY 2027 ESRD PPS payments compared to estimated ESRD PPS payments to ESRD facilities in CY 2026.

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TABLE 30: Impacts of the Final Changes in Medicare Payments to ESRD Facilities for CY 2027

Facility Type	Number of Facilities (A)	Treatments (in millions) (B)	Routine Outlier Update (C)	TDAPA and Post-TDAPA (incl phosphate binder incorporation) (D)	Pediatric Changes (incl LVPA) (E)	Adult LVPA Changes (F)	Training Add-on Changes (G)	Wage Index and LRS (H)	All Changes (I)
All Facilities	7,570	24.0	-1.6%	2.5%	0.0%	0.0%	0.0%	0.0%	2.7%
Type									
Freestanding	7,238	23.1	-1.5%	2.4%	0.0%	0.0%	0.0%	0.0%	2.7%
Hospital-based	332	0.9	-4.0%	5.1%	0.1%	0.1%	-0.1%	-0.1%	2.7%
Ownership Type									
Large dialysis organization	5,841	18.6	-1.4%	3.1%	0.0%	0.0%	0.0%	-0.1%	3.5%
Regional chain	890	3.0	-2.2%	-2.6%	0.0%	-0.3%	0.0%	0.4%	-2.9%
Independent	500	1.5	-1.8%	5.9%	0.0%	0.0%	-0.1%	0.3%	6.2%
Hospital-based ¹	332	0.9	-4.0%	5.1%	0.1%	0.1%	-0.1%	-0.1%	2.7%
Unknown	7	0.0	-1.8%	6.2%	0.0%	3.9%	-0.1%	1.8%	12.1%
Geographic Location									
Rural	1,224	3.3	-1.7%	2.7%	0.0%	2.0%	0.0%	-1.1%	3.7%
Urban	6,346	20.7	-1.6%	2.5%	0.0%	-0.3%	0.0%	0.2%	2.6%
Census Region									
East North Central	1,161	3.1	-1.7%	3.0%	0.0%	0.7%	0.0%	-0.3%	3.6%
East South Central	592	1.4	-1.6%	1.9%	0.0%	0.8%	0.0%	-1.5%	1.3%
Middle Atlantic	845	3.0	-1.9%	3.3%	0.0%	-0.2%	0.0%	-0.1%	2.9%
Mountain	425	1.4	-1.2%	3.1%	0.0%	0.1%	0.0%	-0.8%	3.1%
New England	198	0.9	-1.7%	2.9%	0.0%	-0.3%	0.0%	0.6%	3.4%
Pacific ²	974	4.6	-1.3%	2.2%	0.0%	-0.7%	0.0%	1.8%	3.8%
Puerto Rico and Virgin Islands	54	0.1	-1.7%	5.9%	-0.1%	-0.9%	0.1%	0.5%	5.5%
South Atlantic	1,779	5.0	-1.7%	2.3%	0.0%	0.0%	0.0%	-0.7%	1.6%
West North Central	468	1.4	-1.7%	3.5%	0.0%	1.5%	0.0%	-0.3%	4.8%
West South Central	1,074	3.1	-1.6%	1.5%	0.0%	-0.2%	0.0%	-0.5%	0.9%
Facility Size									
Less than 3,000 treatments	556	0.4	-1.7%	4.3%	0.3%	2.6%	0.0%	-0.1%	7.4%
3,000 to 3,999 treatments	432	0.6	-1.5%	3.3%	0.0%	5.3%	0.0%	-0.4%	8.6%
4,000 to 4,999 treatments	516	0.8	-1.6%	3.1%	0.0%	6.5%	0.0%	-0.3%	9.6%
5,000 to 5,999 treatments	567	1.1	-1.7%	2.7%	0.0%	4.6%	0.0%	-0.5%	6.9%

Facility Type	Number of Facilities (A)	Treatments (in millions) (B)	Routine Outlier Update (C)	TDAPA and Post-TDAPA (incl phosphate binder incorporation) (D)	Pediatric Changes (incl LVPA) (E)	Adult LVPA Changes (F)	Training Add-on Changes (G)	Wage Index and LRS (H)	All Changes (I)
6,000 to 6,999 treatments	644	1.4	-1.6%	2.7%	0.0%	2.7%	-0.1%	-0.4%	5.2%
7,000 to 7,999 treatments	641	1.6	-1.7%	2.4%	0.0%	0.3%	0.0%	-0.3%	2.4%
8,000 or more treatments	4,214	18.1	-1.6%	2.4%	0.0%	-1.0%	0.0%	0.1%	1.8%
Percentage of Pediatric Patients									
Less than 2%	7,469	23.8	-1.6%	2.5%	0.0%	0.0%	0.0%	0.0%	2.7%
Between 2% and 49%	48	0.2	-1.3%	3.4%	-0.3%	-0.9%	0.1%	-0.5%	2.3%
More than 50%	53	0.0	-4.0%	7.2%	2.0%	-1.2%	0.0%	0.4%	6.1%

¹ Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

² Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category.

Column B indicates the number of dialysis treatments (in millions).

Column C represents the change in payment to each ESRD facility type based on the changes to the outlier FDL and MAP amounts finalized in section II.B.3. of this final rule. As we previously discussed, we estimate a 1.6 percent reduction in ESRD PPS

payments to reduce outlier payments to better align with the 1.0 percent outlier target in CY 2027. The largest projected decrease will be approximately 4.0 percent for hospital-based ESRD facilities.

Column D represents the changes in simulated payments between CY 2026 and CY 2027 due to routine changes in TDAPA eligibility for Vafseo®, which will become outlier eligible and be included in the post-TDAPA add-on payment adjustment calculation

beginning January 1, 2027, at the end of its TDAPA period, and DefenCath®, which is paid for through the TDAPA until July 1, 2026, and is included in the post-TDAPA add-on payment adjustment calculation for the third and fourth quarters of CY 2026. DefenCath® will continue to be outlier eligible and included in the post-TDAPA add-on payment adjustment in CY 2027. This column also represents the difference between simulated TDAPA payments for phosphate binders in CY 2026 and

simulated payments under the ESRD PPS base rate for these drugs in CY 2027.

Column E represents the impact of final budget neutral changes to payments for pediatric ESRD patients, including the final revisions to the pediatric case-mix adjusters as well as the final expansion of the LVPA to treatments for pediatric ESRD patients. Table 30 shows that these final policies will increase payments by 2.0 percent to ESRD facilities with 50 percent or more pediatric patients, while the largest decrease will be -0.3 percent for ESRD facilities with between 2 and 49 percent pediatric patients.

Column F represents the impact of final budget neutral changes to the LVPA. The largest estimated increase would be 6.5 percent for ESRD facilities, furnishing between 4,000 and 4,999 treatments per year. Conversely, we estimate that payments to ESRD facilities furnishing more than 8,000 treatments per year will decrease approximately 1.0 percent.

Column G represents the impact of final budget neutral changes to the home and self-dialysis training add-on, which includes the impact of the policy change to allow payment of the home and self-dialysis training add-on during the onset period and the corresponding reduction to the onset adjustment factor. We estimate these changes will have distributional impacts of 0.1 percentage point or less for nearly all categories of ESRD facilities.

Column H represents the effect of the final updates to the ESRD PPS wage index for CY 2027, including the continued application of the 5 percent cap on wage index decreases. This column also shows the effect of the update the LRS from 55.2 percent to 63.5 percent in CY 2027. These final updates will be budget neutral, so the total impact of these policy changes is 0.0 percent. However, we estimate there will be distributional impacts because of these updates. The largest increase will be to ESRD facilities in the Pacific Census region, which will receive 1.8 percent higher payments because of the updated ESRD PPS wage index and LRS. The largest decrease will be for ESRD facilities in the East South Central Census region, which will receive 1.5 percent lower payments because of the updated ESRD PPS wage index and LRS.

Column I reflects the overall impact of the policies discussed in this final rule, including the routine updates to the wage index, outlier thresholds, and post-TDAPA add-on payment adjustment amounts as well as the inclusion of phosphate binders into the

base rate, the changes to payments for pediatric ESRD patients, the LVPA changes, and the changes to the home and self-dialysis training add-on payment adjustment. This column also reflects the final ESRD PPS payment rate update for CY 2027 of 1.9 percent, which reflects the final ESRDB market basket percentage increase for CY 2027 of 2.9 percent reduced by the final productivity adjustment of 1.0 percentage point. We expect that overall ESRD facilities will experience a 2.7 percent increase in estimated Medicare payments in CY 2027. The categories of types of ESRD facilities in the impact table show impacts ranging from a 2.9 percent decrease in CY 2027 estimated Medicare payments for regional chain ESRD facilities to a 9.6 percent increase in estimated payments for ESRD facilities which furnish between 4,000 and 4,999 treatments.

(2) Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers or suppliers (for example, laboratories, and durable medical equipment suppliers) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2027, we estimate that the ESRD PPS will have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2027 will be approximately \$9.3 billion. This estimate considers a projected increase in FFS Medicare ESRD beneficiary enrollment of 1.0 percent in CY 2027.

(4) Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 2.7 percent overall increase in the CY 2027 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary coinsurance payments of 2.7 percent in CY 2027, which translates to approximately \$50 million.

(5) Alternatives Considered

(a) Incorporation of Phosphate Binders Into the ESRD PPS Base Rate

In section II.B.7. of this final rule, we discuss our proposal to incorporate phosphate binders into the ESRD PPS base rate and our final policy. We considered, but are not finalizing, a delay of the incorporation of phosphate binders in the ESRDB market basket and

continuing TDAPA for another year. We are not finalizing the continuation of TDAPA for a third year after we evaluated utilization data during the first year of TDAPA and met with several interested parties through public meetings where they recommended incorporation this year.

We also considered alternative ways to account for operational costs when proposing the incorporation of phosphate binders. We considered basing the increased amount on the \$36.41 paid during TDAPA. We also considered not including an increased amount as some operational costs associated with furnishing oral drugs are already included in the ESRD PPS base rate. As discussed in section II.B.7. of this final rule, we are finalizing a recalculation of the operational increase based on more recent utilization and price data. We believe that this final policy strikes the appropriate balance by capturing the operational costs not already included in the ESRD PPS base rate while accounting for the efficiency of the ESRD PPS.

We note that our final base rate modification will cause a relatively uniform and significant increase in payments across all provider types, including small entities. As we have previously discussed, this increase in payments is partially offset by the projected decrease in TDAPA payments from CY 2026 to CY 2027. For small entities, including independent ESRD facilities, hospital-based ESRD facilities, and ESRD facilities furnishing fewer than 3,000 treatments per year, we estimate a net increase of between 4.3 and 4.5 percent in payments as a result of these changes. We believe this final significant increase will appropriately align payment with resource use for these small entities and therefore, we did not consider alternatives to minimize this final increase.

(b) Modifications to the LVPA

As discussed in section II.B.8. of this final rule, we are finalizing extending the LVPA beyond the current treatment volume threshold of 4,000 treatments per year in a budget neutral manner. We considered finalizing this policy non-budget neutrally but did not do so because budget neutrality for this policy is more consistent with our well-established methodologies. As discussed in section II.B.8. of this final rule, we finalized the 6-tier methodology based on our analysis of cost report data, consideration of responses to comments on our CY 2024 RFI on the LVPA, and consideration of comments we received on the CY 2027 ESRD PPS proposed rule.

We are finalizing an extension of the LVPA attestation deadline for payment year 2027 from November 1, 2026, to December 31, 2026. We considered, but are not finalizing, a delay in the implementation of the policy until CY 2028. These approaches both would have provided additional time for ESRD facilities to attest for the LVPA, however we believe that implementing the policy as soon as reasonably feasible is appropriate given our analyses, which indicate that certain ESRD facilities are receiving payments which may not align with relative resource use. Additionally, the estimates on the impact of the proposed payment modifications to the case-mix adjusters for pediatric ESRD patients included the impact of the expanded LVPA. We are concerned that delaying the expansion of the LVPA until CY 2028 could have negative impacts on the payments to pediatric ESRD patients which may not have been fully clear to commenters who evaluated that alternative. In making this decision, we considered the comments of commenters who supported both options.

We note that this final policy will have a positive impact on smaller ESRD facilities that furnish fewer than 8,000 treatments per year. For the smallest ESRD facilities that furnish fewer than 3,000 treatments per year, this increase is estimated to be approximately 2.6 percent. For independent and hospital-based ESRD facilities, we estimate an impact of 0.1 percentage point or less. We believe this final change to the LVPA will appropriately align payment with resource use for small entities and therefore, we did not consider alternatives to minimize the impact of the final increases for those categories of small entities that will be significantly impacted.

(c) Payment for Pediatric ESRD Patients

As discussed in section II.B.9. of this final rule, we are finalizing the recalculation of the case-mix adjustment factors for pediatric ESRD patients. We considered, but are not finalizing, an extension of the TPEAPA for a year

rather than establishing permanently increased adjustment factors effective for CY 2027. We considered this in concert with the previously mentioned delay to the effective date of the LVPA to CY 2028 so that the policy changes would become effective at the same time. Furthermore, we discussed in the proposed rule that we considered a TPEAPA extension so that we could have more time to collect and evaluate pediatric-specific cost report data. However, as noted in section II.B.9. of this final rule, we believe that we have enough information to establish permanent adjusters for CY 2027, and our evaluation of cost report data indicates that the final adjusters are appropriate.

For small entities, including independent ESRD facilities and hospital-based ESRD facilities, we note that the impact of these finalized policies is estimated to be 0.1 percentage point or less. For ESRD facilities furnishing fewer than 3,000 treatments per year, we estimate a 0.3 percentage point increase in payment. Therefore, we did not consider alternatives to mitigate the impact of this final increase on small entities.

(d) Modifications to the Home and Self-Dialysis Training Add-On

As discussed in section II.B.10. of this final rule, we are finalizing a reduction to the onset adjustment factor to account for the estimated training add-on payment adjustment during the onset period. This change will prevent duplicative payments during the onset period while maintaining budget neutrality for the expansion of the training add-on payment adjustment during the onset period. We considered not finalizing this reduction and instead finalizing a reduction to the base rate, which is what we proposed. However, after reviewing comments which raised concerns on the impact of the budget neutrality factor on the base rate and comments which raised methodological concerns with expanding the training add-on during the onset period without corresponding decreases to the onset

adjustment factor, we decided that a reduction to the onset factor was most appropriate.

For small entities, including independent ESRD facilities, hospital-based ESRD facilities, and ESRD facilities furnishing fewer than 3,000 treatments per year, we note that the impact of these finalized policies is estimated to be 0.1 percentage point or less and therefore, we did not consider alternatives to mitigate the impact of this final change on small entities.

c. Payment for Renal Dialysis Services Furnished to Individuals With AKI

(1) Effects on ESRD Facilities

To understand the impact of the final changes affecting Medicare payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated Medicare payments in CY 2026 to estimated Medicare payments in CY 2027. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the Medicare payment estimates in CY 2026 and CY 2027 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this final rule, we used CY 2025 data from the Medicare Part A and Part B Common Working Files as of July 31, 2026, as a basis for Medicare renal dialysis services furnished to individuals with AKI. We updated the 2025 claims to 2026 and 2027 using various updates. The final updates to the AKI dialysis payment amount are described in section III.C. of this final rule. Table 27 shows the impact of the estimated CY 2027 Medicare payments for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for renal dialysis services furnished to individuals with AKI in CY 2026.

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TABLE 31: Impacts of the Final Changes in Medicare Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2027

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Phosphate Binder Incorporation (C)	Combined Impact of Budget Neutral Proposals (Pediatrics and LVPA) (D)	Training Add-On (E)	Wage Index and LRS (F)	All Changes (G)
All Facilities	5,229	321.7	4.6%	-1.1%	0.0%	0.0%	5.3%
Type							
Freestanding	5,119	315.8	4.6%	-1.1%	0.0%	0.0%	5.3%
Hospital-based	110	5.9	4.6%	-1.1%	0.0%	-0.2%	5.2%
Ownership Type							
Large dialysis organization	4,279	245.3	4.6%	-1.1%	0.0%	-0.1%	5.3%
Regional chain	620	35.9	4.6%	-1.1%	0.0%	0.3%	5.7%
Independent	217	34.4	4.6%	-1.1%	0.0%	-0.1%	5.2%
Hospital-based ¹	110	5.9	4.6%	-1.1%	0.0%	-0.2%	5.2%
Unknown	3	0.2	4.6%	-1.1%	0.0%	1.6%	7.0%
Geographic Location							
Rural	858	45.4	4.6%	-1.1%	0.0%	-1.1%	4.2%
Urban	4,371	276.4	4.6%	-1.1%	0.0%	0.1%	5.5%
Census Region							
East North Central	829	56.5	4.6%	-1.1%	0.0%	-0.5%	4.9%
East South Central	385	18.3	4.6%	-1.1%	0.0%	-1.4%	3.9%
Middle Atlantic	571	40.9	4.6%	-1.1%	0.0%	0.1%	5.5%
Mountain	319	23.0	4.6%	-1.1%	0.0%	-0.9%	4.4%
New England	152	7.7	4.6%	-1.1%	0.0%	0.5%	5.9%
Pacific ²	690	50.6	4.6%	-1.1%	0.0%	2.3%	7.8%
Puerto Rico and Virgin Islands	6	0.1	4.6%	-1.1%	0.0%	-4.0%	1.1%
South Atlantic	1,253	73.4	4.6%	-1.1%	0.0%	-0.8%	4.6%
West North Central	328	16.5	4.6%	-1.1%	0.0%	-0.4%	4.9%
West South Central	696	34.7	4.6%	-1.1%	0.0%	-0.7%	4.6%
Facility Size							
Less than 3,000 treatments	178	5.9	4.6%	-1.1%	0.0%	-0.4%	5.0%
3,000 to 3,999 treatments	231	9.1	4.6%	-1.1%	0.0%	-0.4%	5.0%
4,000 to 4,999 treatments	309	14.2	4.6%	-1.1%	0.0%	-0.6%	4.7%
5,000 to 5,999 treatments	366	16.9	4.6%	-1.1%	0.0%	-0.7%	4.7%
6,000 to 6,999 treatments	463	23.0	4.6%	-1.1%	0.0%	-0.6%	4.8%
7,000 to 7,999 treatments	469	23.6	4.6%	-1.1%	0.0%	-0.4%	5.0%

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Phosphate Binder Incorporation (C)	Combined Impact of Budget Neutral Proposals (Pediatrics and LVPA) (D)	Training Add-On (E)	Wage Index and LRS (F)	All Changes (G)
8,000 or more treatments	3,213	229.1	4.6%	-1.1%	0.0%	0.1%	5.5%
Percentage of Pediatric Patients							
Less than 2%	5,207	320.9	4.6%	-1.1%	0.0%	0.0%	5.3%
Between 2% and 49%	21	0.8	4.6%	-1.1%	0.0%	-0.5%	4.9%
More than 50%	1	0.0	4.6%	-1.1%	0.0%	-1.5%	3.8%

¹ Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

² Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category, and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the final policy to increase the ESRD PPS base rate to incorporate payment for phosphate binders, which directly increases the AKI dialysis payment rate by approximately 4.6 percent. Column D shows the combined budget neutral impact associated with the final pediatric adjustment and LVPA changes, which do not apply to AKI dialysis payments, but which reduce the ESRD PPS base rate and by extension the AKI dialysis payment rate by approximately 1.1 percent. The main driver of this estimated decrease is the application of the budget neutrality factor of 0.98901 associated with the final changes to the LVPA. As we noted earlier in this rule, the final changes to pediatric payments result in a budget neutrality factor of 0.99999.

Column E shows the impact from the changes to the home dialysis training adjustment add-on, which have a 0.0 percentage point reduction to total payments and have small distributional impacts for the small number of AKI dialysis claims that include home dialysis training sessions. We note that the onset adjustment does not apply for AKI beneficiaries, so the change to allow home dialysis training payments during the onset period does not have any impact on this population, nor does the corresponding decrease to the onset adjustment factor. Column F shows the effect of the final CY 2027 wage index described in section II.B.2. of this final

rule as well as the increase to the LRS for CY 2027.

Column G shows the overall impact of all policies discussed in this final rule, including the final 1.9 percent ESRDB market basket update, which reflects the final ESRDB market basket percentage increase for CY 2027 of 2.9 percent reduced by the final productivity adjustment of 1.0 percentage point as well as the final incorporation of phosphate binders into the ESRD PPS base rate. We expect that overall ESRD facilities will experience a 5.4 percent increase in estimated Medicare payments in CY 2027 for treatment of AKI beneficiaries. The categories of types of ESRD facilities in the impact table show impacts ranging from an increase of 1.1 percent for ESRD facilities in Puerto Rico and the U.S. Virgin Islands to an increase of 7.8 percent for ESRD facilities in the Pacific Census Region in CY 2027 estimated Medicare payments for renal dialysis services provided by ESRD facilities to individuals with AKI.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are finalizing updates to the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two types of Medicare providers and suppliers authorized to furnish these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this final change will have zero impact on other types of Medicare providers.

(3) Effects on the Medicare Program

We estimate that approximately \$95 million in total payments will be paid to ESRD facilities in CY 2027 because of patients with AKI receiving renal dialysis services in an ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

(4) Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent coinsurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients will continue to be responsible for 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we expect beneficiaries to pay less coinsurance when AKI dialysis is furnished by ESRD facilities.

(5) Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI dialysis payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. Similarly, we considered applying other facility-level or case-mix adjustment factors, for example the LVPA with the changes finalized in this rule. As with past adjustments, we ultimately determined that treatment for AKI is substantially different from

treatment for ESRD, and the case-mix and facility-level adjustments applied to ESRD patients may not be applicable to AKI patients, and as such, including those policies and adjustments is inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring will assist us in developing knowledgeable, data-driven proposals.

d. ESRD QIP

(1) Effects of the PY 2029 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to promote improvements in the quality of ESRD

dialysis facility services provided to beneficiaries. The general methodology that we use to calculate a facility's Total Performance Score (TPS) is described in our regulations at § 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2029 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2029, consistent with our regulations at § 413.177.

For the PY 2029 ESRD QIP, we estimate that, of the 7,551 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 37.1 percent or 2,802 of the facilities

will receive a payment reduction for PY 2029. Among an estimated 2,802 facilities that will receive a payment reduction, approximately 57.2 percent or 1,603 facilities will receive the smallest payment reduction of 0.5 percent. Based on our proposals finalized in this rule, the total estimated payment reductions for all the 2,802 facilities expected to receive a payment reduction in PY 2029 will be approximately \$18,726,589. Facilities that do not receive a TPS do not receive a payment reduction.

Table 32 shows the overall estimated distribution of payment reductions resulting from the PY 2029 ESRD QIP.

TABLE 32: Estimated Distribution of PY 2029 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	4609	62.2%
0.5%	1603	21.6%
1.0%	839	11.3%
1.5%	283	3.8%
2.0%	77	1.0%

* 140 facilities not scored due to insufficient data

To estimate whether a facility will receive a payment reduction for PY 2029, we scored each facility on achievement and improvement on several clinical measures for which

there were available data from EQRS and Medicare claims. Payment reduction estimates (specified in Table 32) were calculated using the most recent data available in accordance with

the proposals finalized in this final rule. Measures and time periods used for the simulation are shown in Table 33.

TABLE 33: Data Used to Update the Estimate of the PY 2029 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2024-Dec 2024	Jan 2025-Dec 2025
SRR	Jan 2024-Dec 2024	Jan 2025-Dec 2025
SHR	Jan 2024-Dec 2024	Jan 2025-Dec 2025
PPPW	Jan 2024-Dec 2024	Jan 2025-Dec 2025
Kt/V Dialysis Adequacy Measure Topic		
Adult HD Kt/V	Jan 2024-Dec 2024	Jan 2025-Dec 2025
Pediatric HD Kt/V	Jan 2024-Dec 2024	Jan 2025-Dec 2025
Adult PD Kt/V	Jan 2024-Dec 2024	Jan 2025-Dec 2025
Pediatric PD Kt/V	Jan 2024-Dec 2024	Jan 2025-Dec 2025
VAT Long-term Catheter Rate	Jan 2024-Dec 2024	Jan 2025-Dec 2025
STrR	Jan 2024-Dec 2024	Jan 2025-Dec 2025
NHSN BSI	Jan 2024-Dec 2024	Jan 2025-Dec 2025
Clinical Depression	Jan 2024-Dec 2024	Jan 2025-Dec 2025
Hyperphosphatemia	Jan 2024-Dec 2024	Jan 2025-Dec 2025

For all measures except the SHR clinical measure, the SRR clinical measure, the STrR measure, and the ICH CAHPS measure, measures with less than 11 eligible patients for a facility were not included in that facility’s TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility’s TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility’s TPS. For the ICH CAHPS measure, facilities were required to have at least 30 survey-eligible patients to be included in the

facility’s TPS. Each facility’s TPS was compared to an estimated mTPS and an estimated payment reduction table consistent with the finalized policies outlined in section IV.B. of this final rule. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2029 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2025 and December 2025 by the facility’s estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 34 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2029. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2029 ESRD QIP, the actual impact of the PY 2029 ESRD QIP may vary significantly from the values provided here.

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TABLE 34: Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2029

	Number of Facilities	Number of Medicare Treatments 2025 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7551	23.6	7411	2802	-0.30%
Facility Type:					
Freestanding	7225	22.8	7132	2704	-0.30%
Hospital-based	326	0.8	279	98	-0.28%
Ownership Type:					
Large Dialysis	5817	18.4	5777	2111	-0.27%
Regional Chain	883	2.9	870	290	-0.27%
Independent	484	1.5	457	293	-0.70%
Hospital-based (non-chain)	326	0.8	279	98	-0.28%
Unknown	41	0.0	28	10	-0.27%
Facility Size:					
Large Entities	6700	21.3	6647	2401	-0.27%
Small Entities ¹	810	2.3	736	391	-0.54%
Unknown	41	0.0	28	10	-0.27%
Rural Status:					
1) Yes	1222	3.2	1190	428	-0.27%
2) No	6329	20.4	6221	2374	-0.31%
Census Region:					
Northeast	1042	3.9	1017	346	-0.26%
Midwest	1628	4.4	1587	636	-0.33%
South	3432	9.3	3382	1402	-0.33%
West	1386	5.8	1363	392	-0.21%
US Territories ²	63	0.2	62	26	-0.25%
Census Division:					
East North Central	1161	3.1	1131	480	-0.35%
East South Central	592	1.4	585	214	-0.29%
Middle Atlantic	844	3.0	823	294	-0.29%
Mountain	425	1.4	421	125	-0.21%
New England	198	0.9	194	52	-0.17%
Pacific	961	4.4	942	267	-0.21%
South Atlantic	1773	4.9	1742	770	-0.36%
West North Central	467	1.3	456	156	-0.28%
West South Central	1067	3.0	1055	418	-0.32%
US Territories ²	63	0.2	62	26	-0.25%
Facility Size (# of total treatments)					
Less than 3,000 treatments	655	0.6	550	151	-0.25%
3,000-3,999 treatments	440	0.7	434	132	-0.26%
4,000-4,999 treatments	493	0.8	483	176	-0.29%
5,000-5,999 treatments	586	1.1	581	200	-0.28%
6,000-6,999 treatments	625	1.4	621	206	-0.28%
7,000-7,999 treatments	609	1.5	607	253	-0.33%
8,000 or more treatments	4143	17.5	4135	1684	-0.31%

¹ Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.² Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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(2) Effects on the Medicare Program
For PY 2029, we estimate that the ESRD QIP will contribute approximately \$18,726,589 in Medicare savings. For comparison, Table 35 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2029.

TABLE 35: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2029

Payment Year	Estimated Payment Reductions
PY 2029	\$18,726,589
PY 2028	\$20,624,345 (90 FR 53134)
PY 2027	\$21,652,956 (90 FR 53134)
PY 2026	\$15,990,524 (88 FR 76500)
PY 2025	\$32,457,693 (87 FR 67297)
PY 2024	\$17,104,031 (86 FR 62011)
PY 2023	\$5,548,653 (87 FR 67297)
PY 2022	\$0 (86 FR 62011)
PY 2021	\$32,196,724 (83 FR 57062)
PY 2020	\$31,581,441 (81 FR 77960)
PY 2019	\$15,470,309 (80 FR 69074)
PY 2018	\$11,576,214 (79 FR 66257)

(3) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program’s inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We continue to monitor and evaluate trends in the quality and cost

of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more by examining these impacts through the analysis of available data from our existing measures.

(4) Alternatives Considered

In section IV.B.2. of this final rule, we are finalizing replacing the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure beginning with PY 2029. We considered retaining the Hypercalcemia measure in the ESRD QIP. However, we believe removal is appropriate because the Hyperphosphatemia clinical measure captures a related clinical

concept while reducing reporting burden and improving alignment with clinical care priorities. We believe adoption of the Hyperphosphatemia measure in its place is appropriate because it addresses an important clinical outcome associated with dialysis care and aligns the ESRD QIP with current clinical priorities related to mineral and bone disease management among dialysis patients.

D. Accounting Statement

Consistent with OMB Circular A–4 (available at <https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf>), we have prepared an accounting statement in Table 36 showing the classification of the impact associated with the provisions of this final rule.

TABLE 36: Accounting Statement: Classification of Estimated Transfers, and Costs

ESRD PPS and AKI (CY 2027)	
Category	Primary Estimate
Annualized Monetized Transfers	\$195 million
From Whom To Whom	Federal Government To ESRD Facilities
Category	Primary Estimate
Increased Beneficiary Co-insurance Payments	\$50 million
From Whom To Whom	Beneficiaries To ESRD Facilities
ESRD QIP for PY 2029	
Category	Primary Estimate
Annualized Monetized Transfers	-\$18.7 million
From Whom To Whom	Federal Government To ESRD Facilities
Category	Primary Estimate
Annualized Monetized Costs (Reduction in Burden Associated with Measure Updates	-\$12.6 million

E. Regulatory Flexibility Act (RFA)

The RFA requires agencies to evaluate alternatives that may reduce regulatory burden on small entities when a rule is expected to have a significant impact on a substantial number of small entities. This section presents a detailed analysis of the anticipated effects of this final rule on small entities. Overall, this final rule includes final updates to the ESRD QIP, as well as final revisions to payment rates and policies applicable to the ESRD PPS and AKI dialysis payment. These final changes are expected to have a significant positive impact on small entities. The anticipated benefits are primarily attributable to projected cost savings and increases in payments, as discussed in the sections that follow.

For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. This final rule will likely impact ESRD facilities, which are classified under NAICS category 621492, Kidney Dialysis Centers. There could also be impacts to hospitals that operate a hospital-based ESRD facility, including NAICS category 622110, hospitals, and NAICS category 622310, specialty hospitals (which can include children's hospitals). We focused our analysis on Kidney Dialysis Centers (NAICS category 621492), because we generally believe that hospital-based ESRD facilities make up

only a portion of a hospital's revenues and therefore payment updates finalized in this rule will not have significant impact on hospitals overall.

Furthermore, as shown in Table 30, we estimate that payments to hospital-based ESRD facilities will increase by approximately 2.7 percent overall, and payments to ESRD facilities with more than 50 percent pediatric patients, which are more likely to be owned by children's hospitals, will increase by approximately 6.1 percent.

We also do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity. Therefore, the number of small entities estimated in this RFA analysis includes the number of ESRD facilities that are either considered small businesses or nonprofit organizations.

According to the Small Business Administration's (SBA) March 2023 size standards, an ESRD facility (NAICS code 621492) is classified as a small business if it has average revenues of less than \$47 million across the past 5 years.¹¹¹ The U.S. Census Statistics of U.S. Businesses (SUSB) data shows there are 459 firms below this threshold.

As shown in Table 37, approximately 459 ESRD facilities, at the firm level, can be considered small according to

the SBA. As we stated earlier, the SBA defines small ESRD facilities (firms) as businesses having less than \$47 million in total annual revenue. According to the U.S. Census, a firm is a legal entity or parent company that owns and operates the business, or ESRD facility, in this case. Therefore, Table 37 only reflects data at the firm level and not at the establishment level, where multiple establishments could be owned by a firm. However, we note that according to the SUSB data, the 459 firms identified as small kidney dialysis centers in Table 37 account for 589 establishments, and no firm under \$2.5 million in annual revenue has more than 1 establishment.

HHS uses a change in revenue of more than 3 to 5 percent as its measure of significant economic impact on small entities. The agency considers the rule to have a significant impact on a substantial number of small businesses when more than 5 percent of impacted small entities meet the significant impact threshold defined previously.

As shown in Table 37, the impact of the finalized QIP measure changes in this rule will result in a cost savings impact of 3.5 percent for the smallest category of ESRD facilities, which comprise approximately 7.8 percent of small firms. For all other categories the changes have an impact that falls below the 3 to 5 percent threshold.

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¹¹¹ <https://legacy.sba.gov/document/support-table-size-standards>.

TABLE 37: (NAICS 621492) ESRD Facilities Impacts On Small Entities

Firm Size (by Receipts)	Avg. Annual Revenue	Firm Count	Annualized Cost Savings per Firm	% of Small Firms	Revenue Test
All Kidney Dialysis Centers	\$57,952,874	507	\$1,636	N/A	0.0%
Large Kidney Dialysis Centers	\$579,653,354	48	\$1,636	N/A	0.0%
Small Kidney Dialysis Centers	\$3,395,961	459	\$1,636	100%	0.0%
<100,000	\$46,055	36	\$1,636	7.8%	3.5%
100,000- 499,999	\$309,604	91	\$1,636	19.8%	0.5%
500,000- 999,999	\$770,338	65	\$1,636	14.2%	0.2%
1,000,000- 2,499,999	\$1,635,250	112	\$1,636	24.4 %	0.1%
2,500,000- 4,999,999	\$3,709,628	70	\$1,636	15.3 %	0.0%
5,000,000- 7,499,999	\$6,270,675	37	\$1,636	8.1%	0.0%
7,500,000- 9,999,999	\$8,409,545	11	\$1,636	2.4%	0.0%
10,000,000- 14,999,999	\$11,228,363	11	\$1,636	2.4%	0.0%
15,000,000- 19,999,999	\$16,243,333	9	\$1,636	2.0%	0.0%
20,000,000- 24,999,999	\$15,160,250	4	\$1,636	0.9%	0.0%
25,000,000- 29,999,999	\$27,083,333	3	\$1,636	0.7%	0.0%
30,000,000- 34,999,999	\$22,241,000	4	\$1,636	0.9%	0.0%
35,000,000- 39,999,999	\$35,356,333	3	\$1,636	0.7%	0.0%
40,000,000- 49,999,999	\$34,958,000	4	\$1,636	0.9%	0.0%

Source: US Census 2022 SUBS.

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We also considered the impacts of changes in transfers due to final payment policy changes in this final rule. For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by large dialysis organizations (LDOs) and regional chains, which will have total revenues of more than \$6.5 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because

we lack data on individual ESRD facilities' receipts, we applied a different analytic framework to identify ESRD facilities that are likely small businesses and to assess the impact of payment policy changes on those entities. Accordingly, we consider the 500 ESRD facilities that are independent and 332 ESRD facilities that are hospital-based, as shown in the ownership category in Table 30, to be small businesses. These ESRD facilities

represent approximately 11 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 766 ESRD facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 353 nonprofit ESRD facilities that are also considered small businesses, there are 1,245 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately

16 percent of all ESRD facilities in our data set.

As we noted earlier in this final rule, HHS's practice in interpreting the RFA is to consider effects economically "significant" on a "substantial" number of small entities only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. As shown in Table 30, we estimate that the overall revenue impact of this final rule on all ESRD facilities is a positive increase to Medicare FFS payments by approximately 2.7 percent. For the ESRD PPS updates finalized in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 2.7 percent increase in Medicare FFS payments for CY 2027. An independent facility (as defined by ownership type) is likewise estimated to receive a 6.2 percent increase in Medicare FFS payments for CY 2027. Although not displayed in Table 30, we have found that among the 832 ESRD facilities that are small businesses, approximately 28.7 percent (239 out of 832) furnish fewer than 3,000 treatments per year. These ESRD facilities are estimated to receive a 7.8 percent increase in Medicare FFS payments. By contrast, those furnishing 3,000 or more treatments per year are estimated to receive a 4.7 percent increase in Medicare FFS payments. Additionally, among the 766 nonprofit ESRD facilities, approximately 18.4 percent (141 out of 766) furnish fewer than 3,000 treatments per year. These ESRD facilities are estimated to receive an 8.5 percent increase in Medicare FFS payments. By contrast, those furnishing 3,000 or more treatments per year are estimated to receive a 2.7 percent increase in Medicare FFS payments. For AKI dialysis, we are unable to estimate whether patients will go to certain types of ESRD facilities, however, we have estimated there is a potential for \$95 million in total CY 2027 payments for AKI dialysis treatments that could potentially be furnished in ESRD facilities that are small businesses or nonprofits.

Based on the estimated Medicare payment impacts described previously, we believe that the change in revenue threshold will be reached by some categories of small entities as a result of the policies in this final rule. This analysis is based on the assumptions described earlier in section VII.C of this final rule, which includes a discussion of data sources, general assumptions, and alternatives considered.

For the ESRD QIP, we estimate that of the 2,802 ESRD facilities expected to receive a payment reduction as a result

of their performance on the PY 2029 ESRD QIP, 391 are ESRD small entity facilities. As shown in Table 32 ("Estimated Distribution of PY 2029 ESRD QIP Payment Reductions"), the maximum ESRD QIP payment reduction is 2.0 percent. Therefore, none of the 391 small entity facilities expected to receive a PY 2029 ESRD QIP payment reduction would experience a reduction attributable to the ESRD QIP that reaches the 3 to 5 percent threshold HHS uses to assess significant economic impact. Table 34 ("Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2029") shows the updated estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2029 and also details the distribution of ESRD facilities by size, geography, and facility type.

Therefore, the Secretary has determined that the final policies in this rule are expected to have a significant positive economic impact on a substantial number of small entities, primarily through increased revenues associated with the final ESRD PPS base rate increase. In addition, the final updates to the ESRD QIP are expected to generate cost savings for small entities. As discussed in section VII.C.5.a.(5) of this CY 2027 ESRD PPS final rule, CMS considered alternative policy approaches to minimize the impact of this final rule on small entities. However, CMS did not finalize these alternatives, because the final policies are expected to more appropriately align payments with resource utilization in CY 2027. This RFA section, together with the RIA, constitutes our Initial Regulatory Flexibility Analysis. We did not receive any comments from small business interests in response to the analysis presented in the proposed rule.

In addition, section 1102(b) of the Act requires the preparation of a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not anticipate that this final rule will have a significant adverse impact on a substantial number of small rural hospitals, as the majority of dialysis facilities operate as freestanding entities. Although there are 111 rural hospital-based ESRD facilities, we do not have sufficient information to determine how many of these ESRD facilities are affiliated with hospitals

that have fewer than 100 beds. Nevertheless, the 111 rural hospital-based ESRD facilities are projected to experience an average payment increase of 4.7 percent under this final rule. Accordingly, the Secretary has determined that the final rule is expected to have a significant positive impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately \$193 million. We do not interpret Medicare payment rules as being unfunded mandates but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, State, local, or Tribal. Therefore, this final rule does not mandate any requirements for State, local, or Tribal governments, or for the private sector.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of State, local, or Tribal government.

H. Executive Order 14192, "Unleashing Prosperity Through Deregulation"

Executive Order 14192, entitled "Unleashing Prosperity Through Deregulation," was issued on January 31, 2025. The Executive Order requires that, to the extent permitted by law, "any new incremental costs associated with new regulations shall be offset by the elimination of existing costs associated with at least 10 prior regulations." This final rule is expected to constitute a deregulatory action under Executive Order 14192. We estimate that the rule will result in approximately \$8.74 million in annualized cost savings, calculated

using a 7 percent discount rate and discounted to 2024, over a perpetual time horizon.

I. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

VIII. Files Available to the Public

The Addenda for the annual ESRD PPS proposed and final rule will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and will be posted on CMS's website under the regulation number, CMS-1846-F, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>. In addition to the Addenda, limited data set files (LDS) are available for purchase at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile>. Readers who experience any problems accessing the Addenda or LDS files should contact CMS by sending an email to CMS at the following mailbox: ESRDPayment@cms.hhs.gov.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 23, 2026.

List of Subjects in Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 413 as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

- 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395www.

- 2. Section 413.232 is amended by—

- a. Revising paragraphs (b)(1), (c) introductory text, (e)(3), and (4);
- b. Adding paragraph (e)(5);
- c. Revising paragraphs (f), (g)(5), and (g)(6)(i), (ii), and (iv); and
- d. Adding paragraph (g)(7).

The revisions and additions read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) * * *

(1) Furnished fewer than 8,000 total treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraphs (g)(4) and (5) of this section) preceding the payment year; and

* * * * *

(c) For the purpose of determining the number of treatments under paragraph (b)(1) of this section, except as specified at paragraph (g)(7) of this section, the number of treatments considered furnished by the ESRD facility shall equal the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both:

* * * * *

(e) * * *

(3) For payment year 2016, the attestation must be provided by December 31, 2015;

(4) For payment year 2021, the attestation must be provided by December 31, 2020; and

(5) For payment year 2027, the attestation must be provided by December 31, 2026.

(f) The low-volume adjustment applies for dialysis treatments provided to all ESRD patients.

(g) * * *

(5) For payment year 2024 and subsequent payment years, an ESRD facility may attest in the attestation specified in paragraph (e) of this section that it would have met the requirements of paragraph (b)(1) of this section, except that for one or more of the most recent 3 cost reporting years the facility furnished 8,000 or more treatments because of temporary patient-shifting as a result of the closure or operational disruption of another ESRD facility due to a disaster or other emergency. For the purposes of the exception in this paragraph (g)(5), temporary patient-shifting is defined as providing renal dialysis services to one or more displaced patient(s) at any time through the end of the CY following the 12-month period beginning when an ESRD facility first begins providing renal

dialysis services to one or more displaced patients. For any facility that so attests—

(i) The facility must also attest that it furnished treatments equal to or in excess of 8,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(ii) The facility must request an exception under this paragraph (g)(5) from CMS, in the form and manner specified by CMS, no later than the attestation deadline specified in paragraph (e) of this section or 30 calendar days after the end of the cost reporting year, whichever is later, for each cost reporting year that the facility furnishes treatments equal to or in excess of 8,000 due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(iii) Within 30 calendar days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility furnished treatments equal to or in excess of 8,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency, or deny the request, and will notify the facility and the MAC of its decision;

(iv) If CMS approves the request, the ESRD facility is paid the low-volume adjustment on claims for Medicare beneficiaries, on the basis of the exception in this paragraph (g)(5), during the payment year in which the temporary patient-shifting occurred, so long as all other requirements for the low-volume adjustment are met. For any future payment year, the ESRD facility would not be prevented from receiving the low-volume adjustment if the ESRD facility meets or exceeds the 8,000 treatment threshold in a cost reporting year due to temporary patient-shifting as a result of the disaster or other emergency that resulted in another ESRD facility's closure or operational disruption, so long as all other requirements for the low-volume adjustment are met; and

(v) The facility must maintain documentation of the number of displaced patients treated and information about the ESRD facility or facilities that closed or experienced operational disruptions due to a disaster or other emergency and previously treated those patients, and must provide such supporting documentation to CMS and the MAC upon request.

(6) * * *

(i) The ESRD facility would need to request such an exception from CMS, in the form and manner specified by CMS, within 60 calendar days of the facility's closure, and the ESRD facility must inform the MAC of this request in writing;

(ii) Within 30 calendar days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility closed due to a disaster or other emergency, or deny the request, and will inform both the facility and the MAC of its decision; and

* * * * *

(iv) The ESRD facility that attests under this paragraph (g)(6) to have closed due to a disaster or other emergency would need to notify CMS and the MAC, in the form and manner specified by CMS, within 30 calendar days of reopening and providing renal dialysis services. Within 30 calendar days of CMS's receipt of the facility's notification, CMS will confirm receipt to the facility and the MAC of the facility's notification and the ESRD facility will be able to receive the low-volume adjustment as of the date of reopening, so long as all other requirements for the low-volume adjustment are met.

* * * * *

(7) ESRD facilities that are children's hospitals, as defined at § 412.23(d), or that furnish more than 50 percent of treatments (Medicare and non-Medicare) to Pediatric ESRD Patients, may request an exception to the aggregation of number of treatments in paragraph (c) of this section.

(i) The ESRD facility must attest that it is either owned and operated by a Medicare-certified children's hospital, as defined at § 412.23(d), or the ESRD facility provides at least 50 percent of its total treatments (Medicare and non-Medicare) to Pediatric ESRD Patients and that it is under common ownership, as defined in paragraph (d) of this section, with one or more ESRD facilities that do not furnish at least 50 percent of its total treatments to Pediatric ESRD Patients;

(ii) The facility must request an exception under this paragraph (g)(7) from CMS, in the form and manner specified by CMS, no later than the attestation deadline specified in paragraph (e) of this section or 30 calendar days after the end of the cost reporting year, whichever is later;

(iii) Within 60 calendar days of CMS's receipt of the facility's request, CMS will review the request and either

approve or deny the request based on a determination of whether the ESRD facility meets the requirements of paragraph (g)(7)(i) of this section, and will notify the facility and the MAC of its decision;

(iv) If CMS approves the request, the ESRD facility's number of treatments, for the purposes of the low-volume adjustment, would not be aggregated with the number of treatments of the commonly-owned facility for which the exception has been granted, on the basis of the exception in this paragraph (g)(7), for all future payment years, so long as the ESRD facility remains a children's hospital or furnishes more than 50 percent of treatments to Pediatric ESRD Patients. To receive the low-volume adjustment the ESRD facility must continue to satisfy all other requirements. Approval of an exception under this paragraph (g)(7) applies only to the ESRD facility for which the exception is granted and does not affect the aggregation of treatment volume for any other commonly-owned ESRD facility; and

(v) The facility must maintain documentation of the number of total treatments and pediatric treatments which it provides and must provide such supporting documentation to CMS and the MAC upon request.

* * * * *

■ 3. Section 413.234 is amended by—

■ a. Revising paragraphs (c) introductory text, (c)(3), and (g)(1) and (2); and

■ b. Adding paragraph (h).

The revisions and addition read as follows:

§ 413.234 Drug designation process.

* * * * *

(c) *Transitional drug add-on payment adjustment.* A new renal dialysis drug or biological product is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of average sales price (ASP), except as provided in paragraph (c)(4) of this section. If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of the wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. If CMS receives negative or zero ASP data for a new renal dialysis drug or biological product after receiving positive ASP data in a previous quarter, the transitional drug add-on payment adjustment would be based on the most recent positive ASP amount carried forward from a previous quarter. Notwithstanding the provisions in paragraphs (c)(1) and (2) of this

section, if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after we begin applying the transitional drug add-on payment adjustment for the product, CMS will no longer apply the transitional drug add-on payment adjustment for that product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. If CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable time period specified in paragraphs (c)(1) or (2) of this section, CMS will no longer apply the transitional drug add-on payment adjustment for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

* * * * *

(3) For any new renal dialysis drug or biological product that is eligible for payment using the transitional drug add-on payment adjustment described in paragraphs (b)(1)(iii) and (c)(1) of this section, CMS applies a post-TDAPA add-on payment adjustment to all ESRD PPS claims that is calculated using the methodology set forth in paragraph (g) of this section. CMS will apply the post-TDAPA add-on payment adjustment beginning 8 calendar quarters after the first calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product and ending 12 calendar quarters after the end of the last calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product. If CMS stops receiving the latest full calendar quarter of ASP data for the applicable renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) of this section or during the 3-year period following such applicable time period, CMS will not pay any post-TDAPA add-on payment adjustment for such product in any future quarter.

* * * * *

(g) * * *

(1) CMS bases the calculation on the most recent 12-month period of utilization for the new renal dialysis drug or biological product and the most recent available full calendar quarter of ASP data. If the most recent full calendar quarter of ASP data reflects zero or negative sales, then the calculation is based on 100 percent of the most recent positive ASP amount from a previous quarter; if there is no

previous quarter of positive ASP data, then the calculation is based on 100 percent of WAC; and, if WAC is not available, the payment is based on the drug manufacturer's invoice.

(2) CMS calculates the post-TDAPA add-on payment adjustment quarterly as the expenditure for the new renal dialysis drug or biological product divided by the total number of ESRD PPS treatments during the same period.

* * * * *

(h) *Methodology for modifying the ESRD PPS base rate to account for the costs of phosphate binders in the ESRD PPS bundled payment.* For dates of service on or after January 1, 2027, payment for phosphate binders is included in the ESRD PPS base rate using the following data sources and methodology:

(1) The methodology specified in paragraph (h)(2) of this section for determining the average per treatment payment amount for phosphate binders that is added to the ESRD PPS base rate uses the following data sources:

(i) Total units of phosphate binders and total number of paid hemodialysis-equivalent dialysis treatments furnished, as derived from Medicare ESRD facility claims (the 837-institutional form with bill type 072X) for the second, third, and fourth

quarters of calendar year 2025 and for the first and second quarters of calendar year 2026.

(ii) The weighted average ASP based on the most recent determinations by CMS.

(2) CMS uses the following methodology to calculate the average per treatment payment amount for phosphate binders that is added to the ESRD PPS base rate:

(i) Determines utilization of each phosphate binder by aggregating the total units of phosphate binders from the claims data described in paragraph (h)(1)(i) of this section.

(ii) Determines a price for each phosphate binder by calculating 100 percent of the value from the most recent calendar quarter ASP calculations available to the public for each HCPCS code describing phosphate binders.

(iii) Calculates the total phosphate binder expenditure amount by multiplying the utilization of each phosphate binder determined in paragraph (h)(2)(i) of this section by their respective prices determined in paragraph (h)(2)(ii) of this section and summing the expenditure amounts across all phosphate binder products.

(iv) Calculates an adjusted phosphate binder expenditure amount that

accounts for operational cost expenditures associated with furnishing phosphate binders by increasing the total phosphate binder expenditure amount determined in paragraph (h)(2)(iii) of this section by 6 percent of the total phosphate binder expenditure amount.

(v) Calculates the average per treatment payment amount by dividing the adjusted phosphate binder expenditure amount determined in paragraph (h)(2)(iv) of this section by the total number of paid hemodialysis-equivalent dialysis treatments during the same period described in paragraph (h)(1)(i) of this section.

(vi) Calculates the amount added to the ESRD PPS base rate by reducing the average per treatment payment amount determined in paragraph (h)(2)(v) of this section by 1 percent to account for the outlier policy under § 413.237.

(3) Phosphate binders will be eligible ESRD outlier services under § 413.237 beginning January 1, 2027.

Robert F. Kennedy, Jr.,
Secretary, Department of Health and Human Services.

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Part IV

The President

Proclamation 11076—Further Modifying the Scope of Products of Canada
Subject to the Additional Duties Imposed To Offset Canadian
Discrimination Against the Commerce of the United States With Respect to
Motor Vehicles

Presidential Documents

Title 3—

Proclamation 11076 of October 23, 2026

The President

Further Modifying the Scope of Products of Canada Subject to the Additional Duties Imposed To Offset Canadian Discrimination Against the Commerce of the United States With Respect to Motor Vehicles

By the President of the United States of America

A Proclamation

1. In Proclamation 11048 of July 20, 2026 (Imposing Additional Duties To Offset Canadian Discrimination Against the Commerce of the United States With Respect to Motor Vehicles), I found as a fact that Canada is discriminating in fact against the commerce of the United States through Canada's motor vehicle tariff scheme; that this discrimination places the commerce of the United States at a disadvantage compared to the commerce of other countries; and that Canada's imposition is unreasonable, is not equally enforced upon the like articles of every foreign country, and places a burden on the commerce of the United States. To offset the burden or disadvantage on U.S. commerce from Canada's discrimination or unreasonable and unequal imposition on U.S. auto and auto parts exports, I imposed under section 338 of the Tariff Act of 1930 (19 U.S.C. 1338) (section 338) additional *ad valorem* duties, effective August 19, 2026, on certain products of Canada.

2. In Proclamation 11056 of August 18, 2026 (Temporary Suspension of Additional Duties To Offset Canadian Discrimination Against the Commerce of the United States With Respect to Alcoholic Beverages, Dairy, and Motor Vehicles), I temporarily suspended for 3 days the effective date of the additional *ad valorem* duties imposed under Proclamation 11048 after Canada expressed a commitment to remove the discrimination or unreasonable and unequal imposition at issue in Proclamation 11048.

3. On August 21, 2026, Canada reneged on its commitment, ceased negotiating in good faith, and did not remove the discrimination or unreasonable and unequal imposition at issue in Proclamation 11048.

4. Accordingly, at 12:01 a.m. eastern time on August 22, 2026, the 3-day suspension imposed by Proclamation 11056 lapsed, and the additional *ad valorem* duties imposed under Proclamation 11048 became effective.

5. In Proclamation 11065 of September 8, 2026 (Modifying the Scope of Products of Canada Subject to the Additional Duties Imposed To Offset Canadian Discrimination Against the Commerce of the United States With Respect to Motor Vehicles), I modified the duties imposed under Proclamation 11048 after receiving certain information, opinions, and recommendations from senior executive branch officials to continue offsetting the burden or disadvantage on U.S. commerce and better serve the public interest.

6. I have received certain additional information, opinions, and recommendations from senior executive branch officials on the status of the circumstances involved in Proclamation 11048 and the effect of the additional *ad valorem* duties imposed in Proclamation 11048, as amended, including how effectively those duties are offsetting the burden or disadvantage on U.S. commerce. According to senior executive branch officials, although the additional *ad valorem* duties imposed in Proclamation 11048, as amended, offset the burden or disadvantage on U.S. commerce, modifying the scope of products

subject to the additional *ad valorem* duties imposed in Proclamation 11048, as amended, would still offset the burden or disadvantage on U.S. commerce and better serve the public interest. In my senior executive branch officials' opinion, modifying the scope of products subject to the additional *ad valorem* duties imposed in Proclamation 11048, as amended, is required by the public interests and is consistent with the interests of the United States.

7. After considering the information, opinions, and recommendations that have been provided to me by senior executive branch officials, among other relevant information and considerations, I determine that the public interests require modifying the scope of products subject to the additional *ad valorem* duties imposed in Proclamation 11048, as amended.

8. In my judgment, the modification in this proclamation will offset the burden or disadvantage on U.S. commerce, is consistent with the public interests and the interests of the United States, is required by the public interests, and will better serve the public interest.

9. Section 338 authorizes the President, if he determines it will serve the public interest, to offset any burden or disadvantage placed on the commerce of the United States by an unequal imposition or discrimination by a foreign country by specifying and declaring additional duties not to exceed 50 percent *ad valorem* (or its equivalent) and not to take effect earlier than 30 days after the President's proclamation finding that a foreign country is imposing an unreasonable charge, exaction, regulation, or limitation that is not equally enforced on the like articles of every foreign country, or discriminates in fact against U.S. commerce in a way that places the commerce of the United States at a disadvantage compared to the commerce of any foreign country. Section 338 also authorizes the President to suspend, revoke, supplement, or amend any proclamation under section 338 whenever the President deems that the public interests require such action. Further, section 338 authorizes the President to exclude from importation articles of the foreign country if the foreign country maintains or increases the discrimination against the commerce of the United States and the President deems the exclusion to be consistent with the public interests and the interests of the United States.

10. Section 604 of the Trade Act of 1974, as amended (19 U.S.C. 2483) (section 604), authorizes the President to embody in the Harmonized Tariff Schedule of the United States (HTSUS) the substance of statutes affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States, including section 338; section 301 of title 3, United States Code; and section 604, do hereby proclaim as follows:

(1) Except as otherwise provided in this proclamation, certain products of Canada, as set forth in Annex I, Part A to this proclamation, imported into the United States shall no longer be subject to the additional *ad valorem* duty of 50 percent imposed pursuant to Proclamation 11048, as amended. In addition, certain products of Canada, as set forth in Annex I, Part B to this proclamation, imported into the United States shall be subject to the additional *ad valorem* duty of 50 percent imposed pursuant to Proclamation 11048, as amended. The duties imposed pursuant to Proclamation 11048, as amended, and as modified in this proclamation, shall apply in addition to duties imposed pursuant to section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862). These changes shall be effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern time on October 30, 2026.

(2) The HTSUS is modified as provided in Annex II to this proclamation, effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern time on October 30, 2026, and the modifications shall continue in effect unless this action is expressly suspended, revoked, supplemented, amended, or terminated.

(3) The head of each executive department and agency (agency) is authorized to and shall take all appropriate measures within the agency's authority to implement this proclamation. The head of each agency may, consistent with applicable law, including section 301 of title 3, United States Code, redelegate the authority to take such appropriate measures within the agency.

(4) The Commissioner of U.S. Customs and Border Protection (CBP), in consultation with the Secretary of the Treasury, the Secretary of Commerce, and the United States Trade Representative, is authorized to issue such rules, regulations, guidance, instructions, or determinations as may be necessary to implement this proclamation and is authorized to take any necessary measures to administer this proclamation.

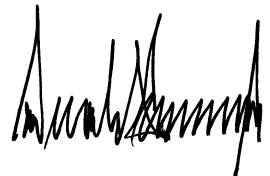
(5) The Commissioner of CBP, in consultation with the Secretary of the Treasury, the Secretary of Commerce, the United States Trade Representative, the Chairman of the United States International Trade Commission, and any other senior executive branch official the Commissioner of CBP deems appropriate, shall determine whether any additional modifications to the HTSUS are necessary to effectuate this proclamation and shall make such modifications to the HTSUS through notice in the *Federal Register*, including any technical or ministerial correction to the annexes to this proclamation.

(6) For any rule or regulation the Commissioner of CBP makes to implement this proclamation, the Commissioner of CBP shall, to the extent required by law, obtain the approval of the President or the United States Trade Representative. The United States Trade Representative is delegated the President's approval authority in 19 U.S.C. 1338(h).

(7) Any provision of previous proclamations and Executive Orders that is inconsistent with this proclamation is superseded to the extent of such inconsistency.

(8) If any provision of this proclamation or the application of any provision to any individual or circumstance is held to be invalid, the remainder of this proclamation and the application of its provisions to any other individuals or circumstances shall not be affected.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-third day of October, in the year of our Lord two thousand twenty-six, and of the Independence of the United States of America the two hundred and fifty-first.



Annex I

Part A. – Products No Longer Covered by Section 338 Tariffs

Note: A 50% *ad valorem* Section 338 tariff shall no longer apply to the following articles of Canada. The product descriptions that are contained in this Annex are provided for informational purposes only and are not intended to delimit in any way the scope of the action. Any questions regarding the scope of particular HTSUS provisions should be referred to U.S. Customs and Border Protection. In the product descriptions, the abbreviation “nesoi” means “not elsewhere specified or included.”

Product	Description
1212.21.00	Seaweeds and other algae, fresh, chilled, frozen or dried, whether or not ground, fit for human consumption
3920.20.00	Nonadhesive plates, sheets, film, foil and strip, noncellular, not reinforced or combined with other materials, of polymers of propylene
3923.10.90	Other boxes, cases, crates and similar articles for the conveyance or packing of goods, of plastics
3923.21.00	Sacks and bags (including cones) for the conveyance or packing of goods, of polymers of ethylene
4412.33.06	Plywood sheets not over 6 mm thick, birch face ply, not surface covered beyond clear or transparent
4412.33.26	Plywood sheets not over 6 mm thick, walnut face ply, not surface covered beyond clear or transparent
4412.33.32	Plywood sheets not over 6 mm thick, outer ply of specified nonconiferous wood excluding walnut and birch, not surface covered beyond clear or transparent
4412.33.57	Plywood sheets not over 6 mm thick, outer ply of specified nonconiferous wood including birch and walnut, surface covered beyond clear or transparent
4412.34.26	Plywood sheets not over 6 mm thick, outer ply of nonconiferous wood not specified under subheading 4412.33, Spanish cedar face ply, not surface covered beyond clear or transparent
4412.34.32	Plywood sheets not over 6 mm thick, outer ply of nonconiferous wood not specified under subheading 4412.33, face ply nesoi, not surface covered beyond clear or transparent
4412.34.57	Plywood sheets not over 6 mm thick, outer ply of nonconiferous wood not specified under subheading 4412.33, face ply nesoi, surface covered beyond clear or transparent
4811.51.20	Bleached paper and paperboard, coated, impregnated or covered with plastics, weighing more than 150 g/m ² , 0.3mm or more in thickness, in strips or rolls over 15 cm wide or in rectangular sheets exceeding 36 cm on one side and 15 cm on the other
4811.51.40	Bleached paper and paperboard, coated, impregnated or covered with plastics, weighing more than 150 g/m ² , less than 0.3 mm in thickness, in strips or rolls over 15 cm wide or in rectangular sheets exceeding 36 cm on one side and 15 cm on the other

4819.10.00	Cartons, boxes and cases of corrugated paper or paperboard
4819.40.00	Sacks and bags, nesoi, including cones, of paper, paperboard, cellulose wadding or webs of cellulose fibers
4823.70.00	Molded or pressed articles of paper pulp
4823.90.10	Articles of paper pulp, nesoi
8418.69.01	Refrigerating or freezing equipment nesoi
8419.89.95	Industrial machinery, plant or equipment for the treatment of materials, by process involving a change in temperature, nesoi
8422.30.91	Machinery for filling, closing, sealing, capsuling or labeling bottles, cans, boxes or other containers; machinery for aerating beverages; nesoi
8422.40.91	Packing or wrapping machinery, nesoi
8433.60.00	Machines for cleaning, sorting or grading eggs, fruit or other agricultural produce

Part B. – New Products Covered by Section 338 Tariffs

Note: A 50% *ad valorem* Section 338 tariff shall apply to the following articles of Canada, unless they are articles of civil aircraft or aircraft parts that meet the criteria of General Note 6 of the HTSUS. The product descriptions that are contained in this Annex are provided for informational purposes only and are not intended to delimit in any way the scope of the action. Any questions regarding the scope of particular HTSUS provisions should be referred to U.S. Customs and Border Protection. In the product descriptions, the abbreviation “nesoi” means “not elsewhere specified or included.”

Product	Description
1806.10.05	Cocoa powder, sweetened, with less than 65% by dry weight of sugar, described in General Note 15 of the HTSUS
1806.10.10	Cocoa powder, sweetened, with less than 65% by dry weight of sugar, subject to additional U.S. note 1 to chapter 18
1806.10.15	Cocoa powder, sweetened, with less than 65% by dry weight of sugar, not subject to general note 15 or additional U.S. note 1 to chapter 18
1806.10.22	Cocoa powder, containing over 65% but less than 90% by dry weight of sugar, described in general note 15 of the HTSUS
1806.10.24	Cocoa powder, containing over 65% but less than 90% by dry weight of sugar, described in additional U.S. note 2 to chapter 17: and U.S. note 7 to chapter 17
1806.10.28	Cocoa powder, containing over 65% but less than 90% by dry weight of sugar, described in additional U.S. note 2 to chapter 17: not subject to additional U.S. note 7 to chapter 17
1806.10.34	Cocoa powder, containing over 65% but less than 90% by dry weight of sugar, nesoi, described in additional U.S. note 1 to chapter 18
1806.10.38	Cocoa powder, containing over 65% but less than 90% by dry weight of sugar, nesoi, not subject to additional U.S. note 1 to chapter 18
1806.10.43	Cocoa powder, containing 90% or more by dry weight of sugar, described in General Note 15 of the HTSUS

1806.10.45	Cocoa powder, containing 90% or more by dry weight of sugar, described in additional U.S. note 2 to chapter 17: subject to additional U.S. note 7 to chapter. 17
1806.10.55	Cocoa powder, containing 90% or more by dry weight of sugar, described in additional U.S. note 2 to chapter 17: not subject to additional U.S. note 7 to chapter 17
1806.10.65	Cocoa powder, containing 90% or more by dry weight of sugar, nesoi, described in additional U.S. note 1 to chapter 18
1806.10.75	Cocoa powder, containing 90% or more by dry weight of sugar, nesoi
3208.20.00	Paints and varnishes (including enamels and lacquers) based on acrylic or vinyl polymers in a nonaqueous medium
3214.10.00	Glaziers' putty, grafting putty, resin cements, caulking compounds and other mastics; painters' fillings
3305.10.00	Shampoos
3401.11.50	Soap, nesoi; organic surface-active products used as soap, in bars, cakes, pieces, soap-impregnated paper, wadding, felt, for toilet use
3402.50.51	Preparations of organic surface-active agents, put up for retail sale, not containing any aromatic or modified aromatic surface-active agent
3403.19.50	Lubricating preparations containing less than 50% by weight of petroleum oils or of oils from bituminous minerals
3403.99.00	Lubricating preparations (incl. lubricant-based preparations), nesoi
3404.90.51	Artificial waxes and prepared waxes, nesoi
3822.19.00	Other diagnostic or laboratory reagents, other than for malaria, Zika or blood-grouping
3822.90.00	Certified reference materials relating to diagnostic or laboratory reagents
3825.10.01	Residual products of the chemical or allied industries, nesoi; Municipal waste
3825.20.00	Residual products of the chemical or allied industries, nesoi; Sewage sludge
3825.30.00	Residual products of the chemical or allied industries, nesoi; Clinical waste
3907.61.00	Polyethylene terephthalate, having a viscosity number of 78 ml/g or higher
3909.50.10	Polyurethanes, elastomeric, in primary forms
3918.10.20	Vinyl flooring, excluding vinyl tile
3926.90.30	Parts for yachts or pleasure boats of heading 8903 and watercraft not used with motors or sails, of plastics
4016.91.00	Floor covering and mats, of noncellular vulcanized rubber other than hard rubber
4409.10.05	Coniferous wood continuously shaped along any of its ends, whether or not also continuously shaped along any its edges or faces
4411.12.10	MDF , <= 5mm thick, not mechanically worked or surface covered
4411.12.90	MDF, <= 5mm thick, not for construction, nesoi
4411.92.10	Fiberboard of a density exceeding 0.8 g/cm ³ , not mechanically worked or surface covered
4415.10.30	Packing boxes and cases of wood with solid sides, lids and bottoms
4418.75.70	Assembled wood flooring panels, other than of bamboo, other than for mosaic, multilayer, having a face ply less than or equal to 6 mm in thickness

4418.91.91	Builders' joinery and carpentry of wood, of bamboo, other than drilled or notched lumber studs
4421.20.20	Wooden coffins not of bamboo
4421.99.60	Skewers, candy sticks, ice cream sticks, tongue depressors, drink mixers and similar wares, other than toothpicks, of wood other than bamboo
4802.56.70	Paper or paperboard for writing, printing, or other graphic purpose, with weight between 40g/m ² -150g/m ² , not over 10% fiber by mechanical or chemical process, other sized sheets
4804.31.60	Uncoated, unbleached kraft paper, nesoi, in rolls or sheets, weighing 150 g/m ² or less
4807.00.94	Composite paper and paperboard, nesoi, not surface-coated or impregnated, in rolls or sheets
4811.41.10	Self-adhesive paper and paperboard, in strips or rolls over 15cm wide or rectangular sheets with one side over 36cm and other side over 15cm in the unfolded state
4811.59.20	Bleached or nonbleached printing paper, coated, impregnated or covered with plastics, in strips or rolls over 15cm wide or certain size sheets
4811.59.40	Bleached or nonbleached paper and paperboard, nesoi, coated, impregnated, or covered with plastics, in certain size strip, rolls, or sheets
4819.30.00	Sacks and bags, having a base of a width of 40 cm or more, of paper, paperboard, cellulose wadding or webs of cellulose fibers
4821.90.20	Pressure-sensitive paper and paperboard labels, not printed
5701.10.16	Carpets & other textile floor coverings, hand-knotted or hand-inserted, with over 50% by weight of the pile of fine animal hair, nesoi
5701.10.40	Carpets and other textile floor coverings, of wool or fine animal hair, hand-hooked (tufts were inserted and knotted by hand or hand tool)
5701.10.90	Carpets and other textile floor coverings, of wool or fine animal hair, not hand-hooked, not hand knotted during weaving
5701.90.10	Carpet and other textile floor covering, knotted, of textile materials (not of wool or fine animalhair) nesoi, pile inserted & knotted during weaving or knitting
5701.90.20	Carpet & other textile floor covering, knotted, of text materials (not of wool or fine animal hair) nesoi, not with pile inserted & knotted during weaving/knitting)
5702.10.90	Kelem, Schumacks, Karamanie and similar hand-woven rugs, other than certified hand-loomed and folklore products
5702.20.10	Floor coverings of coconut fibers (coir), woven, not tufted or flocked, with pile
5702.20.20	Floor coverings of coconut fibers (coir), woven, not tufted or flocked, other than with pile
5702.31.10	Wilton, velvet and like floor coverings of pile construction, woven, not tufted or flocked, not made up, of wool or fine animal hair
5702.31.20	Carpets and other textile floor coverings of pile construction, woven, not tufted or flocked, not made up, of wool or fine animal hair, nesoi
5702.32.10	Wilton, velvet and like floor coverings of pile construction, woven, not tufted or flocked, not made up, of man-made textile materials

5702.32.20	Carpets & other textile floor coverings of pile construction, woven, not tufted or flocked, not made up, of man-made textile materials, nesoi
5702.39.20	Carpets and other textile floor coverings of pile construction, woven, not tufted or flocked, not made up, of other textile materials, nesoi
5702.41.10	Wilton, velvet and like floor coverings of pile construction, woven, not tufted or flocked, made up, of wool or fine animal hair
5702.41.20	Carpets and other textile floor coverings of pile construction, woven, not tufted or flocked, made up, of wool or fine animal hair, nesoi
5702.42.10	Wilton, velvet and like floor coverings of pile construction, woven, not tufted or flocked, made up, of man-made textile materials
5702.42.20	Carpets and other textile floor coverings, of pile construction, woven, not tufted or flocked, made up, of man-made textile materials, nesoi
5702.49.10	Carpets not other textile floor coverings of pile construction, woven, not tufted or flocked, made up, of cotton
5702.49.20	Carpets & other textile floor coverings of pile construction, woven, not tufted or flocked, made up, of other textile materials, nesoi
5702.50.20	Carpets & other textile floor coverings, not of pile construction, woven but not on a power-driven loom, not made up, of wool or fine animal hair
5702.50.40	Carpets & other textile floor coverings, not of pile construction, woven, not made up, of wool or fine animal hair, nesoi
5702.50.52	Carpets & other textile floor coverings, not of pile construction, woven, not made up, of man-made textile materials
5702.50.56	Carpets & other textile floor coverings, not of pile construction, woven, not made up, of cotton
5702.50.59	Carpets & other textile floor coverings, not of pile construction, woven, not made up, of other textile materials, nesoi
5702.91.40	Carpets & other textile floor coverings, not of pile construction, woven nesoi, made up, of wool or fine animal hair, nesoi
5702.92.10	Hand-loomed carpet & other textile floor coverings, not of pile construction, woven, made up, of man-made textile materials, nesoi
5702.92.90	Carpet & other textile floor coverings, not of pile construction, woven, made up, of man-made textile materials, nesoi
5702.99.05	Hand-loomed carpets and other textile floor coverings, not of pile construction, woven, made up, of cotton
5702.99.15	Carpets and other textile floor coverings, not of pile construction, woven, made up, of cotton, nesoi
5702.99.20	Carpets & other textile floor coverings, not of pile construction, woven, made up, of other textile materials, nesoi
5703.10.20	Hand-hooked carpets and other textile floor coverings, tufted, whether or not made up, of wool or fine animal hair
5703.10.80	Carpets and other textile floor coverings, tufted, whether or not made up, of wool or fine animal hair, nesoi
5703.21.00	Turf, tufted, whether or not made up, of nylon or other polyamides
5703.29.10	Carpets and other textile floor coverings, other than turf, tufted, whether or not made up, of nylon or other polyamides, hand-hooked

5703.29.20	Carpets and other textile floor coverings, other than turf, tufted, whether or not made up, of nylon or other polyamides, not hand-hooked, nesoi
5703.31.00	Turf, tufted, whether or not made up, of man-made textile materials (not nylon/other polyamides)
5703.39.10	Carpets & other textile floor coverings, tufted, whether or not made up, of man-made materials (not nylon/other polyamides), hand-hooked
5703.90.00	Carpets and other textile floor coverings, tufted, whether or not made up, of other textile materials, nesoi
5704.10.00	Carpet tiles of felt, not tufted or flocked, whether or not made up, having a maximum surface area of 0.3 m ²
5704.20.00	Carpet tiles of felt, not tufted or flocked, whether or not made up, having a maximum surface area exceeding 0.3m ² but not exceeding 1m ²
5704.90.01	Carpets and other textile floor coverings of felt, not tufted or flocked, whether or not made up, other surface area
5705.00.10	Carpets and other textile floor coverings, whether or not made up, of coir, nesoi
5705.00.20	Carpets and other textile floor coverings, whether or not made up, of other material nesoi
8415.10.30	Window or wall type air conditioning machines, self-contained
8418.30.00	Freezers of the chest type, not exceeding 800 liters capacity, electric or other
8467.29.00	Electromechanical tools for working in the hand, other than drills or saws, with self-contained electric motor
8481.80.30	Taps, cocks, valves and similar appliances for pipes, boiler shells, tanks, vats or the like, hand operated, of iron or steel, nesoi
8903.93.05	Canoes, of a length not over 7.5m
9018.90.60	Electro-surgical instruments and appliances nesoi, other than extracorporeal shock wave lithotripters and parts and accessories thereof
9023.00.00	Instruments, apparatus and models, designed for demonstrational purposes, unsuitable for other uses, and parts and accessories thereof
9027.30.80	Nonelectrical spectrometers, spectrophotometers and spectrographs using optical radiations (ultraviolet, visible, infrared)
9506.99.05	Archery articles and equipment, and parts and accessories thereof

Annex II

A. Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern time on October 30, 2026, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified as follows:

1. Subdivision (b)(3) of U.S. note 51 is modified by:

a. deleting the following subheadings:

1212.21.00	3920.20.00	3923.10.90	3923.21.00
4412.33.06	4412.33.26	4412.33.32	4412.33.57
4412.34.26	4412.34.32	4412.34.57	4811.51.20
4811.51.40	4819.10.00	4819.40.00	4823.70.00
4823.90.10	8418.69.01	8419.89.95	8422.30.91
8422.40.91	8433.60.00		

b. inserting the following subheadings in numerical order:

1806.10.05	1806.10.10	1806.10.15	1806.10.22
1806.10.24	1806.10.28	1806.10.34	1806.10.38
1806.10.43	1806.10.45	1806.10.55	1806.10.65
1806.10.75	3208.20.00	3214.10.00	3305.10.00
3401.11.50	3402.50.51	3403.19.50	3403.99.00
3404.90.51	3822.19.00	3822.90.00	3825.10.01
3825.20.00	3825.30.00	3907.61.00	3909.50.10
3918.10.20	3926.90.30	4016.91.00	4409.10.05
4411.12.10	4411.12.90	4411.92.10	4415.10.30
4418.75.70	4418.91.91	4421.20.20	4421.99.60
4802.56.70	4804.31.60	4807.00.94	4811.41.10
4811.59.20	4811.59.40	4819.30.00	4821.90.20
5701.10.16	5701.10.40	5701.10.90	5701.90.10
5701.90.20	5702.10.90	5702.20.10	5702.20.20
5702.31.10	5702.31.20	5702.32.10	5702.32.20
5702.39.20	5702.41.10	5702.41.20	5702.42.10
5702.42.20	5702.49.10	5702.49.20	5702.50.20
5702.50.40	5702.50.52	5702.50.56	5702.50.59
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