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Contents

Federal Register

Vol. 82, No. 217

Monday, November 13, 2017

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Proclamations:

9672.....52641

7 CFR

Proposed Rules:

3419.....52250

12 CFR

209.....52173

13 CFR

107.....52174

20 CFR

1011.....52186

21 CFR

573.....52207

25 CFR

Proposed Rules:

514.....52253

31 CFR

543.....52209

33 CFR

117.....52210

165 (2 documents) 52210, 52212

37 CFR

201 (2 documents) 52213, 52221

202.....52224

Proposed Rules:

201.....52258

202.....52258

40 CFR

Proposed Rules:

52.....52259

42 CFR

414.....52356

416.....52356

419.....52356

49 CFR

40.....52229

50 CFR

622.....52248

648.....52249

Proposed Rules:

17.....52262

Rules and Regulations

Federal Register
Vol. 82, No. 217
Monday, November 13, 2017

FEDERAL RESERVE SYSTEM

12 CFR Part 209

[Regulation I; Docket No. R–1560]

RIN 7100–AE 68

Federal Reserve Bank Capital Stock

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors (Board) is publishing a final rule that applies an inflation adjustment to the threshold for total consolidated assets in Regulation I. Federal Reserve Bank (Reserve Bank) stockholders that have total consolidated assets above the threshold receive a different dividend rate on their Reserve Bank stock than stockholders with total consolidated assets at or below the threshold. The Federal Reserve Act requires that the Board annually adjust the total consolidated asset threshold to reflect the change in the Gross Domestic Product Price Index, published by the Bureau of Economic Analysis (BEA). Based on the change in the Gross Domestic Product Price Index as of September 28, 2017, the total consolidated asset threshold will be $10,283,000,000 through December 31, 2018.

DATES: This final rule is effective January 1, 2018.

FOR FURTHER INFORMATION CONTACT: Evan Winerman, Counsel (202/872–7578), Legal Division; or Kimberly Zaikov, Financial Project Leader (202/452–2256), Reserve Bank Operations and Payments Systems Division. For users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263–4869.

SUPPLEMENTARY INFORMATION:

I. Background

Regulation I governs the issuance and cancellation of capital stock by the Reserve Banks. Under section 5 of the Federal Reserve Act [1] and Regulation I,[2] a member bank must subscribe to capital stock of the Reserve Bank of its district in an amount equal to six percent of the member bank's capital and surplus. The member bank must pay for one-half of this subscription on the date that the Reserve Bank approves its application for capital stock, while the remaining half of the subscription shall be subject to call by the Board.[3]

Section 7(a)(1) of the Federal Reserve Act [4] provides that Reserve Bank stockholders with $10 billion or less in total consolidated assets shall receive a six percent dividend on paid-in capital stock, while stockholders with more than $10 billion in total consolidated assets shall receive a dividend on paid-in capital stock equal to the *lesser* of six percent and ''the rate equal to the high yield of the 10-year Treasury note auctioned at the last auction held prior to the payment of such dividend.'' Section 7(a)(1) requires that the Board adjust the threshold for total consolidated assets annually to reflect the change in the Gross Domestic Product Price Index, published by the BEA.

Regulation I implements section 7(a)(1) of the Federal Reserve Act by (1) defining the term ''total consolidated assets,'' [5] (2) incorporating the statutory dividend rates for Reserve Bank stockholders [6] and (3) providing that the Board shall adjust the threshold for total consolidated assets annually to reflect the change in the Gross Domestic Product Price Index.[7] The Board has explained that it ''expects to make this adjustment [to the threshold for total consolidated assets] using the final second quarter estimate of the Gross Domestic Product Price Index for each year, published by the Bureau of Economic Analysis.'' [8]

II. Adjustment

The Board annually adjusts the $10 billion total consolidated asset threshold based on the change in the Gross Domestic Product Price Index between the second quarter of 2015 (the baseline year) and the second quarter of the current year.[9] The second quarter 2017 Gross Domestic Product Price Index estimate published by the BEA in September 2017 (113.037) is 2.83% higher than the second quarter 2015 Gross Domestic Product Price Index estimate published by the BEA in September 2017 (109.921). Based on this change in the Gross Domestic Product Price Index, the threshold for total consolidated assets in Regulation I will be $10,283,000,000 as of the effective date of January 1, 2018.

III. Administrative Law Matters

Administrative Procedure Act

The provisions of 5 U.S.C. 553(b) relating to notice of proposed rulemaking have not been followed in connection with the adoption of these amendments. The amendments involve expected, ministerial adjustments that are required by statute and Regulation I and are consistent with a method previously set forth by the Board.[10] Accordingly, the Board finds good cause for determining, and so determines, that notice in accordance with 5 U.S.C. 553(b) is unnecessary.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[11] As noted previously, the Board has determined that it is unnecessary to publish a general notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirements relating to an initial and

[1] 12 U.S.C. 287.

[2] 12 CFR 209.4(a).

[3] 12 U.S.C. 287 and 12 CFR 209.4(c)(2).

[4] 12 U.S.C. 289(a)(1).

[5] 12 CFR 209.1(d)(3) (''Total consolidated assets means the total assets on the stockholder's balance sheet as reported by the stockholder on its Consolidated Report of Condition and Income (Call Report) as of the most recent December 31, except in the case of a new member or the surviving stockholder after a merger 'total consolidated assets' means (until the next December 31 Call Report becomes available) the total consolidated assets of the new member or the surviving stockholder at the time of its application for capital stock'').

[6] 12 CFR 209.4(e), (c)(1)(ii), and (d)(1)(ii); 209.2(a); and 209.3(d)(3).

[7] 12 CFR 209.4(f).

[8] 81 FR 84415, 84417 (Nov. 23, 2016).

[9] The BEA makes ongoing revisions to its estimates of the Gross Domestic Product Price Index for historical calendar quarters. The Board calculates annual adjustments from the baseline year (rather than from the prior-year total consolidated asset threshold) to ensure that the adjusted total consolidated asset threshold accurately reflects the cumulative change in the BEA's most recent estimates of the Gross Domestic Product Price Index.

[10] *See* 12 CFR 209.4(f) and n. 8 and accompanying text, *supra*.

[11] 5 U.S.C. 603 and 604.

final regulatory flexibility analysis do not apply.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,[12] the Board has reviewed this final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the final rule.

List of Subjects in 12 CFR Part 209

Banks and banking, Federal Reserve System, Reporting and recordkeeping requirements, Securities.

Authority and Issuance

For the reasons set forth in the preamble, the Board amends Regulation I, 12 CFR part 209, as follows:

PART 209—ISSUE AND CANCELLATION OF FEDERAL RESERVE BANK CAPITAL STOCK (REGULATION I)

■ 1. The authority citation for part 209 continues to read as follows:

Authority: 12 U.S.C. 12 U.S.C. 222, 248, 282, 286–288, 289, 321, 323, 327–328, and 466.

■ 2. In part 209, remove all references to ''$10,122,000,000'' and add in their place ''$10,283,000,000'', wherever they appear.

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary of the Board under delegated authority, November 7, 2017.

Margaret M. Shanks,

Deputy Secretary of the Board.

[FR Doc. 2017–24553 Filed 11–9–17; 8:45 am]

BILLING CODE 6210–01–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 107

RIN 3245–AG65

Small Business Investment Companies—Administrative Fees

AGENCY: U.S. Small Business Administration.

ACTION: Final rule.

SUMMARY: The U.S. Small Business Administration (SBA) is revising its regulations to increase the Small Business Investment Company (SBIC) licensing and examination fees. The Small Business Investment Act of 1958, as amended, allows SBA to collect licensing and examination fees to offset SBA's costs associated with the administration of these two activities. SBA last increased fees for SBICs in 1996. Current fees offset less than 40% of SBA's administrative expenses related to these activities. This final rule increases SBIC licensing and examination fees in annual steps through October 2020, at which time SBA estimates that the annual fees will recoup approximately 80% of SBA's annual expenses directly related to these activities. Beginning in October 2021, this rule increases licensing and examination fees annually based on inflation.

DATES: This rule is effective December 13, 2017.

FOR FURTHER INFORMATION CONTACT: Theresa Jamerson, Office of Investment and Innovation, (202) 205–7563 or *sbic@sba.gov*.

SUPPLEMENTARY INFORMATION:

I. Background Information

The Small Business Investment Act of 1958, as amended (''Act''), authorizes SBA to collect fees to cover the costs associated with the licensing and examination of SBICs. 15 U.S.C. 681(e)(2)(B) and 687b(b). Although SBA has regulations setting the amount of these fees, SBA has not increased licensing and examination fees for SBICs since 1996. As part of the final rule published January 31, 1996 (61 FR 3177), SBA set licensing fees ''to reflect the Agency's costs of processing applications'' and similarly set examination fees to ''produce total revenue sufficient to cover the current direct costs to SBA of conducting examinations.'' In a subsequent rule published on April 30, 1997 (62 FR 23337), SBA capped examination fees at $14,000, which lowered the fee for SBICs with over $60 million in assets. As part of the rationale for this change, the rule stated, ''many of the largest SBICs are bank-owned and do not use federal leverage, so that fees computed on the basis of total assets do not appropriately reflect the level of effort and risk associated with the examination process.'' Neither rule included an adjustment for inflation.

Although fees set in 1996, as adjusted in 1997, were intended to fully reimburse SBA's costs, by fiscal year (FY) 1999 (the earliest fiscal year for which SBA expenses are readily available), licensing and examination fees only covered approximately 85% of SBA's direct costs. SBA's direct costs are the expenses related to licensing and examination (*e.g.,* personnel compensation and benefits associated with licensing and examinations, technology, subscription services, travel and other costs associated with licensing and examinations), and excludes SBA's overhead costs (*e.g.,* office space, utilities, and other supporting offices within SBA). In FY 2016, licensing and examination fees reimbursed approximately 35% of SBA's direct licensing and examination expenses, and less than a quarter of SBA's licensing and examination expenses when including overhead.

On December 16, 2016, SBA published a proposed rule (81 FR 91049) to gradually increase the SBIC licensing and examination fees each year through October 1, 2020, and thereafter annually based on inflation, beginning on October 1, 2021. The proposed rule detailed the reasons for the widening gap between fees received and SBA related expenses. Key reasons include inflation, changes in the SBIC portfolio, increased capital at risk (SBA-guaranteed leverage and commitments), SBA's efforts to improve SBIC program performance, and technology implementation.

As noted above, the Act authorizes SBA to collect fees to cover the costs associated with the licensing and examination of SBICs. The Act requires SBA to deposit the fees in the account for salaries and expenses of the Administration and authorizes SBA to use licensing fees to cover licensing costs and examination fees to cover the costs of examinations and other program oversight activities. 15 U.S.C. 681(e)(2) and 687b(b). To the extent that SBA does not cover its licensing and examination costs by charging SBICs for these fees, the balance is paid out of Agency funds. In other words, when SBICs do not pay fees sufficient to cover SBA's licensing and examination costs, taxpayers bear the burden of covering those costs. It is an appropriate use of SBA's statutory authority in this final rule to increase SBIC licensing and examination fees to cover a greater percentage of licensing and examination costs.

The effect of the statutory language authorizing SBA to use licensing fees to cover licensing costs and examination fees to cover the costs of examinations and ''other program oversight activities'' is that SBA may use examination fees to cover a broader category of expenses than those for which it may charge (*i.e.,* examination costs alone). Although the current and estimated future costs of compensation and benefits of SBA personnel involved in licensing and examinations, not including any additional related expenses, fully support the fee increases in this final rule, in the proposed rule, SBA identified a number of costs it expected to pay for with the funds made available

[12] 44 U.S.C. 3506; 5 CFR part 1320.

by this rule, such as technology, training, information services and contractor support for examinations. While the expenses other than licensing and examinations personnel compensation and benefits discussed in the proposed rule and this final rule are not necessary to support the fee increases in this final rule, these expenses are priorities of SBA. Accordingly, SBA intends to use the additional funds made available by this rule—whether those funds are fee revenue or Agency funds currently used to pay compensation and benefits of personnel involved in licensing and examinations that are replaced by fee revenue from this rule—to pay for such expenses.

SBA received three sets of comments. These comments are addressed in the Section-by-Section Analysis.

II. Section-by-Section Analysis

A. General Comments on the Proposed Rule

SBA received several comments that were generally directed to the proposed rule (81 FR 91049) rather than a specific section. Each of these is addressed below.

One comment stated that the proposed rule does not comply with the Presidential Executive Order 13771 issued on January 30, 2017, entitled ''Reducing Regulation and Controlling Regulatory Costs.'' OMB issued guidance on April 5, 2017, entitled, ''Guidance Implementing Executive Order 13771,'' which states that Executive Order 13771 applies only to significant rules, as defined by section 3(f) of Executive Order 12866. Since OMB has determined that this rule is not significant, Executive Order 13771 does not apply to this rule.

SBA received a number of comments that centered on the theme that SBA is using dollars that should be directed to the SBIC program for other programs. For example, one comment stated that SBA's Office of Investment and Innovation (OII), which oversees the SBIC program, has been redirecting its human capital and funding from the SBIC program to other programs, such as the Small Business Innovation Research (SBIR) program. Another comment stated that SBICs have no certainty that if higher fees are charged that the additional resources generated would not be used to offset increased spending for non-SBIC matters, and ''there is no limitation on monies that are currently spent on licensing and examinations from being diverted to other uses by the SBA.'' Another comment stated similar concerns and asked what assurances SBA could provide that the fee increase would benefit the SBIC program. A final comment stated that ''OII should use all its resources to support the SBIC program.''

The comments misunderstand or fail to take into account SBA's statutory obligations, extensive transparency with respect to spending, and commitments identified in the proposed rule. First, by statute, SBA must use SBIC licensing fees for licensing expenses and SBIC examination fees for examination and other program oversight expenses. 15 U.S.C 681(e)(2)(A), 687b(b). This statutory obligation governing the use of fees should provide SBICs with certainty that SBA is using the fees generated by this final rule only for SBIC matters. Second, SBA provides comprehensive budget transparency, which should provide additional assurance to SBICs that SBA is using the fee increase in the final rule only for SBIC matters. SBA's Congressional Budget Justification separately tracks and reports the costs for each of its programs, including the costs of the SBIC and SBIR programs. This information is made publicly available every year by SBA, and is available at *www.sba.gov/about-sba/sba-performance/performance-budget-finances/congressional-budget-justification-annual-performance-report*. Current SBIC licensing and examination fees are applied to SBA's account for salaries and expenses, as required by the Act, and are used to pay the salaries of personnel associated with SBIC licensing and examination activities. In FY 2016, SBA spent an estimated $4.8 million on personnel compensation and benefits associated with these activities alone, and $5.4 million including travel, technology, subscription services and other costs associated with these activities. Licensing and examination fees provided only $1.9 million to offset these costs. By FY 2021, SBA estimates that direct costs associated with licensing and examinations will increase to $9.4 million and that this final rule will generate an additional $5 to $6 million in fees annually. Accordingly, even after the fee increases in this rule are fully phased in, a shortfall of $1.5 million to $2.5 million will still exist between aggregate licensing and examination direct expenses. When factoring in overhead, SBA's estimated licensing and examination costs will even further exceed anticipated fees. Third, SBA recognizes the need for additional resources in the SBIC program. Indeed, that is one of the purposes of the rulemaking and should provide assurance that the additional funds made available by this final rule will be used to benefit the SBIC program. As more fully discussed below, SBA intends to allocate the additional funds made available by this rule to pay for needed resources, including technology, subscription services, contractors, and training. Finally, and more broadly, the SBIC program is one of many programs operated by SBA. OII manages several programs, including, but not limited to, the SBIC program and the SBIR program. As is the case with the SBIC program, SBA has statutory obligations with respect to operating the SBIR program. SBA assesses resource needs for each program to efficiently and effectively execute its statutory responsibilities. Consistent with the statute, no SBIC fee revenue has been or will be used for this program.

One comment stated that SBIC program costs have not substantially increased in recent years and questioned the need for increased fees. The comment is correct that SBIC program costs have not substantially increased over the past few years. Nonetheless, excluding SBA overhead, the SBIC program direct operating budget has increased from $7.4 million in FY 1999 (the earliest period for which SBIC budgets are readily available) to approximately $12.9 million in FY 2016. Over half of the increase is due to inflation ($7.4 million in January 1999 would equate to $10.7 million in January 1999 based on the U.S. Bureau of Labor Consumer Price Index calculator located at *data.bls.gov/cgi-bin/cpicalc.pl*) with the remainder due to the addition of subscription services, such as Preqin and Lexis/Nexis, technology improvements, and the costs associated with more experienced analysts necessary to oversee SBA's increased capital at risk (SBA leverage and commitments). As discussed in the proposed rule, SBICs ultimately benefit financially from improvements in the quality of the SBIC program portfolio through lower annual charges on SBA-guaranteed debenture leverage. The SBIC debenture leverage annual charge has decreased from 1% in FY 1999 to an annual charge of 0.347% in FY 2017, reflecting improvements to the SBIC debenture portfolio (a cost savings of $979,500 in just one year for a hypothetical SBIC issuing $150 million of debentures at the lower annual charge). In FY 1999, SBA had less than $3.9 billion in capital at risk; this figure grew to $14.5 billion by the end of FY 2016. Analyzing SBICs and SBIC applicants has become more time

intensive due to the increased complexity of SBIC organizational structures, legal documents, management fees, and financings. As an example, on October 21, 2014, SBA published a final rule (79 FR 62819) requested by the SBIC industry, which allowed the use of up to two levels of passive businesses under 13 CFR 107.720(b)(2) in order to provide more flexibility to its SBICs in structuring investments. To appropriately monitor these financings, SBA must examine each passive business used in the financing in addition to the operating business. While SBA understands such financings provide SBICs additional flexibility in structuring investments, these financings cause additional work for SBA to review and monitor.

One comment asked SBA to identify its priorities for the increased fee revenue associated with this rule. SBA intends to use the additional funds made available by this rule to: (1) Support its continued efforts to migrate from desktop database tools to a secure cloud-based system comparable to the systems used by a typical private equity fund of funds (an investment fund that holds a portfolio of private equity funds); (2) pay for additional contractor services to support examinations and facilitate SBA's transition to a paperless environment; (3) increase travel related to licensing, examination, and other program oversight; (4) train employees; (5) increase access to subscription services typically used by a typical private equity fund of funds, such as industry reports; and (6) to further offset the compensation and benefits of personnel associated with these activities.

One comment stated that the proposed fee increase was excessive and it was unclear why an additional $3 to $4 million in fees is needed to administer the program, noting that the costs cited in the proposed rule only totaled $1.7 million. As support, the comment cited the $100,000 in information subscription services, $500,000 in increased licensing and examination costs for technology improvements, $100,000 to incur additional training costs, and $1 million in contracting resources identified in the proposed rule.

Setting aside the $1.7 million in specific additional expenses needed for licensing and examination expenses identified in the proposed rule, the commenter appears to disregard the licensing and examination expenses that current fees are not covering. The intent of this final rule is to cover more of SBA's existing expenses for these activities and provide sufficient income to pay for the additional and necessary expenses identified in the proposed rule. As discussed above, in FY 2016, SBA expended approximately $5.4 million, excluding overhead, on SBIC licensing and examination activities, but received only $1.9 million in licensing and examination fees, resulting in a $3.5 million shortfall which was paid out of SBA's taxpayer-funded budget. Through this rule, SBA expects to reduce this shortfall.

One comment suggested that SBA should conduct an in-depth accounting of the needs and requirements of OII to provide ''first-class service'' to SBICs to determine the minimum resources necessary to fulfill its mission, identify where costs can be cut, better allocate existing resources, improve efficiencies through private sector solutions, and then present the final accounting of these amounts to the public. Regarding the in-depth accounting requested by the comment, the proposed rule set forth in detail current licensing and examination expenses and the additional expenses related to these functions that SBA believes are critical to fulfilling the statutory mission of the SBIC program. This final rule discusses those costs and future estimates in further detail. In reviewing existing resources, SBA identified five key areas for improvements, which it intends to pay for using the additional funds made available as a result of this final rule, as follows:

(1) *Technology:* SBA's Office of the Chief Information Officer (OCIO) is working closely with OII to improve its systems to provide functionality similar to a typical private sector private equity fund of funds and serve as a virtual data room. In addition to this software, SBA needs to migrate from Microsoft Access and acquire data visualization and analytical tools commensurate with private equity funds and other government loan programs. SBA also expects to periodically update its hardware.

(2) *Outsourced Contractor Services:* SBA intends to utilize contractors to provide certain services for which SBA does not currently have sufficient resources to perform and to assist in certain risk control functions of OII. This includes hiring contractors for scanning, file management, record management, and cyber security to help migrate the entire office to a paperless environment. This also includes valuation services to help support SBIC program oversight and SBIC examinations where SBA determines that an independent valuation is appropriate or necessary. In reviewing the examination function, SBA has established a goal of increasing the frequency with which individual SBICs are examined to further reduce risk of loss to the SBIC program. Due to staffing limitation issues, SBA intends to outsource certain examination functions in order to ensure that it is able to meet statutory examination requirements.

(3) *Travel:* SBA intends to increase staff travel in furtherance of program objectives for licensing, examinations, and other program oversight activities.

(4) *Training:* As noted in the proposed rule, the Office of Inspector General (OIG) noted that ''without proper training and technology examiners may not effectively identify all regulatory violations as intended by the Act.'' OIG Audit Report 13–22 at 11. OII intends to devote a larger portion of its budget for employee training.

(5) *Subscription Services:* SBA is evaluating information sources used by a typical private sector private equity fund of funds to identify which sources may most effectively help its analysts better evaluate and assess SBICs and applicants.

SBA regularly assesses needs and resources for all programs to ensure that SBA is able to meet its statutory obligations in an efficient and effective manner. In assessing the expenses of the SBIC program more broadly than licensing and examination expenses alone, total program costs for the SBIC program are already low compared to cost of the SBIC program from prior eras based on capital at risk and comparable current private sector entities based on assets under management. SBIC program resources have not kept pace with increased capital at risk since FY 1999 (the earliest period for which the SBIC program operating budget is readily available). In FY 1999, SBA spent $7.4 million, excluding overhead, to manage a portfolio of less than $3.9 billion in capital at risk (leverage and commitments); in FY 2016, SBA spent $12.9 million to manage a portfolio of $14.5 billion. SBA's capital at risk continues to increase, reaching $15.3 billion as of May 22, 2017. While SBA's capital at risk has more than tripled in size, SBA's costs to manage its much larger portfolio have not even doubled. As a result, the SBIC program's FY 1999 operating budget, excluding overhead, represented 0.19% of its capital at risk and its FY 2016 operating budget represents 0.09%. If SBA returned to the FY 1999 rate of 0.19%, the SBIC program's direct budget would need to increase to $29 million today, which would still fall significantly below comparable private sector costs. As a comparison, a typical private sector fund of funds commonly charges 1% of

assets under management (AUM) annually to manage the fund; notably, SBICs typically charge 2% in annual management fees.

SBA estimates that by FY 2021 the Agency will need approximately $19.9 million, excluding overhead, to manage the SBIC program (''SBIC Program Direct Cost Estimates''), as shown in Table 1, SBIC Program Direct Cost Estimates (In Millions of Dollars), below. The cost estimate includes increases for inflation through FY 2021 and funding for the five key areas that are targeted for improvement.

TABLE 1—SBIC PROGRAM DIRECT COST ESTIMATES

[In millions of dollars]

Category	FY 2016	FY 2021
Personnel (Compensation & Benefits)	$11.65	$13.53
Technology	0.79	3.16
Outsourced Contractor Services	.....	2.29
Travel	0.22	0.47
Subscription Services	0.19	0.21
Training and Other Expenses	0.09	0.27
Total SBIC Program Direct Cost Estimates	12.94	19.93

Direct licensing costs are expected to increase from approximately $2 million in FY 2016 to almost $3 million by FY 2021, and examination costs are expected to increase from $3.4 million in FY 2016 to almost $6.4 million by FY 2021. Table 2, SBIC Program Direct Cost Estimates for Licensing and Examination Activities (In Millions of Dollars), below provides a breakdown for SBIC licensing and examination costs.

TABLE 2—SBIC PROGRAM DIRECT COST ESTIMATES FOR LICENSING AND EXAMINATION ACTIVITIES

[In millions of dollars]

Category	Licensing costs		Examination costs	
	FY 2016	FY 2021	FY 2016	FY 2021
Personnel (Compensation & Benefits)	$1.80	$2.31	$2.96	$4.12
Technology	0.09	0.31	0.20	0.79
Outsourced Contractor Services	0.00	0.11	0.00	1.11
Travel	0.00	0.06	0.22	0.26
Subscription Services	0.12	0.13	0.00	0.00
Training and Other Expenses	0.01	0.03	0.02	0.07
Total SBIC Direct Cost Estimates	2.02	2.95	3.40	6.35

SBA realized that the cost estimates on which the proposed rule was developed (''proposed rule cost estimate'') significantly underestimated SBA costs for technology, outsourcing, and overhead. The proposed rule identified only $1 million for technology, half of which was allocated to licensing and examinations. After further review of commercially available systems used by private sector funds of funds and tools used by other government financial programs, SBA believes technology costs are likely to be significantly higher than originally estimated in the proposed rule. The proposed rule cost estimate also understated costs for outsourced services, particularly with respect to examinations and cyber security. Most significantly, the proposed rule used an agency overhead rate of less than half a percent (0.48%) of all direct SBIC costs. After publishing the proposed rule, OII became aware that the actual agency overhead rate amounts to approximately thirty percent (30%) of the program's total cost. (For example, if the total program cost were $10 million, $7 million would be the program office's direct costs while the other $3 million would represent agency overhead.) As a result, the fee increase in this final rule is likely to cover less of SBA's license and examination expenses than SBA expected when proposing the rule. After the full increase is phased in by FY 2021, the fees will cover approximately 80% of SBA's direct licensing and examination expenses, and less than 60% of such expenses when including overhead. SBA is concerned that the phased in fee increase in this final rule may not provide SBA with fees necessary to pay for critical resources as quickly as necessary. SBA is also concerned that, after the phase-in is complete, fees collected will not cover all expenses authorized by statute. Accordingly, SBA is considering proposing a new rule after this final rule becomes effective to more fully cover its licensing and examination costs in a more expedited timeframe.

One comment questioned OII's priorities, stating that OII recently created and hired a position which the commenter believes duplicates a currently existing role in OII rather than filling core competencies. How SBA chooses to allocate its non-fee related budget is not the subject of this rule. In addition, as noted above, SBA regularly reviews resource allocations within SBA to maximize efficiency and prioritize resources. Based on this review, SBA is currently seeking to provide additional resources to licensing and examinations.

One comment stated that although more staffing resources should be allocated to SBIC examinations, those resources should come from other areas within OII or sought from congressional appropriations. SBA assesses the needs for all of its programs and cannot reallocate money from one program to another without repercussions to the program that would lose resources. In addition, any reallocations of personnel to examination functions would not lower examination costs. Such resources, therefore, would not reduce the need for the fees set forth in this final rule. SBA could request additional funds from Congress; however, Congress gave SBA the authority to recoup its SBIC licensing and examination expenses by charging SBIC licensing and examination fees. By this final rule, SBA is complying with the statutory intent to cover more of its licensing and examination costs through the use of fees, which will provide SBA with the ability to pay for necessary additional resources required to administer the SBIC program.

Two comments noted that technology improvements, such as a virtual data room, could significantly reduce costs. Neither commenter provided data to support cost reductions. As part of the budget estimate presented in Table 1, SBA considered the use of private sector technology, such as adopting software commonly used by a typical private equity fund of funds, virtual data rooms, and analytical tools to improve the efficiency of its processes. In general, SBA has found that while technology improves the accessibility of information, it does not necessarily decrease the time or manpower required to license or examine a fund. For example, while a virtual data room would help in accessing a business plan, it takes the same amount of time to read and understand the business plan in an electronic version as a paper version. Similarly, while a virtual data room helps SBA access SBIC financing documents, most of SBA's time is spent reviewing the documents, and assessing whether the financing complies with SBIC regulations. SBA also notes that such technology is used by SBIC managers and other professionals (such as accounting and law firms) that charge expenses to SBICs and that their costs have not declined.

One comment stated that the increased fees would significantly deter existing and prospective SBIC fund managers from continuing in the program. The fees identified in this final rule represent a small percentage of a fund's capital or expenses. Regarding the licensing fees, in FY 2016, SBA licensed 21 SBICs with average initial private capital exceeding $55 million. Those intending to issue SBA guaranteed debentures (''leveraged SBICs'') had average initial private capital of $53 million, and those not intending to issue SBA guaranteed debentures (''non-leveraged SBICs'') had average initial capital of $74 million. The FY 2021 licensing fee of $45,000 represents 0.06% of the average non-leveraged SBIC's capital and 0.03% of the leveraged SBIC's total capital (assuming the leveraged SBIC will draw leverage equal to two times private capital). Even after full phase-in by FY 2021, the licensing fee is expected to account for a modest percentage of an SBIC's total organizational costs (*e.g.,* legal fees and other professional and consulting services, fundraising expenses, etc.), which frequently reach or exceed $500,000. Regarding the examination fee, under this final rule, in approximately three years (by October 2020), the examination fee for a leveraged SBIC with $150 million in assets at cost would be $44,000 (0.03% of assets) and for a non-leveraged SBIC $30,000 (0.02% of assets). SBA's goal is to examine leveraged SBICs every twelve months and non-leveraged SBICs every eighteen months. In FY 2016, an SBIC with $150 million in assets typically incurred annual management fees of $3 million and annual audit fees between $50,000 and $60,000. SBA believes that while the increased fees may deter a few funds with limited ability to raise capital from applying to the program, most applicants will not be deterred. To the extent that such deterrence occurs, it may help SBA focus its resources on stronger SBIC applicants.

B. Indexing Fees

Section 107.50—Definition of Terms

Current SBIC regulations do not adjust SBA's administrative fees for inflation. As a result, fees have not increased since 1996 and do not cover SBA's costs. To enable fees to remain current with inflation, SBA is adding the term ''Inflation Adjustment'', which is defined as the methodology used to increase SBIC administrative fees using the consumer price index for all urban consumers (CPI–U), as calculated by the U.S. Bureau of Labor and Statistics (BLS), based on the U.S. city average for all items, not seasonally adjusted, with the base period 1982 − 84 = 100. Beginning on October 1, 2021, and prior to each federal government fiscal year (October 1) thereafter, SBA would recalculate the examination and licensing fees to reflect increases in the CPI–U based on the change in the index from the June CPI–U in the previous year to the most recent June CPI–U. For example, the CPI–U is 238.638 in June 2015 and 241.038 in June 2016; a 1.0057% increase would be applied and then rounded to the nearest $100. If the CPI–U decreases, no change would be made to the fees. SBA would publish the resulting fees in a notice in the **Federal Register** each year prior to October 1.

SBA received one comment that opposed the inflation adjustment, stating that instituting an inflation adjustment removes SBA's accountability for reducing costs and streamlining processes. SBA does not agree. More than half of SBA's SBIC expense increase between 1999 and 2016 was due to inflation. These increased expenses were funded by taxpayers rather than SBICs. Implementing an inflation adjustment to ensure that SBA's licensing and examination fees keep pace with inflation helps to ensure that, consistent with the statutory authority Congress provided to SBA in Sections 301 and 310 of the Act, SBICs, not taxpayers, are paying the costs related to these activities. SBA estimates that if SBA had instituted an inflation adjustment in 1996, over the 5-year period between FYs 2012 and 2016 alone, SBA could have saved taxpayers over $6 million. Further, SBA's budget process ensures accountability by providing disclosure of SBA's costs to the public each year. SBA further notes that using inflation adjustments is in line with other federal financial regulators such as bank examiner fees (For example, pursuant to 12 CFR 8.2, the Office of the Comptroller of the Currency applies an inflation adjustment to the fees it charges for examining and supervising national banks.) Finally, SBA remains committed to ensuring that the SBIC program is operated efficiently and effectively. This final rule adopts the proposed § 107.50 language without change.

C. Licensing Fees

Section 107.300—License Application Form and Fee

Current regulations require SBIC applicants to pay a licensing fee when submitting a complete application. Under those regulations, the licensing fee consisted of a base fee of $10,000 plus additions as follows: $5,000 if the applicant intended to operate as a limited partnership; $5,000 if the applicant intended to issue Participating Securities leverage (a type of leverage no longer available); and $10,000 if the applicant intended to be licensed as an Early Stage SBIC (a type of license no longer issued after September 30, 2016).

SBA proposed to remove the additions and to adopt a uniform licensing fee of $25,000 in FY 2017, which would increase by $5,000 each October through October 1, 2020, resulting in a licensing fee of $45,000 by October 1, 2020. Beginning on October 1, 2021, the rule proposed to increase the amount based on inflation. The proposed rule did not propose changing when the licensing fee was payable. Consistent with SBA's existing practice, the preamble to the proposed rule discussed SBA's licensing phases and what forms and fees are required at each phase as follows:

The first phase in the licensing process (''Initial Review'') begins when a first time applicant submits its Management Assessment Questionnaire (''MAQ''), which consists of SBA Forms 2181 and Exhibits A through F of SBA Form 2182, or when the management of an existing SBIC submits a request to

SBA to be considered for a subsequent SBIC license. (SBIC application forms are available on SBA's Web site at *www.sba.gov/sbic*.) SBA reviews the MAQ or subsequent SBIC applicant materials, performs due diligence, analyzes the management team's performance, interviews those management teams invited for an in-person interview, and ultimately determines whether to issue a formal invitation (''Green Light Letter'') to the applicant to proceed to the final licensing phase of the process. Once an applicant receives a Green Light Letter, the applicant typically has up to 18 months to raise the requisite private capital. During this timeframe, SBA keeps in touch with the applicant, conducts SBIC training classes, and provides guidance as needed. The applicant pays the licensing fee only at the final licensing phase (''Final Licensing''). Final Licensing occurs at the time SBA accepts an applicant's complete license application (consisting of an updated SBA Form 2181 and complete SBA Forms 2182 and 2183), which application is submitted after raising sufficient private capital. A number of applicants fail to raise the requisite capital or for other reasons do not submit a license application. As a result, SBA estimates that less than half of SBIC applicants pay the licensing fee, even though SBA expends resources on all applicants.

As part of the proposed rule, SBA asked for comments as to whether an applicant should pay a licensing fee prior to submitting its complete license application, since SBA expends significant resources prior to that time. SBA received one comment that supported a fee of up to $10,000 at the first phase, Initial Review, with a commensurate decrease in the licensing fee at the second phase, Final Licensing. The commenter also suggested that SBA clarify its licensing standards, since half of all applicants that apply to the program do not receive a Green Light Letter. SBA recommends that applicants use the pre-screening process described on its Web site at *www.sba.gov/sbic/applying-be-sbic/pre-screening-process,* which will remain free of charge after this final rule is published. This process helps applicants identify whether they are likely to qualify for a license before beginning the licensing process.

SBA agrees that a fee at Initial Review is appropriate; this final rule includes a $10,000 fee at Initial Review (''Initial Licensing Fee'') beginning on the effective date of this rule. The amount of the licensing fee due at Final Licensing (''Final Licensing Fee'') in this final rule has been reduced from the amount for such fee in the proposed rule by a commensurate decrease of $10,000. Accordingly, by October 1, 2020, the combined licensing fees for a single applicant will total $45,000, which is the total amount of licensing fees proposed by SBA in the proposed rule. The amount of the Final Licensing Fee is the amount due in effect on the date when SBA accepts an applicant's license application. Due to the timing of this final rule, SBA removed the proposed FY 2017 licensing fee. Table 3, SBIC Initial and Final Licensing Fees, below, identifies the Initial Licensing Fee and Final Licensing Fees in this final rule for each fiscal year.

TABLE 3—SBIC INITIAL AND FINAL LICENSING FEES

Time	Initial licensing fee	Final licensing fee
December 13, 2017–September 30, 2018	$10,000	$20,000
October 1, 2018–September 30, 2019	10,000	25,000
October 1, 2019–September 30, 2020	10,000	30,000
October 1, 2020–September 30, 2021	10,000	35,000

Beginning on October 1, 2021, SBA will increase the Initial Licensing Fee and Final Licensing Fee using the Inflation Adjustment and, prior to the date of the increase, will publish the amount in a Notice in the **Federal Register**.

Section 107.410—Changes in Control of Licensee

SBA treats a change in control of a Licensee as a licensing action since SBA must perform similar functions and processes to those in SBA's licensing processes. Current regulations require SBICs seeking a change in control to pay a $10,000 fee, similar to the licensing fee. Since the procedures and costs are similar to those in the licensing process, the proposed regulations changed the current fee to be equal to the licensing fee identified in § 107.300. SBA received no comments on this section. As noted above, this final rule does not change the total amount of the licensing fee in the proposed rule, but requires two payments rather than one: the Initial Licensing Fee and the Final Licensing Fee. The final § 107.410 modifies the language in proposed § 107.410 to reflect the combined Licensing Fee (Initial Licensing Fee plus the Final Licensing Fee) as defined in the final § 107.300.

D. Examination Fees

Section 107.692(b)—Base Fee

Current § 107.692(b) identifies a base examination fee calculated as a percentage of an SBIC's total assets at cost. As set forth in current § 107.692(b), the percentage decreases as the assets increase, with the maximum base examination fee set at $14,000 for SBICs with total assets greater than $60 million.

SBA proposed to modify § 107.692(b), to replace the base fee calculation with the following formula: Base Fee = Minimum Base Fee + 0.024% of assets at cost, but not to exceed the Maximum Base Fee. The Minimum Base Fee would increase to $5,000 in FY 2017 and increase each October by $1,000 through October 1, 2020. As proposed, the Maximum Base Fee for Non-leveraged SBICs would increase to $20,000 in FY 2017 and increase by $2,500 each October through October 1, 2020. The Maximum Base Fee for Leveraged SBICs would increase to $20,000 in FY 2017 and then by $6,000 each October through October 1, 2020. Beginning on October 1, 2021, the Minimum and Maximum Base Fee (for both Leveraged and Non-leveraged SBICs) would increase using the Inflation Adjustment.

For the purposes of calculating the examination fee, the proposed rule defined Non-leveraged SBICs as SBICs that have no outstanding SBA-guaranteed leverage or leverage commitments and, in the case of SBICs that have issued leverage in the form of Participating Securities, hold no Earmarked Assets. An SBIC that satisfies these requirements must also certify to SBA that it will not seek new SBA leverage in the future.

SBA received one comment supporting SBA's proposal to tie the examination fee to assets, noting that a fee not tied to assets would have been burdensome for smaller funds.

SBA received one comment that the increase is excessive, noting that while there is an increase in the number of SBICs to be examined, there was no evidence provided that the cost of examining an individual SBIC has doubled. As discussed previously, over half of the increase in examination expenses since 1999 is due to inflation, with most of the remainder due to the addition of subscription services, technology improvements, and costs associated with more experienced analysts necessary to oversee SBA's increased capital at risk (SBA leverage and commitments), particularly in larger leveraged SBICs with over $60 million in assets. In December 1996, only 6 of the 28 SBICs with over $60 million in assets used leverage and only 1 of the 12 SBICs with over $120 million in assets used leverage. As of December 31, 2016, 122 of the 129 SBICs with over $60 million in assets used leverage and 72 of the 74 SBICs with over $120 million in assets used leverage. SBA applies a higher level of scrutiny in examining leveraged SBICs than non-leveraged SBICs in exams, since SBA bears credit risk with respect to leveraged SBICs. In addition, larger leveraged SBICs often use complex transaction structures which are more time-consuming to examine. For example, the percentage of SBIC financings made through passive businesses (a type of financing that is generally prohibited, but with permitted exceptions for passive businesses that pass through proceeds to eligible active small businesses) increased from 3% in 1996 to over 14% over the past few years. This is partially due to the expansion of SBIC passive business rules on December 23, 2014 (78 FR 77377), which revised 13 CFR 107.720(b)(2) to allow SBICs to invest in up to two levels of passive businesses under certain circumstances. Although SBA understands that these types of accommodations are necessary to enable SBICs to finance certain small businesses, these transactions require SBA to use more resources to monitor and examine them.

SBA believes the examination base fee is reasonable and consistent with the cost of other auditing services and is finalizing § 107.692(b) as proposed with the exception of one timing-related change. Due to the timing of this final rule, SBA is removing the FY 2017 fee increase identified in the proposed rule and will begin with the FY 2018 fee, after the effective date of this rule. The final § 107.692(b) replaces the base fee calculation with the following formula: Base Fee = Minimum Base Fee + 0.024% of assets at cost, but not to exceed the Maximum Base Fee. Both the Minimum Base Fee and the Maximum Base Fee change each year as shown on Table 4, Minimum and Maximum Base Fees, and are adjusted for inflation each year beginning October 1, 2021:

TABLE 4—MINIMUM AND MAXIMUM BASE FEES

Time period (based on the examination start date)	Minimum base fee	Maximum base fee for non-leveraged SBICs	Maximum base fee for leveraged SBICs
December 13, 2017 to September 30, 2018	$6,000	$22,500	$26,000
October 1, 2018 to September 30, 2019	7,000	25,000	32,000
October 1, 2019 to September 30, 2020	8,000	27,500	38,000
October 1, 2020 to September 30, 2021	9,000	30,000	44,000

Section 107.692(c)—Adjustments to Base Fee and (d) Fee Discounts and Additions Table

Current § 107.692(c) provides for the following adjustments to the base examination fee calculated under § 107.692(b): 15% discount for no prior violations; 10% discount for responsiveness; 5% addition if SBIC is structured as a partnership or limited liability company; 10% addition if the SBIC was licensed with the intent of issuing Participating Securities; 10% addition if SBIC records are maintained at multiple locations; and 10% addition if the SBIC is licensed as an Early Stage SBIC. These adjustments were summarized in tabular form in § 107.692(d).

SBA proposed to revise § 107.692(c) as follows:

• *Retain No Violation Discount:* SBA proposed to retain the no violation discount, which gives a 15% discount on the Base Fee to SBICs that have no outstanding regulatory violations at the time of the examination start date and had no violations as a result of the most recent prior examination.

• *Add Low and Moderate Income (LMI) Investing Discount:* SBICs would receive a discount of 1% of the Base Fee for every $10 million in LMI Investments (in dollars at cost) financed since the Licensee's last examination up to a maximum 10% of the Base Fee. LMI Investments are defined in § 107.50.

• *Remove Fully-responsive Discount; Add Non-Responsiveness Addition:* During development of the proposed rule, SBA found that most SBICs regularly received the 10% discount available under § 107.692(c) for being ''fully responsive to the letter of notification of examination.'' SBA therefore took into account the cost efficiencies resulting from responsiveness when formulating the revised Base Fees in proposed § 107.692(b). To compensate SBA for the additional time required to examine the minority of SBICs that are not responsive, proposed § 107.692(c)(3) included an addition of 15% of the Base Fee for any SBIC that is ''not fully responsive to the letter of notification of examination.''

• *Retain Records/Files at Multiple Location Addition:* Proposed § 107.692(c)(4) also retained the 10% addition charged to SBICs that maintain records located in multiple locations.

• *Add Unresolved Finding Addition:* To encourage SBICs to resolve findings in a timely manner, § 107.692(c)(5) SBA proposed an additional fee equal to 5% of the Base Fee for every 30 calendar days or portion thereof that any examination finding that remains unresolved after a 90 calendar day cure period (beginning on the date that SBA notifies the SBIC that corrective action must be taken), unless SBA ultimately resolves the finding in the SBIC's favor.

• *Remove Additions for Partnership and LLC:* Since almost all SBICs are organized as partnerships and LLCs, the proposed rule removed these additional fees from § 107.692(c) and incorporated the cost into the Base Fee.

• *Remove Additions for Participating Securities Licensees and Early Stage SBICs:* SBA proposed to remove the fee additions for Participating Securities Licensees and Early Stage SBICs, both of which SBA no longer licenses.

SBA received one comment that supported the removal of additions for early stage, participating securities, and

partnership/LLC; this final rule adopts these proposed changes to § 107.692(c).

SBA received one comment that opposed the LMI discount, stating that discounts should not be used for political or social goals. SBA proposed this discount partly in response to a comment submitted by the same commenter on a different rule proposed by SBA, the Impact SBIC Rule (81 FR 5666), which comment stated, ''facilitating investment dollars in LMI areas is consistent with the core statute and the Congressional mandate for the SBIC program'' and suggested that the LMI discount might be helpful. SBA agrees that LMI investments are consistent with the SBIC program mission. Nonetheless, since the public opposed this discount in the context of this rule, and LMI investments do not have a meaningful impact on the amount of time and resources required by SBA in connection with an examination, this final rule § 107.692(c) does not include this discount in § 107.692(c).

SBA received several comments on the proposed adjustments to the examination base fee in the proposed rule. One comment stated that SBA should not make adjustments to the examination fee based on arbitrary decisions by examiners, including the no violation discount, non-responsive addition, records/files at multiple locations addition, and the unresolved finding addition. Examination fee adjustments are not determined arbitrarily, but rather, through a process requiring exam manager review. An examination may only apply an adjustment to the fee if an SBA exam manager agrees with the decision by the examiner that an adjustment is warranted. SBA exam managers review examination fees prepared by each examiner to ensure they are fairly and accurately assessed. Furthermore, SBICs have the right to dispute any examination fee invoice. SBA receives questions from SBICs concerning less than approximately 3% of its examination invoices. Each of the adjustments SBA received comments on is addressed in further detail below:

- *No Violation Discount:* SBA received one comment that supported a uniform examination fee, with no discounts and no additional fees, except in egregious cases. SBA agrees, in part, with this comment, and believes that a more uniform examination fee is desirable. Accordingly, this final rule seeks to avoid any single discount or addition being applied to a majority of SBICs. Although the proposed rule proposed to retain the no violation discount in current SBA regulations, since over 70% of SBICs examined in FY 2016 received the no violation discount, SBA believes it is appropriate not to retain this discount. Further, and consistent with the desire for a more uniform examination fee, the examination base fee identified in this final rule reflects SBA's average cost to examine an SBIC, and examinations resulting in violations require SBA to spend time and resources to identify and address those violations. If SBA were to retain the no violation discount, the examination fee would not fully cover SBA's cost of examining the SBIC. Therefore, and in light of the comment received supporting a more uniform examination fee, SBA removed the no violation discount in this final rule.
- *Non-Responsive Addition:* The comment objecting to this addition was particularly concerned that such an addition would be applied arbitrarily and without warning. SBA agrees with the comment that a written warning would be appropriate prior to assessing this addition. As with all additions, this addition may only be applied with exam manager approval. Over 97% of SBICs examined in FY 2016 received the discount for being responsive, and SBA expects that if SBIC responsiveness remains similar to FY 2016, it will only be necessary to apply the non-responsive addition in less than 3% of cases. For the reasons discussed above regarding SBA's desire for a more uniform examination fee consisting of an examination base fee that reflects SBA's average cost to examine an SBIC with adjustments which increase that cost, the final rule includes the non-responsive addition. Since uncooperative SBICs increase SBA's costs, this final rule adopts the non-responsive addition of 15% as proposed, but with the clarification that SBA will provide a written warning prior to assessment.
- *Records/Files at Multiple Location Addition:* SBA received one comment objecting to this addition, which is currently in SBA regulations and which SBA proposed to retain. SBA notes that there is no risk of arbitrary application of this addition, since SBIC records are maintained either in a single or multiple locations. Further, in FY 2016, less than 2% of SBICs received this addition. This final rule maintains this addition in § 107.692(c) since traveling to multiple locations increases SBA's time and costs.
- *Unresolved Finding Addition:* One comment objected to this addition on the grounds that some resolutions, such as the sale of a portfolio company, may take more than 90 days to resolve. SBA agrees with the comment that certain resolutions may take longer than 90 days to resolve. Accordingly, the final § 107.692(c) adopts this addition, since SBA spends a significant amount of time trying to resolve unresolved findings, but clarifies the language to account for resolutions requiring longer than 90 days to resolve.

A summary of the resulting final § 107.692(c) examination fee additions (also presented in tabular form in final § 107.692(d)) is summarized in Table 5, Proposed Examination Fee Additions, below.

TABLE 5—PROPOSED EXAMINATION FEE ADDITIONS

Examination fee additions	Amount of addition − % of base fee
(1) Non-responsive	15%.
(2) Records/Files at multiple locations	10%.
(3) Unresolved Findings	5% of Base Fee for every 30 days or portion thereof beyond the 90 day cure period or such later date as SBA sets forth in the notice for each unresolved finding.

Just as with current § 107.692, the final examination fee is calculated by taking the Base Fee determined under § 107.692(b) and adding the adjustments identified in § 107.692(c). The following example demonstrates this calculation. Assume that in March 2019, a leveraged SBIC has $125 million in assets at cost. The Base Fee calculation ($7,000 + .024% × $125 million) computes to $37,000. Since the Base Fee may not exceed the Maximum Base Fee for the relevant time period, the Base Fee would be equal to $32,000. If the SBIC is non-responsive to the examiner's requests and has records in multiple locations, the examination fee would be calculated as follows:

TABLE 6—EXAMPLE MARCH 2019 EXAMINATION FEE CALCULATION

Amount	Explanation
$32,000	Base Fee determined per final § 107.692(b).
+ $ 4,800	15% addition for non-responsiveness per final § 107.692(c)(1).
+ $ 3,200	10% addition for records in multiple locations per final § 107.692(c)(2).
$40,000	Examination Fee.

Although the Base Fee has a minimum and maximum, the resulting examination fee does not have a minimum or maximum. Unresolved findings beyond the 90-day cure period could result in increasingly higher examination fees. These additions are intended to incentivize SBICs to be responsive and resolve any findings as quickly as possible.

Section 107.692(e)—Delay Fee

Current § 107.692(e) states that SBA may assess an additional fee of $500 per day if SBA determines the examination is delayed due to the SBIC's lack of cooperation or the condition of its records.

SBA proposed to amend § 107.692(e) to increase the current $500 per day delay fee to $700 per day, to be adjusted annually using the Inflation Adjustment, beginning on October 1, 2021, to coincide with the date on which the other fee inflation adjustments are computed. SBA received one comment objecting to the fee, asserting that it could be assessed arbitrarily in an examiner's discretion. SBA does not assess this fee arbitrarily, and any assessment requires the process set forth in the SBIC Examinations Guidelines Standard Operating Procedure (10 09, October 28, 2013, Ch. 4, § 2(e)), which provides that only the Associate Administrator for Investment and Innovation may assess this delay fee after consulting with the Director of SBIC Examinations. SBA did not assess this delay fee for any of the SBICs examined in FY 2016. Delays can significantly increase SBA examination costs, therefore, SBA maintained this delay fee in cases involving delays due to a lack of cooperation on the part of the SBIC or the poor condition of the SBIC's records. This final rule adopts proposed § 107.692(e) without change.

Compliance With Executive Orders 12866, 12988, 13132 and 13771, the Paperwork Reduction Act (44 U.S.C. Ch. 35) and the Regulatory Flexibility Act (5 U.S.C. 601–612)

Executive Order 12866

The Office of Management and Budget has determined that this rule is not a ''significant'' regulatory action under Executive Order 12866. However, to provide additional transparency for the SBIC community, a Regulatory Impact Analysis is set forth below.

1. Necessity of Regulation

The Act authorizes SBA to collect administrative fees to cover licensing and examination costs. Currently, licensing fees cover less than a quarter of SBA's direct licensing costs and examination fees cover less than half of direct examination costs. It is critical that SBA increase fees in order to cover a larger portion of its licensing and examination expenses as contemplated by Congress. In addition, SBA will use the funds made available as a result of the rule to: (1) Improve technology for both licensing and examinations; (2) improve examiner training; (3) pay for necessary information subscription services; and (4) provide contractor resources to support licensing and examination activities.

2. Alternative Approaches to the Regulation

A. Licensing Fees

SBA considered several alternatives regarding licensing fees. SBA first considered indexing the licensing fees for inflation from 1996 (the year in which SBA most recently raised licensing fees) to 2017. This alternative did not produce sufficient fees to offset SBA licensing costs and produced lower licensing fees than those in this final rule. The increase in SBA's licensing costs has been driven not only by inflation since 1996, but also by the real increase in SBA's capital at risk (SBA guaranteed leverage and commitments) and the increased complexity of SBIC applicant organizational documents. Therefore, SBA rejected the option of adjusting the current fees only for inflation.

Given its technology and processing time concerns, SBA considered higher licensing fees than those proposed and finalized in this rule, in order to obtain the same technology and resources utilized by industry peers, and contractor support to reduce times in the licensing process. SBA did not attempt to fully cover its licensing costs in the proposed rule; at that time, SBA stated that it believed the proposed fee increases would be sufficient to meet essential needs while remaining well within the ability of qualified applicants to pay. In re-evaluating its technology resources utilized in licensing in response to a comment SBA received on the proposed rule, SBA now believes it will require technology and other licensing resources similar to industry peers. Therefore, SBA's licensing costs, excluding overhead, are expected to increase from approximately $2 million in FY 2016 to approximately $3 million by FY 2021. SBA is concerned that this final rule will only offset half of SBA's licensing costs, excluding overhead, by FY 2021. SBA is considering proposing a new rule after this final rule to further offset its costs.

SBA also considered implementing a larger increase immediately in order to offset costs more quickly. For the time being, SBA is opting to pursue the gradual increase identified in the proposed rule to allow potential applicants time to adjust to these increases. However, in order to obtain technology similar to private sector peers more quickly, SBA may consider a future rule to accelerate this phased in schedule.

B. Examination Fees

SBA considered several alternatives to the examination fees in this final regulation. SBA considered indexing the fees in current § 107.692(b) to reflect inflation from 1997 to 2017. This alternative did not produce sufficient fees to offset SBA's examinations costs. In assessing the reasons for this, SBA analyzed the SBIC portfolios from both periods and determined that the SBIC portfolio in 1997 was significantly different than today. In 1997, most of the SBICs with the highest total assets were bank-owned SBICs that did not issue SBA guaranteed debentures, and therefore required less time and resources for SBA to examine. Today, most of the highest-asset SBICs have significant amounts of SBA leverage. Therefore, merely indexing the existing fees would not appropriately reflect the costs associated with examinations.

SBA also considered smaller examination fee increases that were sufficient only to cover current costs and did not provide additional money needed to address technology upgrades,

training, or contractor support. SBA rejected this alternative for three reasons. First, the OIG indicated the need for improved technology and training for examiners and suggested that SBA increase its fees to cover these costs. SBA agrees that such resources would improve the examination function. Second, SBA believes the examination fees in the proposed rule are less than fees charged for similar activities such as financial audits. SBA calculated the median private sector financial audit fee paid by SBICs examined in FY 2016 to be $53,000; this rule would result in an average FY 2021 Examination Fee for those SBICs of less than half of that amount: approximately only $24,000. Third, while SBA's outstanding leverage in its operating portfolio has more than quadrupled from $2.2 billion at the end of September 30, 1999 to $10.7 billion as of March 31, 2017, the number of personnel in SBIC Examinations has declined by almost a third. In order to continue to monitor the SBIC program at the same level as in previous years, SBA intends to hire contractors with specialized skills to support this function.

SBA also considered a flat examination fee applicable to all SBICs regardless of the cost of assets they hold. SBA believes its examination activities are similar to financial auditor or bank examiner activities, which typically charge fees, based on asset cost, and therefore rejected this alternative. SBA also received a comment to the proposed rule that expressed concerns about adverse impact on smaller funds if the examination fee were not based on assets.

SBA considered increasing the fees more quickly to cover most of its estimated costs, but believed that a gradual increase over a multi-year period would allow SBICs time to budget and adjust to the higher fees. As stated above, SBA is now concerned that the gradual approach will not allow SBA to obtain critical resources in a timely manner, and is considering proposing a new rule to accelerate and further increase the fee increase.

3. Potential Benefits and Costs

SBA anticipates this final rule may benefit taxpayers by covering a larger portion of SBIC program administrative costs through the collection of an additional estimated $5 million to $6 million per year by October 2020. As noted previously, these increased fees will (1) improve SBIC program technology for both licensing and examinations, (2) improve examiner training, (3) pay for necessary information subscription services, (4) provide contractor resources to support licensing and examination activities, and (5) cover a higher portion of existing costs of licensing and examination activities. Collections are expected to increase annually each year beginning in October 2021 based on the CPI–U Inflation Adjustment.

SBICs should also benefit from the improved technology SBA expects to acquire with the additional funds made available as a result of this final rule.

This final rule will increase licensing costs for applicants and examination costs for SBICs. Beginning on the effective date, the final rule will increase licensing costs by $10,000 for an applicant applying for Initial Review and by $5,000 for an applicant submitting a complete license application at Final Licensing. The Final Licensing fee will increase by $5,000 each fiscal year, so by October 2020, the fee at Final Licensing will increase by an additional $15,000 from the first increase after the effective date of this Final Rule. SBA estimates that by October 2020, the average non-leveraged examination fee will increase by $7,000 and the average examination fee for leveraged SBICs will increase by $18,000 based on FY 2014–2016 examinations data. Thereafter, SBICs' costs will increase further through the annual increases to reflect inflation adjustments.

Executive Order 13563

A description of the need for this regulatory action and benefits and costs associated with this action is included above in the Regulatory Impact Analysis under Executive Order 12866.

In developing this rule, SBA talked with fund of funds managers, auditors, and contractors to determine whether the fees in this final rule were reasonable and, based in part on those discussions, SBA believes the fees in this final rule are reasonable. In reviewing organizational costs for SBIC applicants, including legal and other professional costs, SBIC applicants often incur organizational costs amounting to $500,000 or more. The increased licensing fee represents a small percentage of the total organizational costs typically incurred by SBIC applicants. SBA also compared Federal bank examiner fees and SBIC auditor fees (based on the SBIC annual Financial Reporting Form 468s submitted in 2015) with SBIC examination fees in this final rule. SBA believes the final licensing and examination fees are reasonable in comparison to the market.

The table below provides the capital and typical SBIC expenses for the average fund size of an SBIC licensed in FY 2016. As shown, SBIC licensing and examination fees represent a small percentage of the SBIC's total capital and its expenses.

TABLE 7—SBA LICENSING AND EXAMINATION FEES IN COMPARISON TO CAPITAL AND TYPICAL EXPENSES FOR SBIC OF AVERAGE FUND SIZE LICENSED IN FY 2016

Description	Leveraged SBIC	Non-leveraged SBIC
Total Capital	$157,500,000	$73,750,000
Private Investor Capital	52,500,000	73,750,000
SBA-Guaranteed Leverage	105,000,000	0
Typical Organizational Costs		
Organizational Costs in FY 2016	500,000	500,000
SBA Licensing Fee in FY 2021	45,000	45,000
Typical Annual SBIC Operating Expenses		
Management Fee (2%)	3,150,000	1,475,000
Other Expenses (Excluding SBA Leverage Interest, Leverage Fees, & Examination Fees)	500,000	250,000
SBA Examination Fee in FY 2021 (Assumes asset cost equal to total capital. Non-leveraged SBICs are typically only examined every 18 months.)	44,000	26,700

Executive Order 12988

This rule meets applicable standards set forth in section 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The rule will not have retroactive or presumptive effect.

Executive Order 13132

For the purpose of Executive Order 13132, SBA has determined that this rule 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. Therefore, for the purpose of Executive Order 13132, Federalism, SBA has determined that this final rule has no federalism implications warranting the preparation of a federalism assessment.

Executive Order 13771

This rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

Paperwork Reduction Act, 44 U.S.C. Ch. 35

For purposes of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA has determined that this rule will not impose any new reporting or recordkeeping requirements.

Regulatory Flexibility Act, 5 U.S.C. 601–612

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601, requires administrative agencies to consider the effect of their actions on small entities, small non-profit businesses, and small local governments. Pursuant to the RFA, when an agency issues a final rule, the agency must prepare a Final Regulatory Flexibility Act (FRFA) analysis, which describes whether the impact of the rule will have a significant economic impact on a substantial number of small entities. However, § 605 of the RFA allows an agency to certify a rule, in lieu of preparing a regulatory flexibility analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities. This final rule will affect all applicants that submit applications (which averaged 50 per year for FYs 2014 to 2016), and all operating SBICs (316 as of May 22, 2017). SBA estimates that approximately 98% of these SBICs are small entities. Therefore, this rule will have an impact on a substantial number of small entities. However, SBA has determined that the rule will not have a significant economic impact on small entities affected by the rule.

As noted above, the final § 107.300 will increase licensing costs by $10,000 for all applicants that submit an application for Initial Review after the effective date of the rule, and by an additional $20,000 by October 1, 2020, for all applicants that submit a license application for Final Review. The combined total increase of $30,000 represents less than 0.05% of the average applicant's Regulatory Capital based on newly licensed SBICs between October 1, 2014, and September 30, 2016. Many applicants have organizational costs totaling around $500,000, and some have far in excess of that amount. The combined FY 2021 initial and final licensing fee of $45,000 would represent a small fraction of those costs.

SBA estimates that § 107.692 in this final rule will eventually increase the average non-leveraged examination fee by $7,000, representing less than 0.02% of the average non-leveraged SBIC's Regulatory Capital, and the average leveraged SBIC examination fee by $18,000, representing 0.02% of the average total capital under management (Regulatory Capital and outstanding SBA guaranteed leverage). As a point of comparison, most SBIC managers charge management fees of approximately 2% of capital under management. (Management fees, like the examination fees, are paid by the SBIC.) For a leveraged SBIC with $50 million in Regulatory Capital and using 2 tiers of leverage charging a 2% management fee, the management fee would equal $3 million a year. If the leveraged SBIC had assets at cost of $150 million, and did not incur any exam fee additions, the exam fee in FY 2021 would amount to $44,000, representing less than 0.03% of the SBIC's total capital. The examination fee would be a very small percentage of the SBIC's expenses.

SBA believes that most applicants with sufficient private equity experience and capital raising ability will not be discouraged from applying to the program based on the administrative fee increases identified in this final rule. SBA asserts that the economic impact of the rule is minimal. Accordingly, the Administrator of the SBA certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 13 CFR Part 107

Examination fees, Investment companies, Loan programs—business, Licensing fees, Small businesses.

For the reasons stated in the preamble, SBA amends 13 CFR part 107 as follows:

PART 107—SMALL BUSINESS INVESTMENT COMPANIES

■ 1. The authority citation for part 107 continues to read as follows:

Authority: 15 U.S.C. 681, 683, 687(c), 687b, 687d, 687g, 687m.

■ 2. Amend § 107.50 by adding a definition of ''Inflation Adjustment'' in alphabetical order to read as follows:

§ 107.50 Definition of terms.

* * * * *

Inflation Adjustment is the methodology used to increase SBIC administrative fees using the Consumer Price Index for Urban Consumers (CPI–U), calculated by the U.S. Bureau of Labor and Statistics (BLS), using the U.S. city average for all items, not seasonally adjusted, with the base period of 1982 − 84 = 100. To calculate the Inflation Adjustment, each year, SBA will divide the CPI–U from the most recent June by the CPI–U from June of the preceding year. If the result is greater than 1, SBA will increase the relevant fees as follows:

(1) Multiply the result by the current fee; and

(2) Round to the nearest $100.

* * * * *

■ 3. Revise § 107.300 to read as follows:

§ 107.300 License application form and fee.

SBA evaluates license applicants in two review phases (initial review and final licensing), as follows:

(a) *Initial review.* Except as provided in this paragraph, SBIC applicants must submit a MAQ and the Initial Licensing Fee. MAQ means the Management Assessment Questionnaire in the form approved by SBA and available on SBA's Web site at *www.sba.gov/sbic.* Initial Licensing Fee means a non-refundable fee of $10,000. An applicant under Common Control with one or more Licensees must submit a written request to SBA, and the Initial Licensing Fee, to be considered for a license and is exempt from the requirement in this paragraph to submit a MAQ unless otherwise determined by SBA in SBA's discretion.

(b) *Final licensing.* (1) An applicant may proceed to the final licensing phase only if notified in writing by SBA that it may do so. Following receipt of such notice, in order to proceed to the final licensing phase, the applicant must submit a complete license application, in the form approved by SBA and available on SBA's Web site at *www.sba.gov/sbic,* within the timeframe identified by SBA; and the Final Licensing Fee. The Final Licensing Fee

means a non-refundable fee (determined as of the date SBA accepts the application) adjusted annually as follows:

Time period	Final licensing fee
December 13, 2017 to September 30, 2018	$20,000
October 1, 2018 to September 30, 2019	25,000
October 1, 2019 to September 30, 2020	30,000
October 1, 2020 to September 30, 2021	35,000

(2) Beginning on October 1, 2021, SBA will annually adjust both the Initial Licensing Fee and Final Licensing Fee using the Inflation Adjustment and will publish a Notice prior to such adjustment in the **Federal Register** identifying the amount of the fee.

■ 4. In § 107.410, revise paragraph (b) to read as follows:

§ 107.410 Changes in Control of Licensee (through change in ownership or otherwise).

* * * * *

(b) *Fee.* A processing fee equal to the combined Licensing Fee (Initial Licensing Fee plus the Final Licensing Fee then in effect) defined in § 107.300 must accompany any application for approval of one or more transactions or events that will result in a transfer of Control.

■ 5. In § 107.692, revise paragraphs (b) through (e) to read as follows:

§ 107.692 Examination fees.

* * * * *

(b) *Base Fee.* (1) The Base Fee will be assessed based on your total assets (at cost) as of the date of your latest certified financial statement, including if requested by SBA in connection with the examination, a more recently submitted interim statement. For purposes of this section, Base Fee means the Minimum Base Fee plus 0.024% of assets at cost, rounded to the nearest $100, not to exceed the Maximum Base Fee. The Minimum and Maximum Base Fees are adjusted annually as follows:

Time period (Based on the examination start date)	Minimum base fee	Maximum base fee for non-leveraged SBICs	Maximum base fee for leveraged SBICs
December 13, 2017 to September 30, 2018	$6,000	$22,500	$26,000
October 1, 2018 to September 30, 2019	7,000	25,000	32,000
October 1, 2019 to September 30, 2020	8,000	27,500	38,000
October 1, 2020 to September 30, 2021	9,000	30,000	44,000

(2) In the table in paragraph (b)(1) of this section, a Non-leveraged SBIC means any SBIC that, as of the date of the examination, has no outstanding Leverage or Leverage commitment, has no Earmarked Assets, and certifies to SBA that it will not seek Leverage in the future. Beginning on October 1, 2021, SBA will annually adjust the Minimum Base Fee and Maximum Base Fees using the Inflation Adjustment and will publish a Notice prior to such adjustment in the **Federal Register** identifying the amount of the fees.

(c) *Adjustments to Base Fee.* In order to determine the amount of your examination fee, your Base Fee, as determined in paragraph (b) of this section, will be increased based on the following criteria:

(1) If you were not fully responsive to the letter of notification of examination (that is, you did not provide all requested documents and information within the time period stipulated in the notification letter in a complete and accurate manner, or you did not prepare or did not have available all information requested by the examiner for on-site review) after a written warning by the SBA, you will pay an additional charge equal to 15% of your Base Fee;

(2) If you maintain your records/files in multiple locations (as permitted under § 107.600(b)), you will pay an additional charge equal to 10% of your Base Fee; and

(3) For any regulatory violation that remains unresolved 90 days from the date SBA notified you that you must take corrective action (as established by the date of the notification letter) or such later date as SBA sets forth in the notice, you will pay an additional charge equal to 5% of the Base Fee for every 30 days or portion thereof that the violation remains unresolved after the cure period, unless SBA resolves the finding in your favor.

(d) *Fee additions table.* The following table summarizes the additions noted in paragraph (c) of this section:

Examination fee additions	Amount of addition − % of base fee
Non-responsive	15%.
Records/Files at multiple locations	10%.
Unresolved Findings	5% of Base Fee for every 30 days or portion thereof beyond the 90 day cure period or such later date as SBA sets forth in the notice for each unresolved finding.

(e) *Delay fee.* If, in the judgment of SBA, the time required to complete your examination is delayed due to your lack of cooperation or the condition of your records, SBA may assess an additional fee of $700 per day. Beginning on October 1, 2021, SBA will annually adjust this fee using the Inflation Adjustment and will publish a Notice prior to such adjustment in the **Federal Register** identifying the amount of the fee.

Dated: November 6, 2017.

Linda E. McMahon,

Administrator.

[FR Doc. 2017–24535 Filed 11–9–17; 8:45 am]

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DEPARTMENT OF LABOR

Veterans' Employment and Training Service

20 CFR Part 1011

[Docket No. VETS–2017–0001]

RIN 1293–AA21

HIRE Vets Medallion Program

AGENCY: Veterans' Employment and Training Service (VETS), Labor.

ACTION: Final rule.

SUMMARY: VETS published a proposed rule implementing the Honoring Investments in Recruiting and Employing (HIRE) American Military Veterans Act of 2017 (HIRE Vets Act or Act). The HIRE Vets Act requires the Department of Labor (DOL or Department) to establish by rule a HIRE Vets Medallion Program (Medallion Program) and annually solicit and accept voluntary information from employers for consideration of employers to receive a HIRE Vets Medallion Award (the award). Under the Program, VETS will review applications and notify recipients of their awards, and announce their names at a time that coincides with Veterans Day. This final rule sets out the criteria for the different categories and levels of HIRE Vets Medallion Awards, the award application process, and the award fees. VETS invited written comments on the proposed rule, and any specific issues related to the proposal, from members of the public.

DATES: This rule is effective on January 12, 2018.

FOR FURTHER INFORMATION CONTACT: Randall Smith, Veterans' Employment and Training Service, U.S. Department of Labor, Room S–1325, 200 Constitution Avenue NW., Washington, DC 20210, *email: HIREVETS@dol.gov, telephone:* (202) 693–4700 or TTY (877) 889–5627 (these are not toll-free numbers). For press inquiries, contact Joe Versen, Office of Public Affairs, U.S. Department of Labor, 200 Constitution Avenue NW., Room S–1032, Washington, DC 20210, *email: versen.joseph.h@dol.gov, telephone:* (202) 693–4696 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The HIRE Vets Act was enacted on May 5, 2017, as Division O of the Consolidated Appropriations Act, 2017, Public Law 115–31. The purpose of the Act is to create a voluntary program for recognizing efforts by employers to recruit, employ, and retain veterans through a HIRE Vets Medallion Award. The Act requires the Department to issue regulations establishing the HIRE Vets Medallion Program.

In preparation for drafting a rule to implement the Act, VETS conducted three stakeholder sessions during the week of June 5, 2017. During these stakeholder sessions, VETS obtained input from large, medium, and small employers, veterans service organizations, military service organizations, and other interested parties.

On August 18, 2017, VETS published a notice of proposed rulemaking (NPRM) to implement the HIRE Vets Act (82 FR 39371). VETS invited public comment on the proposed regulations, and included questions about specific issues. The comment period closed on September 18, 2017, and VETS has considered all timely comments received in response to the proposed regulations.

VETS received 18 comments from a wide variety of sources. Commenters included: Veterans, employers, a national organization representing service providers, an employer association, and members of the public. While a few of the comments were general comments related to the benefit of the program or to veterans issues, the majority of comments specifically addressed issues contained in VETS' proposed rule.

Section-by-Section Summary of the Final Rule and Discussion of Comments

This preamble summarizes the final rule, section by section, and evaluates and responds to the public comments received. The subparts of the preamble generally follow the subparts of the final rule. Within each subpart of the preamble, VETS addresses those public comments related to regulatory sections within that subpart of the rule. If a proposed regulatory section is not addressed in the discussion below, it is because the public comments submitted in response to the NPRM did not substantively address that specific section and no changes have been made to the regulatory text. Further, VETS has made a number of non-substantive changes to improve the readability and conform the document stylistically that are not discussed in the analysis below.

Before beginning the section-by-section analysis, however, VETS acknowledges and responds to comments that did not correspond to specific sections of the rule.

Comments: Several commenters expressed general support for the HIRE Vets Medallion Program and the proposed rule.

Response: VETS looks forward to honoring employers who make it a priority to invest in recruiting, employing, and retaining veterans. The HIRE Vets Medallion Award is based on transparent criteria and aims to honor all employers, from the smallest to the largest, who meet these standards. The example set by recipients of this award will serve as models for other employers committed to hiring and retaining veterans.

Comments: Conversely, several commenters expressed skepticism as to the utility of the proposed program and whether the costs of the proposed program outweighed the program's benefits.

Response: No one is required to apply for a HIRE Vets Medallion Award. If the costs for an employer exceed the benefits, they need not apply. Nevertheless, VETS is of the opinion that some employers will find that the benefits of the award exceed the costs of applying. Congress determined that the HIRE Vets Medallion Program is a constructive way for the Federal Government to recognize companies that have made significant efforts to hire and retain veterans. The HIRE Vets Medallion Program will allow VETS to further leverage its existing Veteran Employment Outreach Program (VEOP) that directly supports efforts to assist employers in recruiting and employing veterans, along with existing partnerships with agencies such as the Small Business Administration (SBA) and State workforce agencies. This Program allows VETS to highlight and model employer efforts that can assist employers nationwide to develop veteran employment efforts further.

Comment: Finally, one commenter questioned why the HIRE Vets Medallion Program is not administered by the U.S. Department of Veterans Affairs.

Response: Under 38 U.S.C. 4102A(a)(1), the Assistant Secretary of Labor for VETS is responsible for all DOL employment and training programs that to the extent that they affect veterans. VETS' mission is to prepare America's veterans, service members, and their spouses for rewarding careers, provide them with employment resources and expertise, protect their employment rights, and promote their

employment opportunities. Consistent with that responsibility, Congress specifically assigned administration of the HIRE Vets Medallion Award to the Secretary of Labor (Secretary). VETS supports workforce resources for employers to develop a globally competitive workforce and the public workforce system is a valuable resource to support human capital development of workers across the country. The system offers essential tools to employers to help transform the workforce to meet the changing demands of the 21st-century economy, and to become more competitive.

Subpart A—Introduction to the Regulations for the HIRE Vets Act

Sections 1011.000 through 1011.015 detail the program's purpose, scope, definitions, and award types. VETS received several comments on the definitions at § 1011.005 and on the employer size categories at § 1011.015.

Definition of Veteran

Comment: One commenter questioned the use of the definition of ''veteran'' at 38 U.S.C. 101. The commenter expressed a desire for VETS to incorporate National Guard members mobilized under U.S.C. title 32 into the definition of ''veteran'' as it implements the statute into final regulatory text.

Response: Section 8(c) of the Act states that the term ''veteran'' has the meaning given such term under 38 U.S.C. 101. Incorporating all mobilization under Title 32 would be inconsistent with the meaning of section 8(c) of the Act. Consequently, VETS declines to make this change. However, as we stated in the NPRM, VETS recognizes that most employers determine which employees are veterans according to the employee's self-identification. VETS does not expect employers to change these practices in order to guarantee that every employee who self-identifies as a veteran meets the definition of veteran set out in the Act. VETS' primary concern is that an employer applying for an award reports as accurately as it is reasonably able. VETS retains the language as proposed.

Employer Size Categories

Comments: Two commenters requested a change to the employer award size categories, expressing that it might be difficult for companies with more than 500 employees but fewer than 10,000 employees to compete with those employers that have more than 10,000 employees. One commenter questioned if perhaps revenue would be a better standard by which to categorize employers, while another recommended defining large employers as those with 10,000 or more employees.

Response: VETS retains the rule language as proposed because the employer category sizes are established by statute in section 3(b) of the Act. Consequently, VETS does not have the discretion to make this change.

Subpart B—Award Criteria

Sections 1011.100 through 1011.120 enumerate the award criteria for the various award categories and levels. VETS received a few comments suggesting additional criteria or requesting clarification on criteria. VETS also received several comments on the violation of labor law provision at § 1011.120. Because many of these comments apply across sections, this preamble first addresses comments that touch on multiple sections, then addresses comments on § 1011.120, and finally addresses comments suggesting new criteria.

Comments on Proposed Criteria

Comment: One commenter suggested that the same criteria should apply to all employers regardless of size.

Response: For the sake of simplicity, VETS retained consistency across awards to the extent possible. However, to recognize that employers of different sizes will likely have different resources, VETS proposed that small employers need not satisfy as many criteria as medium employers and that medium employers need not satisfy as many criteria as large employers. VETS concludes that the proposed language strikes the best balance between these two interests and retains the language as proposed.

Comment: A commenter requested that VETS ensure that there is a meaningful retention requirement. The commenter also suggested companies that hire veterans in order to meet award requirements and subsequently lay off those veterans be made to return any award they receive.

Response: VETS agrees that retention is a very important issue for veteran employees. Consequently, every award has a retention criterion. As to the commenter's concern about employers hiring veterans and then laying them off, these awards recognize actions taken and VETS will not revoke an award if an employer legitimately qualified for the award in the previous year. However, VETS can revoke an award for the reasons described in § 1011.230, including if the employer falsely attested to its retention numbers. Moreover, § 1011.225 allows VETS to review an application, if at any time VETS becomes aware of facts that indicate information provided by an employer may be incorrect, and § 1011.600 requires the employer to retain the information supporting its application for 2 years. VETS retains the language as proposed.

Comment: One commenter stated that for some industries, retention numbers are proprietary information and asked how employers could ensure that information used for judging the award would not be released to the public or their competitors.

Response: VETS cannot ensure that information submitted for evaluating an application will not be released to the public. Therefore, information submitted by an applicant may become available to the public. The HIRE Vets Medallion Program is a voluntary program. In order to ensure reviewability, all applicants must provide the required information in order to qualify for an award. VETS retains the language as proposed.

Comment: One commenter stated that the retained percentage should be compared to the number of actual hires and that employers should present the number of hires along with the number of veterans retained within a given timeframe.

Response: VETS agrees that the awards should include both hiring and retention and such criteria are included.

Comment: A commenter requested that VETS merge the requirements that employers establish internal organizations (such as the veteran organization or resource group) with the requirement that employers establish an assistance or training program. This commenter also suggested that the percentage of veteran employees enrolled in the veteran organization or resource group could be an additional weighted criterion.

Response: VETS retains the language as proposed. Section 3(b)(1) of the Act establishes these criteria as separate criteria intended to serve separate purposes. Veteran organizations or resource groups are support networks for veteran employees while the ''assistance or training program'' focuses on the provision of post-secondary education to veteran employees. However, there can be overlap in how the employer satisfies its criteria. For instance, a large employer's human resources professional might run the employee veteran organization or resource group. Similarly, the tuition assistance program for post-secondary education might overlap with the programs established to enhance the leadership skills of veteran employees. As for the suggestion that the percentage

of veteran employees enrolled in the veteran organization or resource group be an additional criterion, VETS declines to make this change because it would create an additional reporting burden for employers.

Comment: One commenter stated, in regard to the dedicated human resources professional criterion, that large employers might have hiring, training, and retention responsibilities spread across multiple departments.

Response: Large employers can have veteran hiring, training, and retention responsibilities spread across multiple departments and still meet the criterion at § 1011.100(b)(7). Large employers with more than 5,000 employees need to have at least one dedicated human resources professional per the requirements of section 3(b)(1)(C)(iv) of the Act, but the definition of *Dedicated Human Resources Professional* in § 1011.005 states that these duties can be split amongst multiple people so long as the time spent supporting the hiring, training, and retention of veteran employees is the equivalent of one full-time professional. Additionally, large employers that employ 5,000 or fewer employees need not have a dedicated human resources professional but may instead satisfy this criterion by having at least one human resources professional whose regular work duties include supporting the hiring, training, and retention of veteran employees. The proposed language is consistent with the Act and does not prohibit large employers from having veteran hiring, training, and retention responsibilities spread across multiple departments. VETS retains the language as proposed.

Comment: One commenter expressed concern that the pay differential criterion was too vague, as it did not define the types of deployment to which the pay differential criterion applied. The commenter also questioned the length of time an employer would need to offer the pay differential in order to satisfy the criterion and whether small and medium employers would be able to afford the pay differential for more than a year.

Response: The definition of *Active Duty in the United States National Guard or Reserve* at § 1011.005 defines the types of deployment to which the pay differential criterion applies by reference to the definition of active duty in 10 U.S.C. 101(d)(1). Because this definition is well-established and sufficiently clear, VETS retains the proposed language without change. Additionally, VETS appreciates the commenter's concern that the pay differential applies for as long as the employee is on active duty. However, the pay differential is only included as part of the platinum award criteria and is only required for the large employer platinum award. Consequently, employers could receive all awards except the large employer platinum award without satisfying this criterion. VETS concludes that inclusion of the provision of pay differential for as long as the employee is on active duty is consistent with the higher standard expected of platinum awardees. Consequently, VETS retains the language as proposed.

Comment: One commenter requested an explicit list as to which programs constitute ''assistance'' or ''training'' programs.

Response: VETS retains the language as proposed in order to retain flexibility for employers to provide integration assistance that best suits their workforce. However, VETS agrees that a non-exhaustive list of examples of post-secondary education programs that would satisfy the tuition assistance program criterion would be useful for employers. Examples of post-secondary programs and courses for which employers may provide tuition assistance include:

- ☐ Correspondence training
- ☐ Cooperative training
- ☐ Entrepreneurship training
- ☐ Flight training
- ☐ Independent and distance learning
- ☐ Undergraduate and graduate degrees
- ☐ Licensing and certification reimbursement
- ☐ Vocational/technical training and non-college degree programs
- ☐ National testing reimbursement
- ☐ On-the-job training and apprenticeships
- ☐ Tutorial assistance

Also, as the proposed rule explained, the assistance provided through an employer's tuition assistance program may take many forms, including financial assistance, leave assistance, or discounts on post-secondary education.

VETS will continue to offer technical assistance on the types of activities and programs that satisfy the other integration assistance criteria.

Comments on Veteran-Specific Labor Violations Criterion at § 1011.120

Section 1011.120 outlines the circumstances that would disqualify or delay an employer from receiving a HIRE Vets Medallion Award for violations incurred under labor laws protecting veterans as administered by, or in conjunction with, VETS and the Office of Federal Contract Compliance Programs (OFCCP). Commenters supported: The premise that an employer that does not take its obligations under the Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA) and the Vietnam Era Veterans' Readjustment Assistance Act of 1974 (VEVRAA) seriously is undeserving of an award; limiting the covered laws to USERRA and VEVRAA; and retaining discretion to delay an award if VETS has credible information suggesting that a significant violation may have occurred. A commenter also stated that no additional disqualifying events should be added to the list.

Comment: One commenter stated that while most of the regulation tracks the Act, the Act contained no corresponding section to the violation of labor law provision proposed at § 1011.120.

Response: Section 3(b)(1)(E) of the Act grants VETS authority to establish additional criteria for each level of award. VETS used this authority to establish the criterion described in § 1011.120. VETS chose to include this criterion because employers that have been proven to have violated, or have explicitly admitted violating the rights of their veteran employees should not receive an award from VETS for their veteran employment practices. VETS retains the language as proposed.

Comment: One commenter suggested that ''technical or minor'' violations of USERRA or VEVRAA should not be disqualifying. The commenter asserted that this provision in the proposed rule was similar to provisions in the guidance implementing the now rescinded Executive Order 13673, and that the effect could be employers being disqualified for the award for issues unrelated to the recruitment, employment, and retention of veterans.

Response: The disqualification standard proposed in § 1011.120 is far narrower than the one used in the implementation of now rescinded Executive Order (E.O.) 13673. The E.O. covered numerous additional labor statutes (instead of just the veteran employment protections covered here) and would disqualify an employer for violation determinations made by the agency before judicial enforcement proceedings began. Since fairness requires that all applicants be subject to a clear and consistent standard, the final rule will retain the bright line standard instead of adopting a flexible standard. Additionally, VETS declines to revise the regulatory text to distinguish between purportedly major and minor violations for the purposes of this rule.

Comment: One commenter questioned whether one of the proposed disqualifying events, a settlement agreement in which the employer

admits a violation of either USERRA or VEVRAA, should be included given the varying reasons that employers enter into settlement agreements. If VETS were to keep this provision, the commenter opined that it should not be expanded, so as to avoid creating a disincentive for settling allegations.

Response: VETS retains the language as proposed. The rule would only disqualify employers with settlement agreements in which the employer specifically admits to violating USERRA or VEVRAA, two laws closely related to veteran employment. If the employer has violated these laws and admits to doing so in a settlement agreement, VETS has concluded that this is as serious as the judgment of a court or tribunal and, thus, considers it a disqualifying event. Settlement agreements in which the employer does not admit liability for violations of these statutes would not disqualify an employer from consideration.

Comment: One commenter suggested that the regulation more explicitly reference the VEVRAA requirement that covered Federal Government contractors and subcontractors follow mandatory job listing requirements.

Response: VETS retains the language as proposed because the fact that VETS has incorporated USERRA or VEVRAA into the rule should serve to highlight all USERRA and VEVRAA requirements for covered employers. Additionally, it is not appropriate to elevate this single aspect of the VEVRAA requirements when covered employers must comply with all requirements.

Comment: One commenter raised the specific concern that Federal contractors attempting to comply with the mandatory job listing requirement set forth in the VEVRAA statute and regulations may nevertheless have violations alleged against them, which could result in their disqualification from receiving an award. The commenter expressed concern over an employer not being able to qualify for an award because, although the employer provides job vacancies to a State or local employment service as required by law, the employment service fails to post the vacancies.

Response: This concern is misplaced. First of all, the specific situation described by the commenter, in which a contractor provides the required job vacancy information to the employment service delivery system (ESDS) location and the ESDS does not post it, does not constitute a violation of VEVRAA. Per the relevant VEVRAA regulations, so long as the contractor provides the job vacancy information ''in any manner and format permitted'' by the appropriate ESDS, it has satisfied its obligation under the regulations, and would not be disqualified from receiving an award as a result. See 41 CFR 60–300.5(a)(2). Second, an ''alleged'' violation of VEVRAA's mandatory job listing requirement would not alone trigger disqualification. As this final rule makes clear, only a decision of an administrative law judge that is not appealed and becomes the final agency action, or a settlement agreement in which the employer explicitly admits that it violated VEVRAA, could result in disqualification.

Suggested New Criteria

Comment: One commenter requested that VETS create an alternative criterion to the veteran employee percentage criterion that weighs the number of veterans who are applying for employment, potentially tracking progress for employers with nascent veteran hiring programs. The commenter expressed concern that the alternative veteran employee percentage criterion does not always correlate with the effort that employers put into a veterans hiring initiative, favoring employers with already established programs.

Response: The number of veteran applications, while an integral part of recruitment, does not necessarily equate to hiring or retention, the focus of the Act. Therefore, in order to best reflect the focus of the Act and to retain simplicity, VETS retains the language as proposed instead of adding an additional alternative criterion.

Comment: One commenter requested that a portion of the application allow employers to outline military/veteran-friendly initiatives or awards that the employers have received.

Response: The application form contains an optional item that allows employers to describe efforts to support the veteran and military community. However, this item is not a criterion for recognition and will not factor into whether an employer receives an award. It will instead be used to facilitate the sharing of good practices for veteran hiring and retention. The HIRE Vets Medallion Program is a recognition program to honor employer commitment to, and investment in, veteran recruiting and employment. Therefore, VETS declines to establish a criterion for the HIRE Vets Medallion Program related to other military/veteran-friendly initiatives and awards.

Comment: A commenter requested inclusion of an additional criterion more specifically targeting community and charitable services provided by employers to the veteran community.

Response: Section 2(a) of the Act states that the purpose of the Act is to recognize efforts by employers to recruit, employ, and retain veterans and to provide community and charitable services supporting the veteran community. VETS agrees that community and charitable services are an integral part of supporting the veteran community. However, VETS declines to establish an additional criterion related to community and charitable services because these services are already integrated throughout the large employer criteria that serve as the basis for the small and medium employer criteria. Consequently, VETS retains the language as proposed.

Comment: One commenter suggested an additional criterion that employers use the workforce development system to list their job openings, either directly with State job banks or through the National Labor Exchange (NLx). The commenter expressed concern that if such a criterion is not established, then the high-quality jobs offered by employers applying for the award might not reach the veterans, transitioning service members, and spouses served by the Department.

Response: NLx is recognized as a workforce system tool that collects and disseminates job postings, including through State job banks. VETS encourages employers to use State job banks as a resource to help with the recruitment of veteran employees. Although VETS encourages the use of State job banks, it declines to add a related criterion in order to retain flexibility for employers in structuring how they satisfy the award criteria.

Comment: One commenter also suggested an additional criterion requiring engagement with the workforce development system or that, at the very least, additional consideration be provided to applications that reflect collaboration with the workforce development system. The commenter stated that employers could use the workforce development system to screen job applicants and facilitate participation in career and hiring events, as well as for help with many other activities. The commenter noted that these services might be particularly critical for small employers who lack a human resources professional. The commenter also noted that employers can serve on State and Local Workforce Development Boards where they can participate in the design and operation of services in their area.

Response: The public workforce system includes a nationwide network of over 2,400 American Job Centers (AJCs), a network operated in partnership by Local Workforce Development Boards, State Workforce Agencies, and DOL. VETS will continue to work closely with Federal and State partners to provide coordinated information and services to job seekers and employers while continually facilitating and developing meaningful employment and training opportunities for transitioning service members, veterans, and military families. *VETERANS.GOV* enables employers to directly contact VETS' VEOP to request assistance in hiring veterans. Although, as with the comment on including a State job bank or NLx criterion, VETS encourages employers to take advantage of the public workforce system, it declines to add a related criterion in order to retain flexibility for employers.

Comment: One commenter suggested adding a criterion for procedural descriptions of a 6-month onboarding process for veteran employees.

Response: Although VETS agrees that effective onboarding of veteran employees is important to the establishment of a successful working environment for veteran employees, the final rule retains the language as proposed because the various forms of integration assistance covered by the proposed criteria already answer the purpose of this request. For example, the veteran organization or resource group criterion requires that the organization or resource group assist ''*new* veteran employees'' (emphasis added).

Subpart C—Application Process

Subpart C sets out the application process for the HIRE Vets Medallion Award. VETS received two comments on subpart C.

Comment: A commenter asked that VETS reconsider § 1101.210 and that employers be allowed to win an award every year.

Response: The requirement at § 1011.210 is a requirement of the Act. Section 2(d) of the Act states that ''[a]n employer who receives a HIRE Vets Medallion Award for one calendar year is not eligible to receive a HIRE Vets Medallion Award for the subsequent calendar year.'' Consequently, VETS does not have discretion to make this change. However, for purposes of clarity, VETS has amended proposed § 1011.210 to reference section 2(d) of the HIRE Vets Act.

Comment: A commenter also asked VETS to clarify who will be reviewing applications for the medallion awards.

Response: VETS is responsible for the application review and award determination for the HIRE Vets Medallion Program.

VETS also made a nonsubstantive change to § 1011.230(a), clarifying that VETS can deny an award if an employer fails to satisfy all application requirements. This is not a substantive change; this requirement was already included in § 1011.010. However, VETS has added it to the language of § 1011.230 for additional clarity.

Subpart D—Fees and Caps

Subpart D sets out the fees for the HIRE Vets Program and the application caps that VETS can utilize.

Comment: One commenter requested clarity as to whether it is VETS' understanding that the fee authorized by section 5(b) of the Act can only be collected if a future appropriations action triggers the fee collection.

Response: Section 5(b) of the Act grants VETS authority to collect fees and states that VETS ''shall establish the amount of the fee such that the amounts collected as fees and deposited into the [HIRE Vets Medallion Award] Fund are sufficient to cover the costs associated with carrying out this division.'' Therefore, the Act grants VETS authority to collect fees and does not require a future appropriations action to trigger this authority.

Comment: One commenter expressed concern about the accountability of the award fund and asked what safeguards would be in place to protect money in the fund.

Response: Funds contained in the HIRE Vets Medallion Award Fund will be subject to the same protections and safeguards that are applied to all Federal Government funds.

Subpart E—Design and Display

VETS received no comments on subpart E.

Subpart F—Requests for Reconsideration

VETS received no comments on subpart F.

Subpart G—Record Retention

VETS received no comments on subpart G.

Procedural Determinations

Executive Orders 12866 and 13563: Regulatory Planning and Review

Introduction

Executive Order 13563 directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; tailor the regulation to impose the least burden on society, consistent with achieving the regulatory objectives; and in choosing among alternative regulatory approaches, select those approaches that maximize net benefits. Executive Order 13563 recognizes that some benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitative values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

Under Executive Order 12866, the Office of Management and Budget (OMB) must determine whether a regulatory action is significant and therefore subject to the requirements of that Executive Order and to review by OMB (58 FR 51735). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule that: (1) Has an annual effect on the economy of $100 million or more, or adversely affects in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities (also referred to as economically significant); (2) creates serious inconsistency or otherwise interferes with an action taken or planned by another agency; (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. *Id.*

VETS has determined that this rule is not an economically significant regulation—neither the costs nor the benefits exceed $100 million dollars in any given year. VETS has determined that this rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866. VETS analyzed costs and benefits of this rule using 2016 employment and wage data from the Bureau of Labor Statistics (BLS). The cost analysis uses a 10-year time horizon. The benefits analysis is qualitative and appears at the end of this section. Since the benefits analysis is qualitative, there will be no analysis of net benefits (benefits minus costs). VETS' estimates of costs are presented as follows:

- Veteran employment and potential eligibility for the award—Estimates how many employers may meet the application requirements of the award.

• Unit costs—Estimates the unit costs of complying with the application requirements of the award.
• Participation rates—Estimates how many eligible employers will potentially choose to apply for the award.
• Government costs—Estimates the costs to the Government for processing the applications and the costs to develop the system to support the review and approval process.
• Total annualized costs—Estimates the total annualized private and Government costs of the program.

Costs for this regulation are uncertain, due partly to the program being entirely new with no obvious equivalents; VETS cannot anticipate the number of employers that will choose to participate in the program. For this reason, this analysis contains estimates that are based on very limited data. This is the first veteran hiring award established by VETS to recognize employers for their accomplishments in recruiting, retaining, and hiring veterans.

Introduction

The methodology for these estimates will remain the same as those presented in the NPRM. No public comments were received addressing the methodology for estimating costs of the regulation. VETS did receive public comments related to some aspects of the analysis, as well as comments on the benefits to employers and veteran employees. VETS responds to these comments in the remainder of this section.

Veteran Employment and Potential Eligibility for the Award

As of 2016 there were 20.9 million veterans,[1] making up 10 percent of the civilian non-institutionalized population over the age of 18. While the total number of veterans varies over time, there are between 240,000 and 360,000 service members who leave military service each year, according to a 2013 White House report.[2] In 2016 there were 10 million veterans employed according to data collected from the Current Population Survey and reported by BLS, making up close to 7 percent of the U.S. employed population.

The three leading industry sectors for veteran employment are manufacturing (North American Industry Classification System (NAICS) code 31–33), with, 1.3 million veterans; wholesale and retail trade (NAICS code 42, 44–45) with 1.1 million veterans; and professional and business services (NAICS code 54–56) with 1.1 million veterans. Evaluating veteran employment as a percentage of total employment by industry highlights the various industries where veterans make up more than 7 percent of the employed population. Based on the data, it appears there are many industries where a typical employer can readily meet the basic criteria of hiring 7 percent or more veteran employees, while it may be more difficult in other industries.

Veteran employment levels at the 3-digit NAICS level (industry subsectors) were mapped to BLS data from the Current Employment Statistics survey to derive veteran employment as a percentage of total employees by NAICS code. The results of this comparison are presented in Table 1. A majority of private industry subsectors have veteran employment of 7 percent or higher; the industries with the highest percentages were the Petroleum and coal products industry with 22.4 percent veteran employment, followed by Utilities with 20.5 percent veteran employment. The two industries with the lowest percentage of veteran employment are: Management of companies and enterprises with 0.5 percent and Internet publishing and broadcasting and Web search portals with 1.0 percent veteran employment. Other industry sectors where the percentage of veterans employed is lower than the national average are the healthcare and social assistance sector with 3.5 percent, and the accommodations and food services sector with 1.6 percent veteran employment. The concentration of veteran employment in utilities and manufacturing industries is a reflection of the type of military experience many veterans offer when seeking jobs that match their skill set.

TABLE 1—VETERAN EMPLOYMENT IN 2016

Industry	Veteran employment [1] (in thousands)	Total employment [2] (in thousands)	Percent of veterans employed
Total Employment	10,129	151,423	6.7
Mining, Quarrying, and Oil and Gas	92	626	14.7
Construction	588	6,711	8.8
Manufacturing	1,285	12,348	10.4
Durable Goods Manufacturing	898	7,719	11.6
Nonmetallic Mineral Products	39	408	9.6
Primary Metals and Fabricated Metal Products	156	1,763	8.8
Machinery Manufacturing	125	1,080	11.6
Computers and Electronic Products	113	1,048	10.8
Electrical equipment and Appliances	30	383	7.8
Transportation Equipment	269	1,625	16.6
Wood Products	34	392	8.7
Furniture and Fixtures	28	389	7.2
Miscellaneous Manufacturing	103	591	17.4
Nondurable Goods Manufacturing	387	4,629	8.4
Food Manufacturing	92	1,554	5.9
Beverage and Tobacco Products	26	233	11.2
Textiles, Apparel, and Leather	23	371	6.2
Paper and Printing	76	818	9.3
Petroleum and Coal Products	25	112	22.4
Chemicals	106	811	13.1
Plastics and Rubber Products	38	699	5.4
Wholesale and Retail Trade	1,090	21,687	5.0
Wholesale Trade	260	5,867	4.4

[1] BLS, DOL, Current Population Survey, 2016.

[2] Watson, Ben, (2014) Veteran Unemployment Rate Drops, But Still Outpaces the Rest of the Country. *www.defenseone.com,* May 2, 2014. Retrieved from: *http://www.defenseone.com/news/2014/05/D1-Watson-veteran-unemployment-rate-drops-still-outpaces-rest-country/83692/.*

TABLE 1—VETERAN EMPLOYMENT IN 2016—Continued

Industry	Veteran employment [1] (in thousands)	Total employment [2] (in thousands)	Percent of veterans employed
Retail Trade	830	15,820	5.2
Transportation and Utilities	753	5,546	13.6
Transportation and Warehousing	638	4,989	12.8
Utilities	114	556	20.5
Information	180	2,772	6.5
Publishing, Except Internet	15	730	2.1
Motion Pictures and Sound Recording Industries	13	420	3.1
Radio and TV Broadcasting and Cable Subscriptions Programming	42	269	15.6
Internet Publishing and Broadcasting and Web Search Portals	2	201	1.0
Telecommunications	96	795	12.1
Data Processing, Hosting, and Related Services	10	300	3.3
Libraries, Archives, and Other Information Services	2	59	3.4
Financial Activities	496	8,285	6.0
Finance and Insurance	309	6,142	5.0
Finance	174	3,559	4.9
Insurance	135	2,583	5.2
Real Estate and Rental and Leasing	187	2,143	8.7
Real Estate	146	1,559	9.4
Rental and Leasing Services	41	583	7.0
Professional and Business Services	1,092	20,136	5.4
Professional and Technical Services	658	8,877	7.4
Management, Administrative, and Waste Services	433	11,259	3.8
Management of Companies and Enterprises	11	2,241	0.5
Administrative and Support Services	384	8,613	4.5
Waste Management and Remediation Services	38	405	9.4
Education and Health Services	826	22,616	3.7
Educational Services	161	3,560	4.5
Health Care and Social Assistance	664	19,056	3.5
Hospitals	266	5,025	5.3
Health Services, Except Hospitals	322	10,396	3.1
Social Assistance	76	3,636	2.1
Leisure and Hospitality	344	15,620	2.2
Arts, Entertainment, and Recreation	128	2,235	5.7
Accommodation and Food Services	216	13,386	1.6
Accommodation	49	1,947	2.5
Food Services and Drinking Places	167	11,439	1.5
Other Services	351	5,685	6.2
Other Services, Except Private Households	337	4,961	6.8
Repair and Maintenance	150	1,289	11.6
Personal and Laundry Services	68	1,445	4.7
Membership Associations and Organizations	119	2,950	4.0
Government—Local [3]	708	14,339	4.9

Source:
[1] BLS, Current Population Survey, 2016.
[2] BLS, Current Employment Statistics survey, 2016.
[3] U.S. Census of Governments, 2012.
(See Spreadsheets, Docket No. VETS–2017–0001–0002 for all sources and derivation).

The job posting site, *Indeed.com,* identified five occupational categories where veterans have the highest levels of employment: Transportation and material moving, installation maintenance and repair, protective service, management, and construction and extraction. Many veterans find the skills and experience they developed while in the military align better with these occupations than with others, making the transition to a civilian job easier.[3]

Due to the fact the award program requires a fee, it was determined that employers with fewer than five employees are relatively unlikely to participate in the program (although they are still eligible to apply for the award if they choose). Very small employers with fewer than five employees will most likely not hire often or may not choose to invest resources in actions that would qualify them for the award program, thus this analysis contains three groupings of employer size: Small employers with 5 to 49 employees; medium employers with 50 to 499 employees; and large employers with 500 or more employees. These groupings were based on the availability of data in the U.S. Census Bureau 2014 Statistics of U.S. Businesses (SUSB),[4] which closely approximates the definition of small, medium and large employers in the statute. The SUSB data show a total of 2,379,033 employers with more than four employees. However, knowing the percentage of veterans in an industry's workforce does not indicate how many employers in that industry can meet the quantitative criteria for receiving the

[3] Culbertson, Daniel, (2016) A Deep Look at the Data: How Are Veterans Doing in Today's Workforce? Indeed blog, November 10, 2016. Retrieved from: *http://blog.indeed.com/2016/11/10/veterans-employment/.*

[4] U.S. Census Bureau, 2014. SUSB Annual Datasets by Establishment Industry: U.S. & States, NAICS, detailed employment sizes. Accessed on 6/15/2017 at: *https://www.census.gov/data/datasets/2014/econ/susb/2014-susb.html.* Eligibility estimates by VETS. See text and spreadsheets (Docket No. VETS–2017–0001–0002).

award. For example, if 7 percent of an industry's workforce is veterans, there will be many employers that are above and below this average in any given year's hiring. In order to estimate the number of potentially eligible employers (those meeting the quantitative criteria) in an industry, we need to be able to estimate the effects of turnover on the ability to meet retention criteria, the percentage of employers that hire veterans as 7 percent or more of their total number of new hires for the applicable time period, and the percentage with 7 percent veterans in their current workforces. The effects of turnover on the ability to meet retention criteria may be the most difficult quantitative criteria to estimate. Average separation rates across all industries are such that, if veterans' rates are equal to the typical rates of all workers considered together, a 75 percent retention rate would be difficult to meet.[5] However, published separation rates include seasonal and temporary employments, which are excluded under the definition of ''employee'' and subsequently from the calculation of retention rates in this final rule. Absent comments on the methodology and more detailed data, VETS retains its assumption from the NPRM that half of the employers able to meet a 7 percent hiring rate will not be able to meet a requirement for 75 percent retention. For this analysis, if we make the simplifying assumptions that the percentage of veterans currently in the workforce are typical of available new hires in an industry, and that each new hire and each employee have an equal chance of being a veteran, then we can use the binomial distribution to estimate the probability that an employer has more than 7 percent veterans among new hires or more than 7 percent veterans among existing employees. The binomial distribution used here is designed to calculate the probability that 7 percent or more employees in a set of employees are veterans given the probability of an event (whether a given new hire or employee is a veteran). The application of the binomial distribution requires estimates of the number of new hires per year and the number of employees. For this purpose, VETS used 2014 SUSB[6] data on the number of employers and employees for small employers, medium employers and large employers. These averages of new hires were 13 employees per employer for small employers, 123 employees per employer for medium employers and 3,000 employees per employer for large employers. VETS estimated that these employers would hire 25 percent of their workforce in any given year. Of the 2,379,033 employers with more than four employees, VETS estimates that 424,952, or 18 percent of all employers in the three size ranges, would be potentially eligible for the program.

The complete formulas for the probability calculations are given in the supplemental spreadsheets (Docket No. VETS–2017–0001–0002). There are four probabilities needed for these calculations:

PH = the probability that more than 7 percent of new hires are veterans;
PE = the probability that more than 7 percent of employees are veterans;
PR = the probability that 75 percent of veteran hires are retained (estimated to be 0.5 in all cases); and
PLYH = the probability that an employer hired at least one veteran in the year prior to the current year.

Given these probabilities the formula used in the calculations for small and medium employers is:

Total probability = PH + (1 − PH) * PE * PLYH * PR

For large employers, the formula is somewhat simpler:

Total Probability = PH + (1 − PH) * PLYH * PR

Table 2 shows the results for the estimate of potentially eligible employers by size class and industry.

TABLE 2—ESTIMATE OF ELIGIBLE EMPLOYERS

Industry	Total employers (5+)	Potentially eligible employers			
		Small employers (5–49)	Medium employers (50–499)	Large employers (500+)	Total
Forestry, Logging, Fishing, Hunting, and Trapping	2,837	536	389	93	1,017
Mining, Quarrying, and Oil and Gas Extraction	9,350	3,377	1,322	0	4,700
Construction	204,561	51,059	8,464	915	60,438
Nonmetallic Mineral Products	6,136	1,430	699	244	2,374
Primary Metals and Fabricated Metal Products	35,064	7,638	3,613	1,025	12,276
Machinery Manufacturing	14,706	3,928	2,432	682	7,043
Computers and Electronic Products	7,439	1,743	1,279	519	3,541
Electrical Equipment and Appliances	3,359	553	398	210	1,161
Transportation Equipment	6,458	2,121	1,575	550	4,246
Wood Products	7,325	1,588	705	165	2,457
Furniture and Fixtures	7,641	1,417	456	84	1,958
Miscellaneous Manufacturing	11,429	5,057	1,344	340	6,741
Food Manufacturing	13,073	1,812	722	59	2,593
Beverage and Tobacco Products	2,653	773	247	90	1,110
Textiles, Apparel, and Leather	6,238	998	264	24	1,286
Paper and Printing	14,483	3,426	1,404	350	5,179
Petroleum and Coal Products	710	253	197	113	563
Chemicals	6,476	1,746	1,341	589	3,676
Plastics and Rubber Products	7,397	788	517	18	1,323
Wholesale Trade	133,958	15,239	2,664	2	17,905
Retail Trade	258,174	37,563	4,402	42	42,007
Transportation and Warehousing	61,190	20,258	6,418	2,245	28,921
Utilities	2,837	1,185	640	194	2,019
Publishing, Except Internet	9,340	455	37	0	493

[5] BLS Job Openings And Labor Turnover (2017). News Release; For release 10 a.m. (EDT), July 11, 2017, *https://www.bls.gov/news.release/pdf/jolts.pdf*.

[6] U.S. Census Bureau, 2014. SUSB Annual Datasets by Establishment Industry: U.S. & States, NAICS, detailed employment sizes. Accessed on 6/15/2017 at *https://www.census.gov/data/datasets/2014/econ/susb/2014-susb.html*. Eligibility estimates by VETS. See text and spreadsheets (Docket No. VETS–2017–0001–0002).

TABLE 2—ESTIMATE OF ELIGIBLE EMPLOYERS—Continued

Industry	Total employers (5+)	Potentially eligible employers			
		Small employers (5–49)	Medium employers (50–499)	Large employers (500+)	Total
Motion Pictures and Sound Recording Industries	4,802	395	30	0	425
Radio and TV Broadcasting and Cable Subscriptions Programming	2,857	1,127	344	111	1,582
Telecommunications	3,705	1,097	498	160	1,755
Data Processing, Hosting, and Related Services	4,885	334	88	0	422
Libraries, Archives, and Other Information Services	3,237	269	37	0	307
Finance	33,143	3,767	1,228	8	5,003
Insurance	33,515	4,844	476	14	5,334
Real Estate	47,711	12,428	2,509	778	15,714
Rental and Leasing Services	9,613	1,774	424	166	2,364
Professional and Technical Services	205,067	42,079	7,476	2,116	51,670
Management of Companies and Enterprises	23,944	66	6	0	72
Administrative and Support Services	108,014	12,007	2,405	3	14,415
Waste Management and Remediation Services	8,782	2,240	570	168	2,977
Educational Services	43,887	4,718	1,320	1	6,039
Hospitals	3,407	16	388	36	441
Health Services, Except Hospitals	247,348	20,285	1,726	0	22,011
Social Assistance	67,460	3,486	270	0	3,756
Arts, Entertainment, and Recreation	42,698	6,202	1,700	59	7,962
Accommodation	29,467	1,935	130	0	2,065
Food Services and Drinking Places	273,382	10,708	262	0	10,970
Repair and Maintenance	61,091	20,895	1,820	610	23,325
Personal and Laundry Services	58,697	7,987	395	0	8,382
Membership Associations and Organizations	121,174	13,647	1,017	0	14,664
Government—Local	40,882	0	8,273	0	8,273
Total	2,311,602	337,247	74,922	12,784	424,952

Source: U.S. Census Bureau, 2014. SUSB Annual Datasets by Establishment Industry: U.S. & States, NAICS, detailed employment sizes. Accessed on 6/15/2017 at *https://www.census.gov/data/datasets/2014/econ/susb/2014-susb.html.*

U.S. Census Bureau, 2012. Government Organization Summary Report: 2012. Accessed on 7/21/2017 at *https://www2.census.gov/govs/cog/g12_org.pdf.*

Eligibility estimates by VETS.

See text and spreadsheets (Docket No. VETS–2017–0001–0002).

In the NPRM, data from BLS on veteran employment were presented as a key input for estimating the number of eligible employers. VETS did not receive comments on the use of BLS data for estimating the number of employers meeting the criterion of 7 percent veteran employment. The methodology presented in the NPRM to estimate the number of eligible employers has not been modified, although there were various commenters who recommended changes to the regulation that could have impacts on the eligibility estimates. For reasons explained in the responses to public comments above, VETS did not make changes to the rule in response to public comments. Therefore, no changes were made to the employer eligibility estimates used in the NPRM.

Unit Cost

Using the information provided in the stakeholder meetings, as well as estimates from similar analysis done by other DOL agencies, burden costs were estimated by employer size for each aspect of the application process, including rule familiarization, collection, filling out the form, and follow-up/requests for reconsideration. VETS used the data from the May 2016 BLS Occupational Employment Statistics (OES) survey. For the purposes of this analysis, VETS estimates a fully loaded wage rate to include fringe benefits and overhead, resulting in a doubling of the OES wage rate.[7] [8]

Rule familiarization costs are estimated to take 1 hour for all employers regardless of size; this is based on the Occupational Safety and Health Administration's (OSHA's) recordkeeping rule updated in 2014.[9] This activity would typically be performed by a human resources manager at a large or medium employer or by a person with equivalent responsibilities at a small employer. Using the data from the OES survey, the mean hourly wage of the human resources manager is $57.79. Adding overhead and fringe benefits, the fully loaded hourly wage rate being used to estimate the cost of familiarization is $115.58. The regulation is structured by employer size, which would not require employers to consider all aspects of eligibility, but only those that pertain to their size. For these reasons, 1 hour was estimated for rule familiarization of the award program requirements of eligibility and the application form instructions.

The eligibility requirements for the award program require that all employers compile information needed to fill out the application form and retain the information for 2 years. VETS estimated this would require 5 hours for large employers and 3 hours for medium and small employers. Each criterion for eligibility will have an entry in the application form. Information requested will include the following: Employer address and other identifying

[7] The value of two is recommended by HHS in HHS, Guidelines for Regulatory Analysis, 2016, p. 33.

[8] BLS OES survey (2017). Fringe markup is from the following BLS release: Employee Costs for Employee Compensation news release text; For release 10:00 a.m. (EDT), June 9, 2017 *https://www.bls.gov/news.release/pdf/ecec.pdf.*

[9] Occupational Injury and Illness Recording and Reporting Requirements: North American Industry Classification System Update and Reporting Revisions (docket number: OSHA–2010–0019–0127).

information, veteran employment data, descriptions of the relevant veteran programs, and descriptions of the benefits offered to veterans. These estimates are an average for the gold and platinum award requirements. This activity will likely be performed by human resources specialists for a large or medium employer. Using the data from the May 2016 BLS OES survey, the mean hourly wage of the human resources specialist is $31.20. Adding overhead and fringe benefits, the fully loaded hourly wage rate used to estimate the collection of information is $62.40. For a small employer, this activity is anticipated to be done by a payroll and timekeeping clerk, the mean hourly wage for this position as reported by BLS is $20.95, and adding the fringe benefits and overhead results in an hourly wage of $41.90.

Three hours of labor were estimated by VETS for medium and small employers to compile information for the form; this was determined based on the number of award criteria, and due to human resources staff in medium and small employers being more familiar with the day-to-day management of an employer. At the stakeholder meetings held the week of June 5, 2017, smaller employers stated all the information needed to apply would come directly from the owner and would be easily obtained. VETS estimated 5 hours for large employers due to the additional information required to match the criteria for eligibility and the time for a human resources manager to determine if the programs offered by the employer meet the regulation criteria. Larger employers at the stakeholder meetings provided a range of 1 to 4 days, based on their past experience in applying for other award programs such as the Employer Support of the Guard and Reserve (ESGR) Freedom Award.[10] The application form for VETS' award program requires employers to provide employment and descriptive information for as many as seven fields to as few as one field depending on the size of the employer and the award level. This is less time consuming than the information requested for the ESGR Freedom Award. For these reasons, an average of 5 hours was estimated for large employers, and an average of 3 hours for medium and small employers, to collect and retain needed information.

Large and medium employers are expected to incur the cost for running a query to identify the number of veterans hired and veterans retained for the years requested on the application form. The majority of large and medium employers will have a database system for managing their workforce; this system typically includes the hire date and various demographic information about their employees. Running a query specifically for this application form is estimated to take 2 hours by a database administrator at a large or medium employer according to comments received from the stakeholder meeting in early June of 2017. Using the data from the May 2016 BLS OES Survey, the mean wage of the database administrator is $41.89. Adding overhead and fringe benefits,[11] the total wage used to estimate the cost of this task is $83.78. Small employers with 50 or fewer employees typically do not manage their workforce using a database, and due to the closer interactions among employees at small employers, the payroll clerk would know most of the employees individually. Thus, a small employer would not have a need to run a query.

Once the information has been gathered by an employer, applicants will need to enter the information in the form and enter the payment information needed on *www.pay.gov;* this was estimated to take 2 hours for a large employer, 1.5 hours for a medium employer, and 1 hour for a small employer. These burden estimates are an average for the gold and platinum award requirements. A large employer is expected to take 2 hours due to the additional criteria required to be eligible for the award; this activity would be done by a human resources specialist. A medium employer is expected to take 1.5 hours because there are fewer criteria than for a large employer; this activity would be done by a human resources specialist. Using the data from the May 2016 BLS OES survey, the mean wage of a human resources specialist is $31.20. Adding overhead and fringe benefits, the total wage used to estimate the cost of this task is $62.40. A small employer is estimated to take 1 hour because there are fewer criteria than for a medium employer. For a small employer, a payroll and timekeeping clerk would most likely perform this task, with a mean hourly wage of $20.95 as reported in the BLS 2016 OES survey; with added fringe benefits and overhead, this results in an hourly wage of $41.90.

The form requires the attestation of an executive (chief executive officer, chief human resources officer, or equivalent official) that the information on the form is accurate and true. It is expected that this would take 15 minutes for all employers applying for the award and would most likely require the executive to take the time to review the form. For a large or medium employer, this activity will be performed by an executive with a mean hourly wage of $93.44 as reported in the BLS 2016 OES survey; adding fringe benefits and overhead, the hourly wage for this task would be $186.88. At a small employer where the executive positions may not exist, this task may be done by someone with equivalent responsibilities and duties, such as the owner. For the purposes of estimating the cost of attestation for small employers we are using the wage rate of a human resources manager with a mean hourly wage of $57.79 as reported in the BLS 2016 OES survey; adding fringe benefits and overhead results in a fully loaded wage for this task of $115.58.

Following up on incomplete applications is estimated to take 30 minutes for 5 percent of employers applying, and a request for reconsideration would take 30 minutes for 1 percent of employers applying. At a large or medium employer, following up on an application would be done by the human resources specialist with an hourly wage of $62.40 (including fringe benefits and overhead), and a request for reconsideration would be handled by a human resources manager with an hourly wage of $115.58 (including fringe benefits and overhead). At a small employer, the payroll clerk may likely follow up on an application, with an hourly wage of $41.90 (including fringe benefits and overhead), and the human resources manager equivalent would be involved in a request for reconsideration of a denied application, with an hourly wage of $115.58 (including fringe benefits and overhead). The majority of large and medium employers have human resources staff that manage different aspects of the workforce, or outsource the managing of the database for tracking the employer's workforce over time. As a result, large and medium employers are expected to have the same occupations involved in the process of applying for the award, while a different set of occupations were identified for small employers, which typically do not have dedicated human

[10] The ESGR Freedom Award is given to employers who are nominated to recognize those that support their employees who serve in the United States National Guard or Reserve. There are up to 15 awards presented each year by firm size and to the public sector. *http://www.freedomaward.mil/.*

[11] BLS OES (2017). Fringe markup is from the following BLS release: Employee Costs for Employee Compensation news release text; For release 10:00 a.m. (EDT), June 9, 2017 *https://www.bls.gov/news.release/pdf/ecec.pdf.*

resources staff or a database administrator.

TABLE 3—BURDEN COSTS BY EMPLOYER SIZE *

Tasks by employer size	Resource	Wage	Hours	Cost
Large Employer Activities:				
Rule familiarization	HR manager	$116	1.0	$116
Data collection large employers	HR specialists	62	5.0	310
Query report large employers	DB Administrators	84	2.0	168
Filling form, large employers	HR specialists	62	2.0	125
Executive signature	Executive	187	0.25	47
Follow up (assume 5 percent)	HR specialists	62	0.5	31
Reconsideration if denied award (1 percent)	HR manager	116	0.5	58
Average unit cost per employer				855
Medium Employer Activities:				
Rule familiarization	HR manager	116	1.0	116
Data collection medium employers	HR specialists	62	3.0	186
Query report medium employers	DB Administrators	84	2.0	168
Filling form medium employers	HR specialists	62	1.5	93
Executive signature	Executive	187	0.25	47
Follow up (assume 5 percent)	HR specialists	62	0.5	31
Reconsideration if denied award (1 percent)	HR manager	116	0.5	58
Average unit cost per employer				699
Small Employer Activities:				
Rule familiarization	HR manager	116	1.0	116
Data collection small employers	Payroll and timekeeping clerks	42	3.0	126
Filling form, small employers	Payroll and timekeeping clerks	42	1.0	42
Executive signature	HR manager	116	0.25	29
Follow up (assume 5 percent)	Payroll and timekeeping clerks	42	0.5	21
Reconsideration if denied award (1 percent)	HR manager	116	0.5	58
Average unit cost per employer				392

Source: BLS, OES 2016.
* Wages and costs are rounded values.
(See Spreadsheets, Docket No. VETS–2017–0001–0002 for all sources and derivation).

The burden estimates were mainly driven by the duration of time expected for each aspect of the application process, and the type of occupation identified as performing the various activities for the employer size.

The rulemaking docket includes a spreadsheet used to estimate the unit costs to employers who apply for the award. The unit costs in the spreadsheet included burden costs by employer size for each aspect of the application process, including rule familiarization, collection, filling out the form, and follow-up/requests for reconsideration. VETS received a few public comments related to these aspects of the cost estimation. For example, a commenter stated that there are ''small employer[s] who may lack a dedicated Human Resources professional, and rel[y] on the AJC staff for many hiring functions.'' VETS agrees that smaller employers often will not employ the same type of human resources professionals as medium or larger employers do, and this is reflected in the cost estimates and criteria for applying. Other commenters suggested changes in certain program criteria, which, if adopted by VETS, could have impacted unit costs associated with filling out the forms. However, as explained in the responses to public comments above, VETS did not make any changes to the award criteria in response to public comments. Therefore, no changes were made to the unit cost estimates used in the NPRM.

In the NPRM, estimates for cost and burden were based on comments received from stakeholder meetings and OSHA's recordkeeping rule update in 2014.

Government Costs

The cost to the Government involves the intake, review, verification, and processing of the applications, and notification/distribution of the award. To efficiently process applications, VETS will develop and maintain a system to electronically receive applications, review applications to determine eligibility, and issue the awards. The cost for such a system would include IT hardware and software, IT maintenance, helpdesk costs, and VETS program management personnel costs. VETS has estimated lifecycle costs. The estimated cost of creating an application system and form is approximately $933,100, which annualized over 10 years at a 3 percent discount rate results in a cost of $109,388 per year.

The business process for the intake, review, and processing of applications was estimated using average wage data from BLS occupation codes for each phase, including solicitation, application processing, application review, award notification, and reporting to Congress. The cost to the Government for processing is estimated to be $2.5 million dollars per year based on 10,000 applications being processed per year.

As part of the business process there will be costs associated with program outreach, messaging, and notification of award winners. This is estimated to cost $245,086 annually. An outreach specialist is estimated to spend 1,140 hours involved in these tasks. The mean hourly wage rate for an outreach specialist is $45.42, as reported by the Office of Personnel Management (OPM) for a General Schedule (GS)–13 (Step 1) in 2017; [12] plus fringe benefits and

[12] OPM *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB_h.pdf.*

overhead, the hourly wage for this task would be $90.84. These tasks will also involve a program manager spending 1,000 hours with an hourly wage rate of $53.67 (GS–14 Step 1); plus fringe benefits and overhead, the hourly wage would be $107.36. An IT specialist (GS–12 Step 1) would also be involved in supporting tasks with messaging and recognition of award winners, spending 100 hours, with an hourly wage of $38.20; plus fringe benefits and overhead, the hourly wage would be $76.40.

The application process will require support from contractors to set up the process, the receipt of the forms and the processing of the applications; this is estimated to cost $1,896,940 annually. A program specialist will spend 200 hours annually with a mean hourly wage rate of $59.31 as reported in the BLS 2016 OES survey; [13] plus fringe benefits and overhead, the hourly wage rate would be $118.62. An IT specialist will spend 40 hours to support these activities with an hourly wage rate of $42.25; [14] plus fringe benefits and overhead, the hourly wage is $84.50. The program manager [15] is estimated to spend 151 hours processing applications, with an hourly wage rate of $58.70; plus fringe benefits and overhead, the hourly wage is $117.40. A program specialist [16] will perform the bulk of the application review tasks, totaling 18,569 hours with an hourly wage rate of $35.99; plus fringe benefits and overhead, the hourly wage will be $71.98.

As part of the review process of the applications, VETS will need to verify applicants do not have adverse labor law decisions, stipulated agreements, contract debarments, or contract terminations against them under USERRA; or the VEVRAA. This verification process will involve VETS and OFCCP checking their databases for award applicants. VETS estimates it will take each agency, OFCCP and VETS, an average of 15 minutes per application for this review. A GS–13 would perform the check with a loaded hourly wage of $90.84 and spend 13 minutes per employer on the list, and a GS–15 with a loaded hourly wage of $126.28 would spend 2 minutes per employer on the list verifying the findings in the initial check. The IT process developed to support this review will be maintained by a contractor [17] spending 240 hours, with a loaded hourly wage of $84.50 (hourly mean wage from BLS without fringe benefits or overhead is $42.25).

The notification of the award will also be executed by a contractor, and it will involve 50 hours of a program manager's [18] time, with a loaded hourly wage of $117.40, and 40 hours of a program specialist's [16] time, with a loaded hourly wage of $71.98.

The oversight of the contract for the application processing will be done by VETS personnel. This will take 312 hours of a program manager's time (GS–14), with a loaded hourly wage of $107.36, and 120 hours of a program specialist's time (GS–13), with a loaded hourly wage of $90.84.

The statute requires a report to Congress; this will be done by VETS personnel, and it will cost a total of $10,406 dollars annually. This task will take a program manager (GS–14), 80 hours with a loaded hourly wage of $107.36, and another 20 hours of time for a program specialist's time (GS–13), with a loaded hourly wage of $90.84. The cost to the Government was estimated in two parts: The costs to efficiently process applications and the costs of creating the application system. VETS solicited comments on the costs to the Government to develop a system to accept and review applications but none were received.

The supplemental spreadsheet in the docket includes the methodology used in the NPRM to estimate the costs to the Government to process the application and the creation of the application system; no changes are being made to the Government cost calculations.

Application Fee

The HIRE Vets Act provides that the Secretary may assess a reasonable fee on employers that apply for receipt of a HIRE Vets Medallion Award and that the amount of the fee must be sufficient to cover the costs associated with carrying out the HIRE Vets Act. The fee will cover the costs of solicitation of applications, processing applications, vetting applicants for labor law violations, and award notifications, as well as the maintenance cost of the IT system used in the processing of applications.

In processing the applications, VETS will need to verify the information on the form being submitted by employers. Given that the number of criteria varies by employer size, and will consequently require additional review by VETS, the fee will vary by employer size to reflect the cost of reviewing additional criteria. For example, the large employer platinum award requires the applicant to provide information about five types of integration assistance. However, the small employer platinum award only requires that the applicant provide information about two types of integration assistance. Consequently, the large employer award will take longer to review than the small employer award will.

In recognition of these differences in the number of criteria and the amount of information needing to be reviewed and verified as part of processing awards, the fees will be graduated to reflect the differences in the amount of review VETS would need to perform for large, medium, and small employers. The fee for large employers is $495 per applicant, the fee for medium employers is $190 per applicant, and the fee for small employers is $90 per applicant, which covers the anticipated cost to VETS for processing 4,152 applications in the first year. The fees were estimated by taking the average cost to VETS of $300 per application, and multiplying it using factors of time that reflect the information needed to be reviewed. Large employers would take VETS 1.6 times longer than the estimated average cost to process the application; for medium employers it would be 0.6 times the average cost, and for small employers it would be 0.3 times the average cost.

TABLE 4—GOVERNMENT COSTS

Application processing	Employers		
	4,152	6,228	10,728
Solicitation	$245,086	$245,086	$245,086
Receipt and Processing	565,828	823,693	1,382,564
Violation Vetting by VETS and OFCCP	200,119	299,335	514,376

[13] BLS OES occupation code 11–2031 Public Relations and Fundraising Managers.

[14] BLS OES occupation code 15–0000 Computer and Mathematical Occupations.

[15] BLS OES occupation code 11–1021 General and Operations Managers.

[16] BLS OES occupation code 13–1199 Business Operations Specialists.

[17] BLS OES occupation code 15–0000 Computer and Mathematical Occupations.

[18] BLS OES occupation code 11–1021 General and Operations Managers.

TABLE 4—GOVERNMENT COSTS—Continued

Application processing	Employers		
	4,152	6,228	10,728
Award Notification	160,333	236,118	400,366
Contract Oversight	44,397	44,397	44,397
IT Support and Maintenance	20,280	20,280	20,280
Report to Congress	10,406	10,406	10,406
Total Processing Cost	1,246,449	1,679,315	2,617,473
Average Government Cost per Application	300	270	244
Sunk Development Costs:			
Development of Application System	.....	.....	98,625
Application Form Development	.....	.....	834,474
Total Development Costs	.....	.....	933,099

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.
(See Spreadsheets, Docket No. VETS–2017–0001–0002 for all sources and derivation).
Average cost per application = total processing cost/# of employers.

The proposed fee in the NPRM was estimated to cover the cost to the Government, which includes solicitation of applications, processing applications, vetting applicants for labor law violations, and award notifications, as well as the maintenance cost of the IT system used in the processing of applications. VETS did not receive comment on the cost estimates for the Government, nor the estimated graduated fee by employer size.

The same calculation found in the spreadsheet and discussed in the NPRM is used to derive a graduated application fee by employer size.

Participation and Costs per Year

VETS based its estimates of the level of participation partly on the CBO estimate of 4,000 employers in the first year and on the impact the criteria would have on the participation levels.

There were no comments on the estimated level of participation; these estimates will stay the same. As indicated in the Summary and Explanation section of this document, some commenters expressed doubt that employers would be interested in participating in the HIRE Vets Medallion Program but no commenter provided specific data or evidence regarding how this supposition would impact the participation rates estimated in the NPRM.

CBO originally developed an estimate that 4,000 employers would participate in the program in the first year. This estimate was based on the assumption that only 2 percent of employers would be potentially eligible and 25 percent of medium and large employers potentially eligible would apply for the program. In CBO's estimate, small employers were excluded from being able to apply based on an earlier version of the HIRE Vets bill. If CBO had included small employers in their estimate using the same methodology, the number of employers applying would increase to close to 50,000 employers.

As noted above, VETS, making use of BLS veterans' labor force participation rate data, estimates that far more than 2 percent of employers that are eligible may choose to participate. Due to the lack of data for more accurate participation rates, VETS assumes that approximately 4,152 employers will apply in the first year, but that this would increase to 6,228 employers in the second year and to 10,728 per year in succeeding years. Table 5 shows the estimated participation rates by employer size class for each year and the resulting estimated costs of applications.

TABLE 5—ESTIMATED PARTICIPATION RATES AND NUMBERS OF APPLICANTS BY YEAR

Size class	1st year participation rate (%)	1st year number of applicants	2nd year participation rate (%)	2nd year number of applicants	3rd year participation rate (%)	3rd year number of applicants
Small	0.1	304	0.2	674	0.6	2,023
Medium	3.0	2,248	4.0	2,997	6.5	4,870
Large	12.5	1,601	20.0	2,557	30.0	3,835
Total	N/A	4,152	N/A	6,228	N/A	10,728

VETS Estimates (See Spreadsheets, Docket No. VETS–2017–0001–0002 for all sources and derivation).

Table 6 shows the results of multiplying the employer unit costs of applying for the award, developed in the previous Unit Cost section, by the number of anticipated participants to obtain the costs by size class and total application costs for each year. These costs reflect the time and resources incurred by the employer when applying for the award program; this includes all the tasks discussed in the previous Unit Cost section.

TABLE 6—EMPLOYER APPLICATION COSTS BY YEAR

Size class	1st year costs	2nd year costs	3rd year costs
Small	$95,215	$211,589	$634,767

TABLE 6—EMPLOYER APPLICATION COSTS BY YEAR—Continued

Size class	1st year costs	2nd year costs	3rd year costs
Medium	1,377,355	1,836,473	2,984,269
Large	1,230,468	1,965,603	2,948,405
Total	2,703,038	4,013,665	6,567,441

VETS Estimates (See Spreadsheets, Docket No. VETS–2017–0001–0002 for all sources and derivation).

There are multiple factors that would contribute to the participation rate of large, medium, and small employers, such as the application fee, amount of outreach by VETS, and the potential benefits gained by the employers receiving the award. The problem here is a classically difficult one in economics—that of estimating demand for new products. In this case, we have little data and few comparable products on which to base an estimate. VETS is aware that the total costs are dependent on the number of employers that apply and the number could be much lower or higher than VETS' baseline estimates.

At the stakeholder meetings, some representatives from larger employers stated their willingness to pay up to several thousand dollars, while representatives for smaller employers didn't specify a fee amount they would be willing to pay. It would seem reasonable to assume a fee of more than several hundred dollars would discourage many small employers from applying. The total cost, burden plus fees, is estimated to range from $404 for small employers to $1,264 for large employers. Depending on the success of outreach and other messaging, these efforts could attract more applicants than CBO's estimate. Over the long term, employers will want to apply if there are quantifiable benefits in the form of increased revenue if this award attracts more customers, and by increasing the pool of veteran applicants when they are hiring. These factors have the potential to increase the number of participating employers to close to 50,000. Higher participation would result in increased costs relative to the overall cost burden and overall Government cost. However, considering all costs, the program will most likely not have costs in excess of $100 million per year. Such costs would only occur if 100 percent of potentially eligible medium and large employers and 25 percent of potentially eligible small employers apply every year.

Total Annualized Costs

VETS estimated annualized costs to employers for participation in this award program over a 10-year period using 3 percent and 7 percent discount rates based on the costs of application and costs to the Government developed above. These total costs are provided in Table 7.

TABLE 7—TOTAL ANNUALIZED COSTS OF THE FINAL RULE

Cost element	Annualized costs at 3%	Annualized costs at 7%	First year costs (if different from annualized costs)
Costs for Preparing Applications	$5,845,415	$5,735,649	$2,703,038
Costs to Government of Processing Application (to be reimbursed through fees)	2,357,854	2,318,462	1,246,449
Total Private Sector Costs, Including Fees for Government Processing	8,203,269	8,054,111	3,949,487
Costs to Government for Developing System (not reimbursed by fees)	109,388	132,852	933,099
Total	8,312,657	8,186,963	4,882,586

VETS Estimates (See Spreadsheets, Docket No. VETS–2017–0001–0002 for details).

Alternatives

VETS considered alternative quantitative criteria for small and medium employers. One alternative would have been to change the proposed criteria for small and medium employers that require applicants to have both a retention rate of 75 percent (for gold)/85 percent (for platinum) and a veteran employee percentage of 7 percent (for gold)/10 percent (for platinum). Instead, this first proposed alternative criterion would have dropped the veteran employee percentage requirement. Keeping all the participation rates the same, VETS estimates that this change would have increased the number of potentially eligible employers by 38 percent, increased participation in the program by 19 percent, and increased annualized costs from approximately $8 million per year to $11.9 million a year. This alternative had the disadvantage that it would have allowed employers who had not recently achieved a 7 percent hiring goal to win the award.

VETS also considered an option in which small and medium employers could have qualified if they met either of the following: (1) 7 percent of the employer's new hires during the previous year were veterans, or (2) 7 percent of the employees it hired over the last 2 years were veterans and the employer retained 75 percent of those veterans hired in the first year of that timeframe (previous year of the previous year). This alternative would have broadened the hiring eligibility timeframe. This option would have also slightly increased program eligibility, but it would have done so by significantly increasing small employer eligibility while lowering eligibility for medium employers. VETS concluded that this was not a useful effect given that medium employers are more likely to participate in the program than small employers are.

VETS also examined an option in which the only hiring and retention criteria for small and medium employers would have been that 7 percent of new hires over the last 2 years were veterans along with a 75 percent retention criterion from the first of the 2 years (previous year of the previous year). Under this option, employers would no longer have been

able to satisfy the hiring and retention criteria solely by having 7 percent of their new hires in the previous year be veterans. This approach also would have increased small employer eligibility at the expense of decreasing medium employers' eligibility. Again, because of expected high participation rates by medium employers relative to small employers, VETS decided not to adopt this alternative.

None of these estimates take into account the cost savings to both the private sector and the Government of these alternatives.

VETS solicited comments on these proposed alternatives for medium and small employers but did not receive any specific comments to the alternatives proposed. Therefore, the criteria presented in the NPRM will not change for the final rule and VETS will not adopt the alternatives discussed here.

Benefits

VETS expects that employers will want to apply for the award if there are quantifiable benefits in the form of increased revenue generated by attracting more or repeat customers, or a better pool of veteran applicants for jobs.

The unemployment rate of veterans trends lower than the civilian unemployment rate, but regionally, the unemployment rate for veterans can vary from a low of 1.8 percent in Indiana to a high of 7.6 percent in the District of Columbia, as reported in the March 2016 Employment Situation of Veterans release by BLS. The higher unemployment rate for veterans in the District of Columbia can be attributed to the labor market there, which is mostly composed of professional and service industry occupations where historically there are lower employment rates for veteran workers. These veterans are experienced, mission-focused, responsible, independent, and capable workers who often face difficulties finding jobs that match their skills. In a 2016 *Forbes* article [19] highlighting veterans' issues as they adjusted to the civilian workforce, the top challenges reported for veterans are a lack of training or education for the work, lack of advancement opportunities, and employers undervaluing their military experience.

Many employers who seek out veterans to hire have stated there are many benefits in attracting veterans, such as the experience they bring, more focused attention, and the ability to work independently.[20] Employers who attain the award will be able to market themselves as a veteran friendly employer and be able to attract more veterans for job openings.

VETS received some comments regarding the benefits described in the NPRM. The purpose of the HIRE Vets Medallion Award is to recognize employers who have recruited and retained veterans, as well as the efforts by these employers to establish employee development programs for veterans and to offer veteran specific benefits to improve retention. Those employers who meet the criteria to receive the award most likely recognize the benefits of employing veterans and would want to attract more veteran employees in the future. A recipient of this award would have the opportunity to utilize the medallion in the marketing of their firm when hiring, as well as to attract additional business. One commenter stated that employers already have a means to ''advertise that they hire vets,'' concluding that this award would not result in new added benefits to employers. In addition, a couple commenters questioned if employers would be interested in applying given the burden of applying and the lack of quantifiable benefits. While benefits were not quantified, the employers in the stakeholder meetings and in the 2016 *Forbes* article [19] discussed above both asserted that there are benefits employers receive from hiring veterans, and this award will enable employers to attract more veterans to their job openings.

Other comments supported the idea that a HIRE Vets Medallion Award would yield tangible benefits to employers. For example, a commenter expressed that ''[o]nce employers who participate in this program start hiring more veterans, other companies will see the positive impact it has on business and hopefully will follow in the same direction'' (VETS–2017–0001–0018). This award program was mandated by an act of Congress to recognize those employers who currently meet those criteria in hiring, retaining, and supporting veteran employees. These employers have engaged with veteran employees because there are benefits gained, but as stated above, these benefits are not easily quantified. A *Time* article from April 25, 2016, ''Paying Their Workers' College Tuition Can Pay Off for Companies,'' stated that tuition reimbursement, ''reduced employee turnover and lower[ed] recruiting costs,'' demonstrating the financial benefit these programs can have to employers' bottom lines.[21] Employee resources groups, leadership training, differential pay, and tuition reimbursement have all been shown to reduce turnover.[22] In an article from the *Huffington Post,* ''How Much Does Employee Turnover Really Cost,'' posted on January 19, 2017, the author found that ''the cost of losing an employee can range from tens of thousands of dollars to 1.5–2.0x the employee's annual salary.'' As these articles demonstrate, employers applying for a HIRE Vets Medallion Award are reaping many benefits, and this award will allow them to maximize the return on their investment in the employee programs they offer.

Attaining awards can also result in benefits to businesses in the form of increased marketing potential, improved standing in their industry, recognition as a leader, and improved employee engagement.[23] These benefits discussed are all reasons that businesses participate in awards and offer employee development programs.

Regulatory Flexibility Certification

For regulatory flexibility purposes for this rule, economic impacts are considered significant in any given sector if costs are greater than 1 percent of revenues or 5 percent of profits. For the purpose of determining impacts on small employers, VETS considered costs as a percentage of revenues and profits by industry sector for employers with 5 to 500 employees. (Note that this definition of ''small employers'' is consistent with SBA's definition and differs from that established by Congress for purposes of the HIRE Vets Medallion Program.) Table 8 shows the minimum and maximum impacts for each 3-digit subsector within the 2-digit sector shown. (Full impacts and derivation are given in the supplemental spreadsheets, Docket No. VETS–2017–0001–0002.) Table 8 shows that no industry sector has costs in excess of 1 percent of revenues or 5 percent of profits.

[19] Strauss, Karsten, (2016) How Veterans Adjust To The Civilian Workforce, November 11th, 2016. Retrieved from: *https://www.forbes.com/sites/karstenstrauss/2016/11/11/how-veterans-adjust-to-the-civilian-workforce/2/#2d316ff8395d.*

[20] Military & Defense team, (2016) 10 Reasons Companies Should Hire Military Veterans, November 11, 2016. Retrieved from: *http://www.businessinsider.com/reasons-companies-should-hire-military-veterans-2016-11.*

[21] Mulhere, Kaitlin, (2016) Paying Their Workers' College Tuition Can Pay Off for Companies. April 25, 2016. Retrieved from: *http://time.com/money/4305549/paying-their-workers-college-tuition-can-pay-off-for-companies/.*

[22] Altman, Jack, (2017) How Much Does Employee Turnover Really cost? January 18th, 2017. Retrieved from: *https://www.huffingtonpost.com/entry/how-much-does-employee-turnover-really-cost_us_587fbaf9e4b0474ad4874fb7.*

[23] Narayanan, Sukruti, (2017) The 5 Benefits of Receiving Corporate Awards. January 15, 2017. Retrieved from: *https://www.linkedin.com/pulse/5-benefits-receiving-corporate-awards-sukruti-narayanan.*

TABLE 8—ECONOMIC IMPACTS

NAICS	Title	Average revenue per establishment	Average cost to revenues		Average cost to profits	
			Minimum (%)	Maximum (%)	Minimum (%)	Maximum (%)
11	Agriculture, Forestry, Fishing, and Hunting.	4,244,996	0.009	0.026	0.176	0.844
21	Mining	13,371,157	0.002	0.009	0.068	0.068
22	Utilities	21,521,736	0.003	0.003	−0.220*	−0.220*
31–33	Manufacturing	10,225,679	0.002	0.021	0.030	0.485
42	Wholesale Trade	20,024,426	0.002	0.006	0.014	0.203
44–45	Retail Trade	3,928,643	0.005	0.042	0.243	0.243
48–49	Transportation	5,700,083	0.004	0.039	0.051	4.545
51	Information	4,990,489	0.009	0.020	−0.165*	0.192
52	Finance and Insurance	5,367,956	0.007	0.019	0.015	0.314
53	Real Estate	4,371,291	0.007	0.025	0.038	0.566
54	Professional, Scientific, and Technical Services.	2,986,458	0.020	0.020	0.517	0.517
55	Management	2,306,072	0.026	0.026	0.131	0.131
56	Administrative and Support, Waste Management and Remediation Services.	2,727,336	0.018	0.030	0.426	0.765
61	Educational Services	2,514,535	0.024	0.024	0.522	0.522
62	Health Care	8,435,099	0.003	0.051	0.052	0.964
71	Arts, Entertainment, and Recreation	2,963,512	0.014	0.039	0.236	2.414
72	Accommodation and Food Services	1,381,321	0.033	0.065	0.505	1.224
81	Other Services	1,319,709	0.030	0.094	1.222	2.905

Source: VETS based on data from IRS (U.S. Internal Revenue Service), 2013. Corporation Source Book, 2013. *https://www.irs.gov/statistics/soi-tax-stats-corporation-source-book-us-total-and-sectors-listing,* Accessed by Eastern Resource Group, Inc., 2016.
U.S. Census Bureau, 2012. SUSB Employment and Payroll Summary: 2012-Data by enterprise employment size, Accessed on 7/11/2017 at *https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html.*
See Spreadsheets, Docket No. VETS–2017–0001–0002, for full derivation.
*Negative profit rates reported for these industries.

As a result of these considerations, per section 605 of the Regulatory Flexibility Act (RFA), VETS certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

VETS did not receive comments on this certification. Further, it should be noted that small employers are only subject to this rule if they choose to apply for the award. Thus, no small business needs to incur the costs unless they find that the benefits exceed the costs for them.

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Paperwork Reduction Act

Overview

The final HIRE Vets Medallion Award regulations contain collections of information (paperwork) requirements that are subject to review by OMB. The Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* and its implementing regulations, 5 CFR part 1320, require that the Department consider the impact of paperwork and other information collection burdens imposed on the public. 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 it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person may generally be subject to penalty for failing to comply with a collection of information that does not

display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

Solicitation of Comments

On August 18, 2017, VETS published two separate **Federal Register** Notices that allowed the public an opportunity to comment on the proposed Information Collection Request (ICR) containing the collections of information contained in the proposed regulations and the HIRE Vets Medallion Award application and forms. First, in accordance with the PRA (44 U.S.C. 3507), the HIRE Vets Medallion Program NPRM provided 30 days for the public to comment on the ICR (82 FR 39390). However, the PRA requires that agencies provide a 60-day public comment period on the collections of information in accordance with 44 U.S.C. 3506(c). As a result, VETS published a second companion notice to the NPRM (82 FR 39460) allowing the public the full 60 days to comment on the collections of information contained in the proposal. On August 18, 2017, VETS submitted an ICR for the proposed rule to OMB for review in accordance with 44 U.S.C. 3507(d).

On October 25, 2017, OMB issued a Notice of Action (NOA) commenting on the proposal's ICR. OMB commented that the NOA is not an approval to conduct or sponsor the collections of information contained in the proposal. OMB noted that this action has no effect on any current approvals and assigned the ICR control number 1293–0015 to be used in future ICR submissions. Also, OMB instructed the Agency to resubmit this ICR when the final rule is issued.

Collection of Information Requirements

VETS received comments addressing the collections of information and the burden hour cost analysis. Responses to these comments are found in the *Section-by-Section Summary of the Final Rule and Discussion of Comments* and *Executive Orders 12866 and 13563: Regulatory Planning and Review Introduction* sections of the preamble.

As related to this rulemaking, VETS submitted the final ICR, containing the full analysis and description of the burden hours and costs associated with the final rule, to OMB on the date of publication for approval. A copy of this ICR is available at *https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=1293-0015* (this link will become active on the day following publication of the final rule). This request also seeks authority for VETS to engage in a demonstration of the information collection and award in 2018, before the implementation of this rule; this demonstration would not involve the collection of application fees.

The regulations implementing the HIRE Vets Act require the Secretary annually to solicit and accept voluntary information from employers for consideration of employers to receive a HIRE Vets Medallion Award. The Act establishes specific criteria at two levels, ''Gold'' and ''Platinum,'' for large employers (those with 500 or more employees) and allows the Secretary discretion in establishing criteria for small and medium employers to qualify for similar awards.

The final rule includes the application process and criteria VETS will use to receive, review, and process applications; verify the information provided; and award the HIRE Vets Medallion Award to those employers meeting the criteria. VETS developed the HIRE Vets application forms [VETS–1011LP, VETS–1011LG, VETS–1011MP, VETS–1011MG, VETS–1011SP, VETS–1011SG] for employers to complete and submit to VETS to fulfill the regulatory requirements to receive an award. The Act establishes a fund, designated as the ''Hire Vets Medallion Award Fund,'' and allows the Secretary to assess a reasonable fee from the applicants to cover the costs associated with carrying out the HIRE Vets Medallion Program. The final rule provides the fee amount and how to submit the fee.

The final rule, like the proposed rule, provides specific award criteria for large employers to qualify for the gold and platinum awards. Although the number of criteria an employer is required to satisfy in the final rule differs by award, the large employer criteria established by statute are generally incorporated across the large employer, medium employer, and small employer awards. The applications require employers to provide information to meet award criteria dependent upon the size of the employer and the level of award the employer is requesting, gold or platinum. The following table provides the corresponding regulatory citation for each award type. In addition, employers must maintain documentation of the information relied upon to complete the application for 2 years after the application is submitted to VETS (§ 1011.600).

FINAL REGULATORY PROVISION

Employer size	Gold award	Platinum award
Large	§ 1011.100(a)	§ 1011.100(b)
Medium	§ 1011.105(a)	§ 1011.105(b)
Small	§ 1011.110(a)	§ 1011.110(b)

The applications solicit information that VETS will review and evaluate to determine if an employer will receive an award. Employers are required to maintain information relied upon to complete their application for 2 years, as previously noted. VETS may request this information if additional verification is needed, or in case VETS becomes aware of facts that may indicate information submitted on the application may be incorrect.

Title of Collection: Honoring Investments in Recruiting and Employing American Military Veterans Act.

OMB Control Number: 1293–0015.

Total Estimated Number of Respondents: 7,036.

Total Estimated Number of Responses: 34,245.

Total Estimated Annual Time Burden Hours: 58,716.

Total Estimated Annual Other Costs Burden: $1,847,746.

Small Business Regulatory Enforcement Fairness Act of 1996

VETS has determined that this final rule does not impose a significant economic impact on a substantial number of small entities under the RFA; therefore, VETS is not required to produce any Compliance Guides for Small Entities, as mandated by the Small Business Regulatory Enforcement Fairness Act for rules with such impacts.

Unfunded Mandates Reform Act of 1995

For purposes of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, this final rule does not include any Federal mandate that may result in excess of $100 million in expenditures by State, local, and Tribal governments in the aggregate or by the private sector.

Executive Order 13132 (Federalism)

VETS has reviewed this final rule in accordance with Executive Order 13132 regarding federalism and has determined that it does not have ''federalism implications.'' This rule 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.''

Executive Order 13084 (Consultation and Coordination With Indian Tribal Governments)

This final rule does not have Tribal implications under Executive Order 13175 that require a Tribal summary impact statement. The final rule 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.

Plain Language

The final rule uses plain language.

Effects on Families

The undersigned hereby certifies that the final rule would not adversely affect the well-being of families.

Executive Order 13045 (Protection of Children)

This final rule would have no environmental health risk or safety risk that may disproportionately affect children.

Environmental Impact Assessment

A review of this final rule in accordance with the requirements of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.;* the regulations of the Council on Environmental Quality, 40 CFR part 1500 *et seq.;* and DOL NEPA procedures, 29 CFR part 11, indicates the final rule would not have a significant impact on the quality of the human environment. There is, thus, no corresponding environmental assessment or an environmental impact statement.

Executive Order 13211 (Energy Supply)

This final rule is not subject to Executive Order 13211. It will not have a significant adverse effect on the supply, distribution, or use of energy.

Executive Order 12630 (Constitutionally Protected Property)

This final rule is not subject to Executive Order 12630 because it does not involve implementation of a policy that has takings implications or that could impose limitations on private property use.

Executive Order 12988 (Civil Justice Reform Analysis)

This final rule was drafted and reviewed in accordance with Executive Order 12988 and will not unduly burden the Federal court system. The final rule was reviewed to eliminate drafting errors and ambiguities, written to minimize litigation, and written to provide a clear legal standard for affected conduct and to promote burden reduction.

List of Subjects in 20 CFR Part 1011

Employment, Veterans, Employer Recognition, Medallion.

■ For the reasons set out in the preamble, the Veterans' Employment and Training Service amends 20 CFR chapter IX by adding part 1011 to read as follows:

PART 1011—HIRE VETS MEDALLION PROGRAM

Subpart A—General Provisions

Sec.

Subpart B—Award Criteria

Subpart C—Application Process

Subpart D—Fees and Caps

Subpart E—Design and Display

Subpart F—Requests for Reconsideration

Subpart G—Record Retention

Authority: Division O, Pub. L. 115–31, 131 Stat. 135.

Subpart A—General Provisions

§ 1011.000 What is the HIRE Vets Medallion Program?

The HIRE Vets Medallion Program is a voluntary employer recognition program administered by the Department of Labor's Veterans' Employment and Training Service. Through the HIRE Vets Medallion Program, the Department of Labor solicits voluntary applications from employers for the HIRE Vets Medallion Award. The purpose of this award is to recognize efforts by applicants to recruit, employ, and retain veterans and to provide services supporting the veteran community.

§ 1011.005 What definitions apply to this part?

Active Duty in the United States National Guard or Reserve means active duty as defined in 10 U.S.C. 101(d)(1).

Dedicated human resources professional means either a full-time professional or the equivalent of a full-time professional dedicated exclusively to supporting the hiring, training, and retention of veteran employees. Two half-time professionals, for example, are equivalent to one full-time professional.

Employee means any individual for whom the employer furnishes an IRS Form W–2, excluding temporary workers.

Employer means any person, institution, organization, or other entity that pays salary or wages for work performed or that has control over employee opportunities, except for the Federal Government or any State or foreign government. For the purposes of this regulation, VETS will recognize employers based on the Employer Identification Number, as described in 26 CFR 301.7701–12, used to furnish an IRS Form W–2 to an employee. However, in the case of an agent designated pursuant to 26 CFR 31.3504–1, a payor designated pursuant to 26 CFR 31.3504–2, or a Certified Professional Employer Organization recognized pursuant to 26 U.S.C. 7705, the employer shall be the common law

employer, client, or customer, respectively, instead of the entity that furnishes the IRS Form W–2.

Human Resources Veterans' Initiative means an initiative through which an employer provides support for hiring, training, and retention of veteran employees.

Post-secondary education means post-secondary level education or training courses that would be acceptable for credit toward at least one of the following: associate's or bachelor's degree or higher, any other recognized post-secondary credential, or an apprenticeship.

Salary means an employee's base pay.

Temporary worker means any worker hired with the intention that the worker be retained for less than 1 year and who is actually retained for less than 1 year.

Veteran has the meaning given such term under 38 U.S.C. 101.

VETS means the Veterans' Employment and Training Service of the Department of Labor.

§ 1011.010 Who is eligible to apply for a HIRE Vets Medallion Award?

All employers who employ at least one employee are eligible to apply for a HIRE Vets Medallion Award. To qualify for a HIRE Vets Medallion Award, an employer must satisfy all application requirements.

§ 1011.015 What are the different types of the HIRE Vets Medallion Awards?

(a) There are three different categories of the HIRE Vets Medallion Award:

(1) *Large Employer Awards* for employers with 500 or more employees.

(2) *Medium Employer Awards* for employers with more than 50 but fewer than 500 employees.

(3) *Small Employer Awards* for employers with 50 or fewer employees.

(4) *Timing.* The correct category of award is determined by the employer's number of employees as of December 31 of the year prior to the year in which the employer applies for an award.

(b) Within each award category, there are two levels of award:

(1) A Gold Award; and

(2) A Platinum Award.

Subpart B—Award Criteria

§ 1011.100 What are the criteria for the large employer HIRE Vets Medallion Award?

(a) *Gold Award.* To qualify for a large employer gold HIRE Vets Medallion Award, an employer must satisfy all of the following criteria:

(1) The employer is a large employer as specified in § 1011.015 of this part;

(2) The employer is not found ineligible under § 1011.120 of this part;

(3) Veterans constitute not less than 7 percent of all employees hired by such employer during the prior calendar year;

(4) The employer has retained not less than 75 percent of the veteran employees hired during the calendar year preceding the preceding calendar year for a period of at least 12 months from the date on which the employees were hired;

(5) The employer has established an employee veteran organization or resource group to assist new veteran employees with integration, including coaching and mentoring; and

(6) The employer has established programs to enhance the leadership skills of veteran employees during their employment.

(b) *Platinum Award.* To qualify for a large employer platinum HIRE Vets Medallion Award, an employer must satisfy all of the following criteria:

(1) The employer is a large employer as specified in § 1011.015 of this part;

(2) The employer is not found ineligible under § 1011.120 of this part;

(3) Veterans constitute not less than 10 percent of all employees hired by such employer during the prior calendar year;

(4) The employer has retained not less than 85 percent of the veteran employees hired during the calendar year preceding the preceding calendar year for a period of at least 12 months from the date on which the employees were hired;

(5) The employer has established an employee veteran organization or resource group to assist new veteran employees with integration, including coaching and mentoring;

(6) The employer has established programs to enhance the leadership skills of veteran employees during their employment;

(7) The employer employs a dedicated human resources professional as defined in § 1011.005 of this part to support hiring, training, and retention of veteran employees;

(8) The employer provides each of its employees serving on active duty in the United States National Guard or Reserve with compensation sufficient, in combination with the employee's active duty pay, to achieve a combined level of income commensurate with the employee's salary prior to undertaking active duty; and

(9) The employer has a tuition assistance program to support veteran employees' attendance in post-secondary education during the term of their employment.

§ 1011.105 What are the criteria for the medium employer HIRE Vets Medallion Award?

(a) *Gold Award.* To qualify for a medium employer gold HIRE Vets Medallion Award, an employer must satisfy all of the following criteria:

(1) The employer is a medium employer per § 1011.015 of this part;

(2) The employer is not found ineligible under § 1011.120 of this part;

(3) The employer has achieved at least one of the following:

(i) Veterans constitute not less than 7 percent of all employees hired by such employer during the prior calendar year; or

(ii) The employer has achieved both of the following:

(A) The employer has retained not less than 75 percent of the veteran employees hired during the calendar year preceding the preceding calendar year for a period of at least 12 months from the date on which the employees were hired; and

(B) On December 31 of the year prior to the year in which the employer applies for the HIRE Vets Medallion Award, at least 7 percent of the employer's employees were veterans; and

(4) The employer has at least one of the following forms of integration assistance:

(i) The employer has established an employee veteran organization or resource group to assist new veteran employees with integration, including coaching and mentoring; or

(ii) The employer has established programs to enhance the leadership skills of veteran employees during their employment.

(b) *Platinum Award.* To qualify for a medium employer platinum HIRE Vets Medallion Award, an employer must satisfy all of the following criteria:

(1) The employer is a medium employer as specified in § 1011.015 of this part;

(2) The employer is not found ineligible under § 1011.120 of this part;

(3) The employer has achieved at least one of the following:

(i) Veterans constitute not less than 10 percent of all employees hired by such employer during the prior calendar year; or

(ii) The employer has achieved both of the following:

(A) The employer has retained not less than 85 percent of the veteran employees hired during the calendar year preceding the preceding calendar year for a period of at least 12 months from the date on which the employees were hired; and

(B) On December 31 of the year prior to the year in which the employer

applies for the HIRE Vets Medallion Award, at least 10 percent of the employer's employees were veterans;

(4) The employer has the following forms of integration assistance:

(i) The employer has established an employee veteran organization or resource group to assist new veteran employees with integration, including coaching and mentoring; and

(ii) The employer has established programs to enhance the leadership skills of veteran employees during their employment; and

(5) The employer has at least one of the following additional forms of integration assistance:

(i) The employer has established a human resources veterans' initiative;

(ii) The employer provides each of its employees serving on active duty in the United States National Guard or Reserve with compensation sufficient, in combination with the employee's active duty pay, to achieve a combined level of income commensurate with the employee's salary prior to undertaking active duty; or

(iii) The employer has a tuition assistance program to support veteran employees' attendance in post-secondary education during the term of their employment.

§ 1011.110 What are the criteria for the small employer HIRE Vets Medallion Award?

(a) *Gold Award.* To qualify for a small employer gold HIRE Vets Medallion Award, an employer must satisfy all of the following criteria:

(1) The employer is a small employer as specified in § 1011.015 of this part;

(2) The employer is not found ineligible under § 1011.120 of this part; and

(3) The employer has achieved at least one of the following:

(i) Veterans constitute not less than 7 percent of all employees hired by such employer during the prior calendar year; or

(ii) The employer has achieved both of the following:

(A) The employer has retained not less than 75 percent of the veteran employees hired during the calendar year preceding the preceding calendar year for a period of at least 12 months from the date on which the employees were hired; and

(B) On December 31 of the year prior to the year in which the employer applies for the HIRE Vets Medallion Award, at least 7 percent of the employer's employees were veterans.

(b) *Platinum Award.* To qualify for a small employer platinum HIRE Vets Medallion Award, an employer must satisfy all of the following criteria:

(1) The employer is a small employer as specified in § 1011.015 of this part;

(2) The employer is not found ineligible under § 1011.120 of this part;

(3) The employer has achieved at least one of the following:

(i) Veterans constitute not less than 10 percent of all employees hired by such employer during the prior calendar year; or

(ii) The employer has achieved both of the following:

(A) The employer has retained not less than 85 percent of the veteran employees hired during the calendar year preceding the preceding calendar year for a period of at least 12 months from the date on which the employees were hired; and

(B) On December 31 of the year prior to the year in which the employer applies for the HIRE Vets Medallion Award, at least 10 percent of the employer's employees were veterans; and

(4) The employer has at least two of the following forms of integration assistance:

(i) The employer has established an employee veteran organization or resource group to assist new veteran employees with integration, including coaching and mentoring;

(ii) The employer has established programs to enhance the leadership skills of veteran employees during their employment;

(iii) The employer has established a human resources veterans' initiative;

(iv) The employer provides each of its employees serving on active duty in the United States National Guard or Reserve with compensation sufficient, in combination with the employee's active duty pay, to achieve a combined level of income commensurate with the employee's salary prior to undertaking active duty;

(v) The employer has a tuition assistance program to support veteran employees' attendance in post-secondary education during the term of their employment.

§ 1011.115 Is there an exemption for certain large employers from the dedicated human resources professional criterion for the large employer platinum HIRE Vets Medallion Award?

Yes. Large employers who employ 5,000 or fewer employees need not have a dedicated human resources professional to support the hiring and retention of veteran employees. A large employer with 5,000 or fewer employees can satisfy the criterion at § 1011.100(b)(7) by employing at least one human resources professional whose regular work duties include supporting the hiring, training, and retention of veteran employees.

§ 1011.120 Under what circumstances will VETS find an employer ineligible to receive a HIRE Vets Medallion Award for a violation of labor law?

(a) Any employer with an adverse labor law decision, stipulated agreement, contract debarment, or contract termination, as defined in paragraphs (b) through (e) of this section, pursuant to either of the following labor laws, as amended, will not be eligible to receive an award:

(1) Uniformed Services Employment and Reemployment Rights Act (USERRA); or

(2) Vietnam Era Veterans' Readjustment Assistance Act (VEVRAA);

(b) For purposes of this section, an adverse labor law decision means any of the following, issued in the calendar year prior to year in which applications are solicited or the calendar year in which applications are solicited up until the issuance of the award, in which a violation of any of the laws in paragraph (a) of this section is found:

(1) A civil or criminal judgment;

(2) A final administrative merits determination of an administrative adjudicative board or commission; or

(3) A decision of an administrative law judge or other administrative judge that is not appealed and that becomes the final agency action.

(c) For purposes of this section, a stipulated agreement means any agreement (including a settlement agreement, conciliation agreement, consent decree, or other similar document) to which the employer is a party, entered into in the calendar year prior to the year in which applications are solicited or the calendar year in which applications are solicited up until the issuance of the award, that contains an admission that the employer violated either of the laws cited in paragraph (a) of this section.

(d) For purposes of this section, a contract debarment means any order or voluntary agreement, pursuant to the laws listed in paragraph (a) of this section, that debars the employer from receiving any future Federal contract. Employers shall be ineligible for an award for the duration of time that the contract debarment is in effect.

(e) For purposes of this section, a contract termination means any order or voluntary agreement, pursuant to the laws listed in paragraph (a) of this section, that terminates an existing Federal contract prior to its completion. Employers shall be ineligible for the award if this termination occurred in

the calendar year prior to the year in which applications are solicited or the calendar year in which applications are solicited up until the issuance of the award.

(f) VETS may delay issuing an award to an employer if, at the time the award is to be issued, VETS has credible information that a significant violation of one of the laws in paragraph (a) of this section may have occurred that could lead to an employer being disqualified pursuant to any of paragraphs (b) through (e) of this section.

Subpart C—Application Process

§ 1011.200 How will VETS administer the HIRE Vets Medallion Award process?

The Secretary of Labor will annually—

(a) Solicit and accept voluntary applications from employers in order to consider whether those employers should receive a HIRE Vets Medallion Award;

(b) Review applications received in each calendar year;

(c) Notify such recipients of their awards; and

(d) At a time to coincide with the annual commemoration of Veterans Day—

(1) Announce the names of such recipients;

(2) Recognize such recipients through publication in the **Federal Register**; and

(3) Issue to each such recipient—

(i) A HIRE Vets Medallion Award; and

(ii) A certificate stating that such employer is entitled to display such HIRE Vets Medallion Award.

§ 1011.205 What is the timing of the HIRE Vets Medallion Award process?

VETS will review all timely applications that fall under any cap established in § 1011.305 of this part to determine whether an employer should receive a HIRE Vets Medallion Award, and, if so, of what level.

(a) *Performance period*—except as otherwise noted in § 1011.120 of this part, only the employer's actions taken prior to December 31 of the calendar year prior to the calendar year in which applications are solicited will be considered in reviewing the award.

(b) *Solicitation period*—VETS will solicit applications not later than January 31 of each calendar year for the HIRE Vets Medallion Award to be awarded in November of that calendar year.

(c) *End of acceptance period*—VETS will stop accepting applications on April 30 of each calendar year for the awards to be awarded in November of that calendar year.

(d) *Review period*—VETS will finish reviewing applications not later than August 31 of each calendar year for the awards to be awarded in November of that calendar year.

(e) *Selection of recipients*—VETS will select the employers to receive HIRE Vets Medallion Awards not later than September 30 of each calendar year for the awards to be awarded in November of that calendar year.

(f) *Notice of awards and denials*—VETS will notify employers who will receive HIRE Vets Medallion Awards not later than October 11 of each calendar year for the awards to be awarded in November of that calendar year. VETS will also notify applicants who will not be receiving an award at that time.

§ 1011.210 How often can an employer receive the HIRE Vets Medallion Award?

Per section 2(d) of the HIRE Vets Act, an employer who receives a HIRE Vets Medallion Award for 1 calendar year is not eligible to receive a HIRE Vets Medallion Award for the subsequent calendar year.

§ 1011.215 How will the employer complete the application for the HIRE Vets Medallion Award?

(a) VETS will require all applicants to provide information to establish their eligibility for the HIRE Vets Medallion Award.

(b) VETS may request additional information in support of the application for the HIRE Vets Medallion Award.

(c) The chief executive officer, the chief human resources officer, or an equivalent official of each employer applicant must attest under penalty of perjury that the information the employer has submitted in its application is accurate.

(d) Interested employers can access the application form via the HIRE Vets Web site accessible from *https://www.hirevets.gov/*.

(e) Applicants will complete the application form and submit it electronically.

(f) Applicants who need a reasonable accommodation in accessing the application form, submitting the application form, or submitting the application fee may contact VETS at (202) 693–4700 or TTY (877) 889–5627 (these are not toll-free numbers).

(g) Should the information provided on the application be deemed incomplete, VETS will attempt to contact the applicant. The applicant must respond with the additional information necessary to complete the application form within 5 business days or VETS will deny the application.

§ 1011.220 How will VETS verify a HIRE Vets Medallion Award application?

VETS will verify all information provided by an employer in its application to the extent that such information is relevant in determining whether or not such employer meets the criteria to receive a HIRE Vets Medallion Award or in determining the appropriate level of HIRE Vets Medallion Award for that employer to receive. VETS will verify this information by reviewing all information provided as part of the application.

§ 1011.225 Under what circumstances will VETS conduct further review of an application?

If at any time VETS becomes aware of facts that indicate that the information provided by an employer in its application was incorrect or that the employer does not satisfy the requirements at § 1011.120, VETS may conduct further review of the application. As part of that review, VETS may request information and/or documentation to confirm the accuracy of the information provided by the employer in its application or to confirm that the employer is not ineligible under § 1011.120. Depending on the result of the review, VETS may either deny or revoke the award. If VETS initiates such review prior to issuing the award, VETS will not be required to meet the timeline requirements in this part.

§ 1011.230 Under what circumstances can VETS deny or revoke an award?

(a) *Denial of award.* VETS may deny an award for any of the following reasons:

(1) The applicant fails to provide information and/or documentation as requested under § 1011.225 of this part;

(2) VETS determines that the chief executive officer, the chief human resources officer, or an equivalent official of the applicant falsely attested that the information on the application was true;

(3) The employer is ineligible to receive an award pursuant to § 1011.120 of this part; or

(4) The application does not satisfy all application requirements.

(b) *Revocation of award.* Once the HIRE Vets Medallion Award has been awarded, VETS may revoke the recipient's award for the following reasons:

(1) The HIRE Vets Medallion Award recipient fails to provide information and/or documentation as requested under § 1011.225 of this part;

(2) VETS determines that the chief executive officer, the chief human

resources officer, or an equivalent official of the recipient falsely attested that the information on the application was true;

(3) The employer was ineligible to receive an award pursuant to § 1011.120 of this part; or

(4) The employer violated the display restrictions at § 1011.405 of this part.

(c) If VETS decides to deny or revoke an award, it will provide the employer with notice of the decision. An employer may request reconsideration of VETS' decision to deny or revoke an award pursuant to § 1011.500 of this part.

Subpart D—Fees and Caps

§ 1011.300 What are the application fees for the HIRE Vets Medallion Award?

(a) The Act requires the Secretary of Labor to establish a fee sufficient to cover the costs associated with carrying out the HIRE Vets Medallion Program.

(b) Table 1 to § 1011.300 sets forth the fees an employer must pay to apply for the HIRE Vets Medallion Award. VETS will adjust the fees periodically according to the Implicit Price Deflator for Gross Domestic Product published by the U.S. Department of Commerce and notify potential applicants of the adjusted fees.

(1) If a significant adjustment is needed to arrive at a new fee for any reason other than inflation, then a proposed rule containing the new fees will be published in the **Federal Register** for comment.

(2) VETS will round the fee to the nearest dollar.

TABLE 1 TO § 1011.300

Application Fees	
Small Employer Fee	$90.00
Medium Employer Fee	190.00
Large Employer Fee	495.00

(c) All applicants must submit the appropriate application processing fee for each application submitted. This fee is based on the fees provided in table 1 to § 1011.300. Payment of this fee must be made electronically through the U.S. Treasury *pay.gov* system or an equivalent.

(d) Once a fee is paid, it is nonrefundable, even if the employer withdraws the application or does not receive a HIRE Vets Medallion Award.

§ 1011.305 May VETS set a limit on how many applications will be accepted in a year?

Yes, VETS may set a limit on how many applications will be accepted in any given year.

Subpart E—Design and Display

§ 1011.400 What does a successful applicant receive?

(a) The award will be in the form of a certificate and will state the year for which it was awarded.

(b) VETS will also provide a digital image of the medallion for recipients to use, including as part of an advertisement, solicitation, business activity, or product.

§ 1011.405 What are the restrictions on display and use of the HIRE Vets Medallion Award?

It is unlawful for any employer to publicly display a HIRE Vets Medallion Award, in connection with, or as a part of, any advertisement, solicitation, business activity, or product—

(a) For the purpose of conveying, or in a manner reasonably calculated to convey, a false impression that the employer received the award through the HIRE Vets Medallion Program, if such employer did not receive such award through the HIRE Vets Medallion Program; or

(b) For the purpose of conveying, or in a manner reasonably calculated to convey, a false impression that the employer received the award through the HIRE Vets Medallion Program for a year for which such employer did not receive such award.

Subpart F—Requests for Reconsideration

§ 1011.500 What is the process to request reconsideration of a denial or revocation?

(a) An applicant may file a request for reconsideration of VETS' decision to deny or revoke a HIRE Vets Medallion Award or of VETS' decision as to the level of award by mailing a request for reconsideration to the following address no later than 15 business days after the date of VETS' notice of its decision. Requests for reconsideration must be sent to: HIRE Vets Medallion Program, DOL VETS, 200 Constitution Ave. NW., Room S1325, Washington, DC 20210.

(b) Requests for reconsideration pursuant to paragraph (a) of this section must contain the following:

(1) The employer name and identification number;

(2) The reason for the request; and

(3) An explanation, accompanied by any necessary documentation to support that explanation, of why VETS' decision was incorrect.

(c) VETS may request from the employer filing such request any additional evidence or explanation it finds necessary for reconsideration.

(d) Within 30 business days after the later of the receipt of the request or the receipt of any additional evidence or explanation requested, VETS will issue a determination about whether to grant or deny the request.

(e) No additional Department of Labor review is available.

Subpart G—Record Retention

§ 1011.600 What are the record retention requirements for the HIRE Vets Medallion Award?

Applicants must retain a record of all information used to support an application for the HIRE Vets Medallion Award for 2 years from the date of application.

Signed at Washington, DC, this 1st day of November 2017.

J.S. Shellenberger,

Deputy Assistant Secretary for the Veterans' Employment and Training Service.

[FR Doc. 2017–24214 Filed 11–9–17; 8:45 am]

BILLING CODE 4510–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2014–F–0988]

Food Additives Permitted in Feed and Drinking Water of Animals; Ammonium Formate and Formic Acid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, the Agency) is amending food additive regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of formic acid and ammonium formate. This action is in response to a food additive petition filed by BASF Corp for Feed Grade Sodium Formate (FAP 2286), which also proposed to amend the animal food additive regulations for formic acid and ammonium formate to limit formic acid and formate salts from all added sources.

DATES: This rule is effective November 13, 2017. Submit either written or electronic objections and requests for a hearing by December 13, 2017. See section V of this document for information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted

on or before December 13, 2017. The *https://www.regulations.gov* electronic filing system will accept objections until midnight Eastern Time at the end of December 13, 2017. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting objections. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection 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 objections submitted to the Dockets Management Staff, FDA will post your objection, 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–2014–F–0988 for ''Food Additives Permitted in Feed and Drinking Water of Animals; Ammonium Formate and Formic Acid.'' Received objections, those filed in a timely manner (see **ADDRESSES**), 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.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies in 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 objections. 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 objections 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.gpo.gov/fdsys/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 objections 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.

FOR FURTHER INFORMATION CONTACT: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6729, *chelsea.trull@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the **Federal Register** of July 25, 2014 (79 FR 43325), FDA announced that we had filed a food additive petition (animal use) (FAP 2286) submitted by BASF Corp., 100 Park Ave., Florham Park, NJ 07932. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of feed grade sodium formate as a feed acidifying agent in complete swine feeds. The notice of petition provided for a 30-day comment period on the petitioner's request for categorical exclusion from preparing an environmental assessment or environmental impact statement.

In addition, the petition proposed that the animal food additive regulations for formic acid and ammonium formate be amended to limit formic acid and formate salts from all added sources to 1.2 percent of complete feeds. This element of the petition was not described in the July 2014 notice of petition for FAP 2286, but was later described in a September 30, 2016, notice of petition (81 FR 67260).

II. Conclusion

FDA became concerned about the safety of higher levels of formic acid and formate salts in complete feeds when multiple sources of formic acid and its salts are used in combination. FDA concludes that the data establish the safety of formic acid and ammonium formate for use as a feed acidifying agent in complete feeds, that formic acid and formate salts should be limited to 1.2 percent on complete feed, and that the food additive regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure.

IV. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment, nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the

regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the office of the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. In § 573.170, redesignate paragraphs (c) and (d) as paragraphs (d) and (e), add new paragraph (c) and paragraph (d)(3) to newly redesignated paragraph (d), and revise newly redesignated paragraph (e) introductory text to read as follows:

§ 573.170 Ammonium formate.

* * * * *

(c) To ensure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

* * * * *

(d) * * *

(3) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(e) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (d) of this section, the label and labeling shall contain:

* * * * *

■ 3. In § 573.480, redesignate paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5), add new paragraph (b)(3) and paragraph (b)(4)(iii) to newly redesignated paragraph (b)(4), and revise newly redesignated paragraph (b)(5) introductory text to read as follows:

§ 573.480 Formic acid.

* * * * *

(b) * * *

(3) To ensure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(4) * * *

(iii) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(5) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (b)(4) of this section, the label and labeling shall contain:

* * * * *

Dated: November 3, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24366 Filed 11–9–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 543

Removal of Côte d'Ivoire Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is removing from the Code of Federal Regulations the Côte d'Ivoire Sanctions Regulations as a result of the termination of the national emergency on which the regulations were based.

DATES: *Effective:* November 13, 2017.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's Office of Foreign Assets Control: Assistant Director for Licensing, tel.: 202/622–2480, Assistant Director for Regulatory Affairs, tel.: 202/622–4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202/622–2490, or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202/622–2410.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treasury.gov/ofac*).

Background

On February 7, 2006, the President issued Executive Order 13396, ''Blocking Property of Certain Persons Contributing to the Conflict in Côte d'Ivoire'' (E.O. 13396), in which the President declared a national emergency to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States posed by the situation in or in relation to Côte d'Ivoire. That situation, which had been addressed by the United Nations Security Council in Resolution 1572 of November 15, 2004, and subsequent resolutions, had resulted in the massacre of large numbers of civilians, widespread human rights abuses, significant political violence and unrest, and attacks against international peacekeeping forces leading to fatalities. E.O. 13396 blocked all property and interests in property of the persons listed in the Annex to E.O. 13396 and any person determined to meet one or more of the criteria set out in E.O. 13396.

On April 13, 2009, OFAC issued the Persons Contributing to the Conflict in Côte d'Ivoire Sanctions Regulations, 31 CFR part 543 (the ''Regulations''), as a final rule to implement E.O. 13396 (74 FR 16763, April 13, 2009). On July 21, 2009, OFAC issued an amendment to the Regulations to change the heading of the Regulations to the Côte d'Ivoire Sanctions Regulations (74 FR 35802, July 21, 2009). OFAC also amended the Regulations on February 8, 2012, to add a definition of a term used in the Regulations (77 FR 6463, Feb. 8, 2012).

On September 14, 2016, the President issued Executive Order 13739, ''Termination of Emergency With Respect to the Situation in or in Relation to Côte d'Ivoire'' (E.O. 13739). In E.O. 13739, the President found that the situation that gave rise to the

declaration of a national emergency in E.O. 13396 with respect to the situation in or in relation to Côte d'Ivoire had been significantly altered by the progress achieved in the stabilization of Côte d'Ivoire, including the successful conduct of the October 2015 presidential election, progress on the management of arms and related materiel, and the combatting of illicit trafficking in natural resources. Accordingly, and in view of the removal of multilateral sanctions by the United Nations Security Council in Resolution 2283, the President terminated the national emergency and revoked E.O. 13396.

Therefore, OFAC is removing the Regulations from the Code of Federal Regulations. Pursuant to section 202 of the National Emergencies Act (50 U.S.C. 1622) and section 1 of E.O. 13739, termination of the national emergency declared in E.O. 13396 shall not affect any action taken or proceeding pending and not fully concluded or determined as of 8:00 a.m. eastern daylight time on September 14, 2016 (the effective date of E.O. 13739), any action or proceeding based on any act committed prior to the effective date, or any rights or duties that matured or penalties that were incurred prior to the effective date.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, as well as the provisions of Executive Order 13771, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this rule does not impose information collection requirements that would require the approval of the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

List of Subjects in 31 CFR Part 543

Administrative practice and procedure, Banks, Banking, Blocking of assets, Côte d'Ivoire, Credit, Foreign trade, Penalties, Reporting and recordkeeping requirements, Securities, Services.

For reasons set forth in the preamble, and under the authority of 3 U.S.C. 301; 50 U.S.C. 1601–1651; E.O. 13396, 71 FR 7389, 3 CFR, 2006 Comp., p. 209; E.O. 13739, 81 FR 63673 (September 16, 2016), OFAC amends 31 CFR chapter V as follows:

PART 543—[REMOVED]

■ 1. Remove part 543.

Dated: November 7, 2017.

John E. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2017–24521 Filed 11–9–17; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0758]

Drawbridge Operation Regulation; Delaware River, Tacony, PA, and Palmyra, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the SR 73 (Tacony-Palmyra) Bridge across the Delaware River, mile 107.2, in between Tacony, PA, and Palmyra, NJ. The deviation is necessary to facilitate routine maintenance. This deviation allows the bridge to remain in the closed-to-navigation position.

DATES: This deviation is effective from 7 a.m. on December 15, 2017, through 5 p.m. on February 4, 2018.

ADDRESSES: The docket for this deviation, [USCG–2017–0758] is available at *http://www.regulations.gov*. Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Mickey Sanders, Bridge Administration Branch Fifth District, Coast Guard; telephone (757) 398–6587, email *Mickey.D.Sanders2@uscg.mil*.

SUPPLEMENTARY INFORMATION: The Burlington County Bridge Commission, owner and operator of the SR 73 (Tacony-Palmyra) Bridge across the Delaware River, mile 107.2, in between Tacony, PA, and Palmyra, NJ, has requested a temporary deviation from the current operating schedule to accommodate annual maintenance to replace machinery components for the drive system that operates the bascule spans. The bridge has a vertical clearance of 50 feet above mean high water (MHW) in the closed position.

The current operating schedule is set out in 33 CFR 117.716. Under this temporary deviation, the bridge will be maintained in the closed-to-navigation position for six (6) separate four (4) day periods from 7 a.m. until 5 p.m. starting from December 15, 2017, through December 18, 2017; January 4, 2018, through January 7, 2018; January 11, 2018, through January 14, 2018; January 18, 2018, through January 21, 2018; January 25, 2018, through January 28, 2018; and February 1, 2018, through February 4, 2018. The bridge will open on signal at all other times.

The Delaware River is used by a variety of vessels including small commercial vessels, recreational vessels and tug and barge traffic. The Coast Guard has carefully coordinated the restrictions with waterway users in publishing this temporary deviation.

Vessels able to pass through the bridge in the closed position may do so if at least 15 minutes notice is given. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notice to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by this temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of this effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 3, 2017.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2017–24468 Filed 11–9–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–0990]

RIN 1625–AA00

Safety Zone; City of Oswego Fireworks Display; Oswego River, Oswego, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Oswego River, Oswego, NY. This safety zone is intended to restrict vessels from portions of the Oswego River during the City of Oswego fireworks display. This temporary safety zone is necessary to protect mariners and vessels from the navigational hazards associated with a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Buffalo.

DATES: This rule is effective from 7:15 p.m. on November 25, 2017 until 8:15 p.m. on November 26, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2017–0990 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Michael Collet, Chief of Waterways Management, U.S. Coast Guard Sector Buffalo; telephone 716–843–9322, email *D09-SMB-SECBuffalo-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 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 the event sponsor did not submit notice to the Coast Guard with sufficient time remaining before the event to publish an NPRM. Delaying the effective date of this rule to wait for a comment period to run would be impracticable and contrary to the public interest by inhibiting the Coast Guard's ability to protect spectators and vessels from the hazards associated with a fireworks display.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register** because doing so would be impracticable and contrary to the public interest. Delaying the effective date would be contrary to the rule's objectives of ensuring safety of life on the navigable waters and protection of persons and vessels near the event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Buffalo (COTP) has determined that a fireworks display presents significant risks to public safety and property. Such hazards include premature and accidental detonations, dangerous projectiles, and falling or burning debris. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the fireworks display takes place.

IV. Discussion of the Rule

This rule establishes a safety zone on November 25, 2017, or in the event of inclement weather November 26, 2017, from 7:15 p.m. to 8:15 p.m. The safety zone will encompass all waters of the Oswego River; Oswego, NY contained within 210-foot radius of: 43°27′15.37″ N., 076°30′28.34″ W. (NAD 83).

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

V. 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, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 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 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget.

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and enforced for a relatively short time. Also, the safety zone is designed to minimize its impact on navigable waters. Furthermore, the safety zone has been designed to allow vessels to transit around it. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. 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. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions

annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 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.

C. 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).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), 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 establishes a temporary safety zone. It is categorically excluded under section 2.B.2, figure 2–1, paragraph 34(g) of the Instruction, which pertains to establishment of safety zones. A Record of Environmental Consideration (REC) supporting this determination is available in the docket where indicated in the **ADDRESSES** section of this preamble.

G. Protest Activities

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

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: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0990 to read as follows:

§ 165.T09–0990 Safety Zone; City of Oswego Fireworks Display; Oswego River, Oswego, NY.

(a) *Location.* The safety zone will encompass all waters of the Oswego River; Oswego, NY contained within a 210-foot radius of: 43°27′15.37″ N., 076°30′28.34″ W. (NAD 83).

(b) *Enforcement period.* This regulation will be enforced from 7:15 p.m. until 8:15 p.m. on November 25, 2017, or in the event of inclement weather, on November 26, 2017, from 7:15 p.m. until 8:15 p.m.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The ''on-scene representative'' of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone must contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.

Dated: November 6, 2017.

J.S. Dufresne,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2017–24498 Filed 11–9–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–1011]

RIN 1625–AA00

Safety Zone, Delaware River; Pipeline Removal

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; correcting amendment.

SUMMARY: The Coast Guard is correcting a temporary final rule that appeared in the **Federal Register** on November 6, 2017. The document issued a temporary safety zone for in the Mifflin Range on the Delaware River to facilitate pipeline removal in preparation for the deepening of the Delaware River. Due to mechanical issues on the SHELBY, the dredging operations will be attended by the towing vessel GRAPE APE for the duration of the safety zone. All vessel contact information remains the same.

DATES: This correction is effective without actual notice from November 13, 2017 until December 4, 2017. For the purpose of enforcement, actual notice

will be used from November 6, 2017, until November 13, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Edmund Ofalt, Waterways Management Branch, U.S. Coast Guard Sector Delaware bay; telephone (215) 271–4814, email *Edmund.J.Ofalt@uscg.mil.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2017–24068, appearing at 82 FR 51347 on Monday, November 6, 2017, § 165.T05–1011(c) incorrectly references ''SHELBY'' instead of ''GRAPE APE.'' This document corrects that error.

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 corrects 33 CFR part 165 by making the following correcting amendment:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

§ 165.T05–1011 [Corrected]

■ 2. In § 165.T05–1011(c), remove ''SHELBY'' wherever it appears and adding in its place ''GRAPE APE''.

Dated: November 6, 2017.

Scott E. Anderson,

Captain, U.S. Coast Guard, Captain of the Port, Delaware Bay.

[FR Doc. 2017–24508 Filed 11–9–17; 8:45 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

U.S. Copyright Office

37 CFR Part 201

[Docket No. 2017–7]

Modernizing Copyright Recordation

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Interim rule.

SUMMARY: The United States Copyright Office is issuing an interim rule amending its regulations governing recordation of transfers of copyright ownership, other documents pertaining to a copyright, and notices of termination. The interim rule adopts a number of the regulatory updates proposed in the notice of proposed rulemaking published on May 18, 2017.

DATES: Effective December 18, 2017.

FOR FURTHER INFORMATION CONTACT: Sarang V. Damle, General Counsel and Associate Register of Copyrights, by email at *sdam@loc.gov,* or Jason E. Sloan, Attorney-Advisor, by email at *jslo@loc.gov.* Each can be contacted by telephone by calling (202) 707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Copyright Act of 1976, the U.S. Copyright Office is responsible for recording documents pertaining to works under copyright, such as assignments, licenses, and grants of security interests.[1] The Office is also responsible for recording notices of termination.[2] As discussed in a notice of proposed rulemaking published in the **Federal Register** on May 18, 2017 (''NPRM''),[3] the current recordation process is a time-consuming and labor-intensive paper-based one, requiring remitters to submit their documents in hard copy.

The Office is engaged in an effort to modernize the recordation process in coming years by developing a fully electronic, online system through which remitters will be able to submit their documents and all applicable indexing information to the Office for recordation. In conjunction with the anticipated development effort, the Office issued the NPRM to propose updates to the Office's current regulations to govern the submission of documents to the Office for recordation once the new electronic system is developed and launched. The NPRM explained that while the Office could not estimate when the new system would be completed, public comments were being sought because the Office needed to make a number of policy decisions critical to the design of the to-be-developed system.[4]

In addition, as most relevant here, the NPRM further stated that while the proposed amendments were designed with a new electronic submission system in mind, at least some of the proposed changes could be implemented in the near future, without the new system. Thus, the Office noted that, to the extent possible under the Office's current paper system, the Office intended to adopt some aspects of the proposed rule on an interim basis until such time as the electronic system is complete and a final rule is enacted.[5]

II. Interim Rule

As indicated in the NPRM, this interim rule adopts those provisions described in the NPRM that the Office believes will help streamline the recordation process prior to completion of the new electronic recordation system.

Unlike a typical interim rule, this one is being promulgated following a notice of proposed rulemaking and a period for public comment. In response to the NPRM, the Office received thirteen comments from a variety of stakeholders.[6] As this interim rule does not cover every issue raised by the NPRM or the commenters, the Office reserves judgment on any matters not expressly discussed herein and no inference should be drawn from the Office's silence on any particular point. Additionally, the Office reserves the right to issue other interim rules during the course of developing the system. The comments received in response to the NPRM not addressed by this interim rule will continue to be evaluated by the Office as system development progresses. The Office intends to issue a final rule under this same rulemaking docket in connection with the public release of the new system.

While some discrete aspects of the proposed rule were opposed, most were either unopposed or affirmatively supported. As such, except as otherwise discussed below, the proposed rule is being adopted largely for the reasons discussed in the NPRM.[7] As stated in the NPRM, the general mechanics of the new regulations are essentially the same as under the Office's current rules and policies.[8] To be eligible for recordation, the document or notice of termination must satisfy certain requirements, be

[1] 17 U.S.C. 205.

[2] A ''notice of termination'' is a notice that terminates a grant to a third party of a copyright in a work or any rights under a copyright. Only certain grants may be terminated, and only in certain circumstances. Termination is governed by three separate provisions of the Copyright Act, with the relevant one depending on a number of factors, including when the grant was made, who executed it, and when copyright was originally secured for the work. *See* 17 U.S.C. 203, 304(c), 304(d).

[3] 82 FR 22771 (May 18, 2017).

[4] *Id.* at 22771.

[5] *Id.* at 22771–72.

[6] The commenters are Author Services, Inc., Authors Alliance, Copyright Alliance, CSC, Dale Adams, Entertainment Software Association (''ESA''), Intellectual Property Owners Association, Kernochan Center for Law, Media and the Arts (''Kernochan''), Motion Picture Association of America, Inc. (''MPAA''), ''Music Parties'' (joint comment by American Association of Independent Music, Recording Industry Association of America, Inc., and National Music Publishers' Association), Music Reports, Inc. (''MRI''); Sergey Vernyuk, and Software and Information Industry Association (''SIIA'').

[7] *See generally* 82 FR 22771.

[8] *See id.* at 22772, 22776.

submitted properly, and be accompanied by the applicable fee. As before, the date of recordation will be the date when all of the required elements are received by the Office, and the Office may reject any document or notice submitted for recordation that fails to comply with the statute or the Office's rules or instructions. While recordation of section 205 documents is optional, pursuant to statute, notices of termination must be recorded with the Office ''as a condition to its taking effect.'' [9]

A. Transfers of Copyright Ownership and Other Documents Pertaining to a Copyright

Cover Sheet and Electronic Title Lists. As was proposed,[10] the interim rule requires paper submissions to be accompanied by a cover sheet that is similar to the current Form DCS. In addition to the information currently collected, the new Form DCS asks for some minor additional indexing information and has some additional checkboxes to help with the document examination process. Additionally, the various required certifications discussed below can also be made using Form DCS. Having all of this information in one place will benefit remitters by aiding them in confirming that their submissions are complete and comply with the requirements for recordation. It should also benefit the Office by making the examination process more efficient, as examiners will no longer need to search through the document itself to find this indexing information.

Also as proposed,[11] remitters may continue to provide electronic lists of certain indexing information about the works to which the document pertains. As the NPRM discussed, much of the current regulation's details surrounding the formatting of electronic title lists are being removed. Instead, the interim rule states that such lists must be prepared and submitted in the manner specified by the Office in instructions it will post on its Web site. This change will allow the Office to develop more flexible instructions for remitters that can be updated and modified as needed without resorting to a rulemaking. No commenter objected to this proposed change.

Originals, Copies, and Actual Signatures. One of the more significant proposals the Office made in the NPRM dealt with the treatment of original documents versus copies, and the definition of ''actual signature.'' [12] The Office proposed to continue requiring, in accordance with section 205(a), that to record a document, remitters must submit either the original document ''bear[ing] the actual signature of the person who executed it'' or a ''true copy of the original, signed document'' accompanied by a ''sworn or official certification.'' In discussing the application of the statute to electronic documents and electronic signatures, the NPRM proposed that to avoid any doubt about the sufficiency of a recordation on the basis of whether or not the submitted document is an original or a copy, the Office would consider any document either submitted electronically through the new system, or lacking a handwritten, wet signature (*e.g.,* any document bearing an electronic signature) to be a ''copy'' within the meaning of section 205.[13] The Office noted that, in practice, this would be unlikely to significantly affect remitters, as the only consequence is that each such submission would need to be accompanied by a sworn or official certification. As no commenter objected, the Office is adopting this as part of the interim rule, to the extent applicable to the current paper-based submission process.

The NPRM also proposed a definition of the statutory term ''actual signature.'' [14] As discussed in the NPRM, that term has been undefined in the Office's regulations, but in practice, the Office has required original documents to bear handwritten, wet signatures and copies of documents to reproduce such handwritten, wet signatures. Electronic signatures have not been permitted. After analyzing the issue, the Office concluded that its regulations and processes should be flexible enough to permit any document that may constitute a transfer of copyright ownership under section 204 of the Copyright Act to be recordable under section 205. Thus, the Office proposed defining ''actual signature'' as any legally binding signature, including an electronic signature as defined by the E-Sign Act.[15]

In connection with this proposal, the Office explained that it disagreed with the suggestion from Professor Brauneis's report, *Transforming Document Recordation at the United States Copyright Office,* that the signature be in a ''discrete and identifiable form'' on the remitted document.[16] Instead, the Office proposed resolving in another way Professor Brauneis's concern that having too broad a definition could potentially include ''acts that do not generate a trace that is easily remitted as 'a signature' on 'a document.' '' [17] The Office proposed that rather than restrict the definition of signature, the rule should require that where an actual signature is not a handwritten or typewritten name, such as when an individual clicks a button on a Web site or application to indicate agreement to contractual terms, the remitter should be required to submit evidence demonstrating the existence of the signature, such as by appending a database entry or confirmation email to a copy of the terms showing that a particular user agreed to them by clicking ''yes'' on a particular date.[18]

To the extent discussed by commenters, the Office's proposal on these issues was largely supported.[19] One commenter, however, took issue with the Office's proposal not to limit signatures to those in a ''discrete and identifiable form'' on the remitted document.[20] That commenter stated that the text of sections 204 and 205 contain materially different requirements and that, while in section 204, Congress adopted a more flexible writing requirement that would ultimately be tested in an adversarial environment, in section 205, Congress was narrower to create more certainty that if the requirements are met one would receive the enumerated benefits of recordation.[21] The commenter contended that the result of the proposed rule would be that the scope of section 205 would be improperly

[9] 17 U.S.C. 203(a)(4)(A), 304(c)(4)(A), 304(d)(1).

[10] 82 FR at 22772.

[11] *Id.*

[12] *Id.* at 22772–74.

[13] *Id.* at 22772–73.

[14] *Id.* at 22773.

[15] *Id.* The E-Sign Act defines ''electronic signature'' as ''an electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.'' 15 U.S.C. 7006(5). While Copyright Alliance and MPAA supported this proposed definition, they asked that the Office not create any requirements above and beyond what is required in the E-Sign Act. *See* Copyright Alliance Comments at 2; MPAA Comments at 2. The interim rule adopts the very broad definition of ''any legally binding signature'' and merely refers to the E-Sign Act as an example of something that would be included within that definition. The Office did not mean to imply that the various requirements applicable to the E-Sign Act were being imported into the Office's new definition of ''actual signature.''

[16] 82 FR at 22773 (quoting Robert Brauneis, Transforming Document Recordation at the U.S. Copyright Office 66 (Dec. 2014), *https://www.copyright.gov/docs/recordation/recordation-report.pdf.* [hereinafter *Brauneis Report*]).

[17] 82 FR at 22773 (quoting *Brauneis Report* at 66).

[18] *Id.* at 22773.

[19] *See* Copyright Alliance Comments at 2; MPAA Comments at 2; Music Parties Comments at 4; Sergey Vernyuk Comments.

[20] SIIA Comments at 2–5.

[21] *Id.* at 4.

subsumed by section 204 (and vice versa).[22]

The Office disagrees. Section 204 describes what is necessary for a transfer of copyright ownership to be valid and section 205 states explicitly that ''[a]ny transfer of copyright ownership . . . may be recorded.'' [23] Thus, any transfer that is valid under section 204 should be recordable under section 205.[24] As explained in the NPRM, the recordation requirement of an ''actual signature'' merely distinguishes the signature on the original document from the reproduction of that signature on a copy of the document, and is not meant to limit the type of signature a document must have in order to be recorded.[25]

Accordingly the Office's interim rule essentially adopts the approach set forth in the NPRM, including the definition of ''actual signature'' as proposed. The interim rule provides that where a signature is not a handwritten or typewritten name, to be recordable, the remitter must provide a description of the nature of the signature and whatever evidence is necessary to demonstrate the existence of the signature. At the same time, the Office recognizes that, in the case of signatures that are not discrete and identifiable, it may prove difficult in practice for recordation examiners to determine on a case-by-case basis whether a document has been actually signed. Thus, the Office will not evaluate the evidence submitted in such cases, but will presume that the signature requirement has been satisfied and record the document (if all other requirements for recordation have been met). The Office will also make any of the ancillary material submitted available for public inspection. The interim rule makes clear, however, that this presumption is without prejudice to any party claiming that the document was not signed, including in court.

Certifications. Given the general lack of opposition to the proposed rule's various certification requirements, they are being adopted for the reasons provided in the NPRM, except as noted below.[26] Thus, under the interim rule, remitters are required to provide essentially two sets of certifications. First, the remitter must personally certify that he or she has appropriate authority to submit the document for recordation and that the indexing and other information submitted to the Office by the remitter is true, accurate, and complete to the best of the remitter's knowledge. These remitter-related certifications concern the remitter's authority to make the recordation and the veracity of the indexing and other information provided as a part of the submission; the certifications do not pertain to the actual document being submitted for recordation. The remitter can make these certifications by signing, either electronically or by hand, the required cover sheet.

Second, the interim rule requires certifications related to the document itself: That the actual document being submitted for recordation conforms to the Office's signature,[27] completeness, legibility, and redaction rules and, where the document is a copy, that it be accompanied by an official or sworn certification.[28] These document-related certifications generally can be made by either the remitter or another individual on the cover sheet submitted with the document to the Office.[29] An official certification, however, would need to be attached separately.

While one commenter voiced concerns that having two sets of certifications that can be made by different individuals could be confusing and burdensome,[30] the Office believes the commenter may have misunderstood the Office's proposed approach. The commenter asked that the Office allow a single representative to make both sets of certifications.[31] That is exactly what the Office intended. Where a single person is in a position to make both the remitter-related and document-related certifications, he or she can make them all on the document cover sheet submitted with the document to the Office. The Office's rules permit different people to make the two sets of certifications simply to provide more flexibility to parties in the event, for example, the person filling out the document cover sheet and remitting the document is not in a position to make the document-related certifications (*e.g.,* if the remitter is a paralegal or an administrative assistant without knowledge of the underlying document). Only in that case would two individuals be making the separate certifications. And even in that case, the remitter would still sign the document cover sheet for the remitter-related certifications; the other individual would make the document-related certifications on a separate page of the cover sheet.

As to the Office's proposed expansion of the categories of people who can make a sworn certification to include any person having an interest in a copyright to which the document pertains, as well as such person's authorized representative, one commenter partially objected. The commenter agreed that successors-in-interest to the original parties and their representatives should be permitted, but took issue with permitting third-party beneficiaries to make the certification, voicing concerns of fraud and/or error by those who mistakenly believe or fraudulently represent themselves as deriving some incidental benefit from a document to be recorded.[32] On further reflection, the Office believes that including third-party beneficiaries is not necessary. The main impetus for the expansion was to cover the types of scenarios noted by the Brauneis Report,[33] which would be covered by successors-in-interest.[34] As was originally proposed,[35] the Office is requiring that any authorized representative specify who they represent and that successors-in-interest

[22] *Id.* at 5.

[23] *See* 17 U.S.C. 204, 205.

[24] *See* Report of the Register of Copyrights on the General Revision of the U.S. Copyright Law 95–96 (Comm. Print. 1961) (in recommending that what would become the current Copyright Act ''require explicitly that any instrument filed for recordation bear the actual signature of the person executing it or a sworn or official certification that it is a true copy of the original signed instrument''—which closely resembles the current text of section 205(a)—the report makes clear that the original intent was that ''the recordation system should embrace all instruments by which the ownership of a copyright is transferred in whole or in part'').

[25] *See* 82 FR at 22773–74; *see also* Report of the Register of Copyrights on the General Revision of the U.S. Copyright Law 96 (Comm. Print. 1961) (explaining that the reason for requiring an ''actual signature'' is because ''[t]here should be practical assurance that the instrument recorded is precisely the same as the one executed'').

[26] *See* 82 FR at 22774.

[27] While the proposed rule did not specifically include a certification concerning the signature, the Office believes that having one will aid the Office's examination just as much as the other proposed certifications, especially in light of the adopted definition of ''actual signature.''

[28] The interim rule does not substantively alter the definition of ''official certification,'' but clarifies that it can be signed electronically. The interim rule does, however, simplify the definition of ''sworn certification,'' as was proposed, 82 FR at 22774, while also making the same clarification regarding electronic signatures.

[29] Commenters affirmatively supported having pre-printed certifications. *See* Authors Alliance Comments at 5; Sergey Vernyuk Comments. They also supported allowing a sworn certification to be made to the best of the certifier's knowledge. *See* Authors Alliance Comments at 5; Sergey Vernyuk Comments; *see also* 82 FR at 22774.

[30] Music Parties Comments at 4.

[31] *Id.*

[32] *Id.*

[33] *See* 82 FR at 22774.

[34] *See Brauneis Report* at 67 (providing examples of wills where the testator is deceased and documents in the current owner's chain of title but which were executed by predecessors-in-interest). While one commenter voiced support for the proposed rule, third-party beneficiaries were not specifically discussed. *See* Authors Alliance Comments at 5.

[35] 82 FR at 22774–75.

briefly describe the nature of their relationship to the document or the original parties to the document.[36]

Completeness and Legibility. In response to the NPRM's proposal on completeness and legibility, the Office received a technical suggestion on the provision's wording that the Office agrees with.[37] Thus, as under current regulations, the Office will continue to require documents submitted for recordation to be complete and legible. But as the NPRM proposed, the completeness requirement is being simplified to mandate that, while the document must be complete by its terms, it need only include referenced schedules, appendices, exhibits, addenda, or other material essential to understanding the *copyright-related* aspects of the document.[38] This is a change from current practice, where the Office requires documents to include all schedules, or provide an explanation for why such material cannot be provided. Thus, under the interim rule, if, for example, a document has several schedules, but only one has any relevance to the copyright-related terms of the agreement, the document would be deemed complete so long as that schedule is included; the other schedules can be omitted. The Office sees no reason to burden remitters with having to submit, and Office staff with reviewing, what can often be a significant volume of material completely unrelated to the copyright terms of the document.

Redactions. The NPRM proposed adopting rules governing redactions of documents, generally limiting redactions to certain enumerated categories of sensitive information, including financial, trade secret, and personally identifiable information.[39] The NPRM further proposed allowing remitters to request in writing the ability to redact other information from a document, which the Office may permit at its discretion. The proposal also required that blank or blocked-out portions of the document be labeled ''redacted'' or an equivalent; that all portions of the document required by the simplified completeness requirement be included (even if an entire page is redacted); and that upon request, for review purposes, the remitter may be required to supply the Office with an unredacted copy of the document or additional information about the redactions. Most commenters discussing redactions took issue with this last requirement to provide the Office with an unredacted copy of the document or additional information about the redactions, voicing serious security, privacy, and confidentiality concerns with the Office receiving, having access to, and storing such sensitive materials.[40] While one commenter did support the proposal,[41] the Office has decided to not include this part of the provision in the interim rule, especially given that the Office was unlikely to require such information in the majority of cases. The Office cautions, however, that, as commenters pointed out, over-redacting a document may affect constructive notice under section 205(c).[42]

Additionally, one commenter also asked that if an unredacted document is submitted accidentally that there be a simple process to replace it with a properly redacted one.[43] This would essentially be a type of correction. As such, the Office will more fully consider it in connection with its evaluation of the final rule on treatment of corrections going forward (see *Correcting Errors* below). The same commenter also suggested that the Office add more flexibility to the proposed rule by adding the phrase ''other similarly sensitive information'' to the acceptable categories of redactable information.[44] The Office declines to adopt this suggestion at this time. Other commenters agreed with the proposed categories, and the ability to make a written request to redact other information should provide an adequate mechanism through which remitters can seek additional redactions without having a catch-all provision.[45] The Office, however, will evaluate whether it is regularly receiving written requests to redact additional categories of information as part of the interim rule, and take that into account when formulating the final rule.

English Language Requirement. In the NPRM, the Office proposed to continue accepting and recording non-English language documents only if accompanied by an English translation signed by the individual making the translation.[46] The Office further proposed to extend the translation requirement to any indexing information provided by the remitter. Because the Office did not receive any objections to this aspect of the proposed rule, and one commenter affirmatively supported it,[47] it is being adopted as part of the interim rule. One commenter did, however, ask the Office to also permit translations made by software or automated translation services.[48] The Office agrees, and has included such a provision in the interim rule. This adjustment should make it easier and less costly to provide a translation. As to any concerns about accuracy, the Office notes that it may reject a translation if it is unintelligible, whether made by a person or through the use of software or automated service.

The Office would also like to clarify that even though the translation requirement is being expanded to indexing information, the Office does not intend to change its current practices concerning non-English titles of works at this time. If a non-English title of a work is natively spelled using only the letters, numbers, and printable characters that appear in the ASCII 128-character set (the character set the Office's current systems are limited to), a translation need not be provided, and if one is, the Office will index both the English and non-English titles of the work. If a non-English title is spelled using characters outside that character set (for example, it is in French but has accented letters, or is in Japanese), a transliteration using the ASCII 128-character set may be provided instead of or in addition to a literal translation. Where both a translation and transliteration are provided, both will be indexed as related titles.

Constructive Notice. The proposed rule sought to make clear that for constructive notice under 17 U.S.C. 205(c) to attach with regard to works to which a recorded document pertains, the document must include or be accompanied by the title *and* copyright

[36] *See* Music Parties Comments at 4 (recommending that successors-in-interest ''describe their relationship to the document or to the signatories to the document'').

[37] *See* MPAA Comments at 6.

[38] 82 FR at 22775.

[39] *Id.*

[40] *See* Copyright Alliance Comments at 3; ESA Comments at 4; MPAA Comments at 4; Music Parties Comments at 4–5.

[41] *See* Kernochan Comments at 2 (''[A]ll material should be made available to the USCO if the USCO so requests.'').

[42] *See* ESA Comments at 4 (noting that ''remitters are motivated by Section 205(c) not to redact information relevant to the purposes of recordation''); Music Parties Comments at 4–5 (''Section 205(c) . . . provides a strong incentive for remitters to redact only material that is irrelevant to the purposes of recordation.'').

[43] MPAA Comments at 4.

[44] *Id.*

[45] *See* ESA Comments at 4 (''[T]his rule generally provides an appropriate framework for addressing cases where a document contains sensitive information.''); MRI Comments at 5 (''These data categories are appropriate for redaction.''); Music Parties Comments at 4 (''We generally agree with the proposed approach to redactions. Allowing financial, trade secret and personally identifiable information to be redacted as of right and other information to be redacted at the discretion of the Office should meet the needs of remitters.'').

[46] 82 FR at 22775.

[47] *See* Sergey Vernyuk Comments.

[48] *See* Copyright Alliance Comments at 3.

registration number of each such work.[49] The Office received several comments objecting to the proposed rule on the ground that it is inconsistent with the statute, which they contended only requires that a title *or* registration number be provided for constructive notice to attach.[50] The Office is continuing to evaluate its proposal and these comments, including by closely examining the relevant legislative history to better discern the intent behind the statutory provision. For now, the Office declines to adopt a rule interpreting section 205(c). Nothing should be inferred from the Office's proposed provision or the Office's decision not to adopt a rule at this time.

B. Notices of Termination

Commenters did not object to any of the proposed submission requirements or procedures for recording notices of termination, and the proposals have largely been adopted. As the NPRM discussed, the requirements governing what must be submitted to the Office to record a notice of termination are remaining essentially unchanged.[51] Thus, under the interim rule, as under the pre-existing rule, remitters are required to provide a complete and legible copy of the signed notice of termination as served on the grantee or successor-in-title. If separate copies of the same notice were served on more than one grantee or successor, only one copy needs to be submitted to the Office for recordation. The interim rule also maintains the requirement that remitters submit a statement setting forth the date on which the notice was served and the manner of service, unless that information is already contained within the notice itself. The interim rule also makes clear that, as previously, where service was made by first class mail, the date of service is the day the notice was deposited with the post office. The Office's timeliness rule also remains unchanged, and the Office will continue to refuse notices if they are untimely. Such scenarios where a notice would be deemed untimely include when the effective date of termination does not fall within the five-year period described in section 203(a)(3) or section 304(c)(3), as applicable, the documents submitted indicate that the notice was served less than two or more than ten years before the effective date of termination, and the date of recordation is after the effective date of termination.

As proposed,[52] the interim rule clarifies that however the notice is signed, what must be submitted to the Office for recordation is a copy of the as-served notice, including the reproduced image of the signature as it appeared on that served notice. The interim rule also adds new certification requirements, as had also been proposed.[53] Lastly, as the NPRM discussed,[54] remitters are now required to include a cover sheet with any notice of termination submitted for recordation. This Recordation Notice of Termination Cover Sheet (''Form TCS'') is similar to and serves the same function as Form DCS does for section 205 document submissions. Form TCS asks for information about the remitter and for certain indexing information. It also includes a space for the remitter to provide a statement of service and make the required certifications.

C. Correcting Errors

In the NPRM, the Office indicated that it was inclined to continue its current general practice of not permitting corrections to be made for any remitter-caused inaccuracies after the document or notice is recorded.[55] Instead, the Office proposed that, as is the current practice, the remitter would need to resubmit the document or notice for recordation with corrected information and it would be treated as any other first-time-submission. For purposes of uniformity and efficiency, the NPRM proposed discontinuing permitting corrections for inaccurate electronic title lists that accompany paper filings.[56] The Office explained that such errors should be treated the same as those made on the cover sheet or through the new electronic system. Lastly, the NPRM concluded that to have an efficient recordation system with an affordable fee, it would simply be impractical for Office staff to review all remitter-provided indexing information, which also means that it would be very difficult to review ''corrected'' submissions against the original to confirm that the remitter is not attempting to do something improper under the guise of a correction.[57]

The Office received comments asking that corrections be permitted under various circumstances.[58] The Office is still evaluating these comments and has not yet made a decision on this issue. For purposes of the interim rule, the Office is not changing the status quo for correcting information after a recordation has been completed. As a result, a slightly modified version of the current provision permitting corrections for electronic title lists has been retained. Mirroring the interim rule's approach to preparing and submitting electronic title lists, the interim rule also omits the current instructions that detail how to submit a corrective filing and instead states that a correction concerning an electronic title list may be requested by following the instructions provided by the Office on its Web site.

D. Consequences of Inaccuracies

In the NPRM, the Office said that it intended to continue its current practice of relying on the information provided by remitters for indexing purposes and requiring parties-in-interest to bear the consequences of any inaccuracies in such remitter-provided information.[59] The NPRM also clarified that it is not necessarily always the remitter who bears the consequences of inaccuracies, but rather, more accurately, it is the parties in interest to the remitted document or notice of termination who bear the consequences, if any, of any inaccuracies in the information provided to the Office by the remitter.

Based on the comments received, the Office has decided to eliminate the part of the proposed rule stating that parties-in-interest to a document or notice bear the consequences, if any, of any inaccuracies in the information the remitter provides to the Office. In response to the NPRM, some commenters expressed confusion over who really bears the consequences in the notice of termination context, while another commenter pointed out that non-parties may also bear the consequences if they rely to their detriment on incomplete or inaccurate recordation information.[60] The Office did not intend for the proposed rule to be an assignment of risk or responsibility to a particular party to a transaction, but merely meant to make clear that the *Copyright Office* bears no responsibility for errors caused by a remitter. To avoid any confusion, the

[49] 82 FR at 22776.

[50] *See* Author Services Comments at 1; Copyright Alliance Comments at 4–5; ESA Comments at 4–5; MPAA Comments at 4–6; Music Parties Comments at 7; SIIA Comments at 5–6.

[51] 82 FR at 22776–77.

[52] *Id.*

[53] *Id.* at 22777.

[54] *Id.*

[55] *Id.* at 22776, 22777.

[56] *Id.* at 22776.

[57] *Id.*

[58] *See* Copyright Alliance Comments at 3; ESA Comments at 5–6; MPAA Comments at 4; Music Parties Comments at 3, 5–6.

[59] 82 FR at 22775–76.

[60] *See* ESA Comments at 6; MRI Comments at 4–5; Music Parties Comments at 7. Another commenter added that the proposed modification would seem to place the burden on any and every party to a document to regularly and continually check the Office's records to ensure no one has submitted inaccurate information. Sergey Vernyuk Comments.

Office has removed the provision. But, to be clear, the Office bears no responsibility or liability if a remitter provides inaccurate indexing information that is then relied upon by the Office in indexing the document.

One commenter also asked that the Office adopt a rule stating that when a non-party relies to its detriment on incomplete or inaccurate recordation records, it should constitute evidence that any resulting infringement was not willful.[61] The Office declines to adopt such a rule. It is for a court to determine willfulness in an infringement action based on all of the particular facts at issue in a given case.

Concerning the Office's reliance on remitter-provided material, the Office did not receive any comments critical of the proposed rule. Consequently, that portion of the provision is being retained. The interim rule makes slight changes to the proposed version of the provision to clarify that the Office will not only rely on remitter-provided indexing information, but also on the certifications that accompany a document or notice and any other remitter-provided information. The interim rule also makes plain that what the Office means by reliance is that it may not necessarily confirm the accuracy of any such certifications or information against the actual document itself.

E. Recordation Certificate and Returning of Document

As before, once recorded, the document or notice of termination will be returned to the remitter with a certificate of recordation. Currently, all recorded documents and notices are digitally imaged and electronically stamped with an official recordation number and page numbers. This stamped copy is then printed and sent to the remitter with a paper recordation certificate. Where an original document is submitted, it is also returned. The Office plans to continue under this paper-based process while the new electronic recordation system is being developed.

F. Scope of Office's Examination and Effect of Recordation

One commenter inquired into the level of review the Office performs in examining recordation submissions, noting that it interpreted the NPRM's proposed language about parties bearing the consequences of their inaccuracies to indicate that the Office will not review submitted materials for accuracy or completeness.[62] The commenter recommended that if that is not the Office's intent, that the Office follow the recommendation from the Brauneis Report,[63] which suggested that the Office cease screening each individual remitted document for compliance with the various recordation requirements.[64] The report recommended that remitters instead should certify that a document satisfies all of the requirements for recordation, and that the Office only ''spot-screen'' a sample of submissions to identify systematic problems, with the goal of trying to reduce them through corrective measures like better education.[65] The report did note, however, that some particular types of submissions, such as notices of termination, might still warrant document-by-document examination.[66]

While the Office declines to adopt this exact approach at this time, the Office has decided to implement something similar. The Office agrees that it need not exhaustively review every recordation submission for compliance with all applicable laws, rules, and instructions, but there is a benefit to both remitters and the public at large in the Office at least examining submissions individually for facially obvious deficiencies[67] so as to ensure that the majority of recorded documents and notices of termination are in compliance with the legal and formal requirements for recordation.[68] As discussed above, and in line with the Brauneis Report's recommendation, the Office is requiring various certifications and certain indexing information to be provided to the Office that, as the interim rule makes clear, the Office will not necessarily check against the remitted document or notice itself. While the Office intends to only examine submissions for facially obvious deficiencies, it may continue to perform a more comprehensive review, such as for notices of termination, at its discretion. Likewise, the Office also reserves the right to engage in a less comprehensive review, closer to what the Brauneis Report recommended, as a matter of administrative convenience.

Even with a more comprehensive level of review there is always the potential that some documents and notices that fail to comply with the requirements for recordation might still get recorded by the Office because the deficiency is simply not caught during the examination process. Consequently, for clarity and avoidance of doubt, the interim rule makes some adjustments to the existing notice of termination provision concerning the legal effect of recordation and adds a similar provision for section 205 documents.[69] The interim rule makes even clearer that the act of recordation should in no way be construed as a determination by the Office that a document or notice is valid or legally effective. The interim rule also makes plain that recordation is without prejudice to any party claiming, including in court, that the requirements for recordation or effectuating termination have not been met.

List of Subjects in 37 CFR Part 201

Copyright, General provisions.

[61] MRI Comments at 4–5.

[62] Kernochan Comments at 2.

[63] *Id.*

[64] *Brauneis Report* at 58, 84.

[65] *Id.*

[66] *Id.*

[67] To be clear, the Office means only those deficiencies pertaining to the requirements for recordation; not other types of deficiencies that could affect the underlying validity or legal effectiveness of the document or notice. *See* U.S. Copyright Office, Compendium of U.S. Copyright Office Practices, sec. 2305 (3d ed. 2017) (''Members of the general public who submit documents for recordation cannot expect the Office to screen a document for even obvious errors or discrepancies. Therefore, parties are strongly advised to review and scrutinize any document to ensure that the document is legally sufficient to accomplish the purpose for which it is intended before it is submitted for recordation.'').

[68] This is in contrast to, for example, examining applications for copyright registration. Registering a work involves a substantive determination by the Office as to a work's copyrightability and can constitute prima facie evidence of a valid copyright. *See* 17 U.S.C. 410(a)–(c). Recordation is a more ministerial act, akin to the Office's acceptance of other types of filings for inclusion in the public record. For example, the Office accepts statements of account under the section 111 cable license after a review for ''obvious errors or omissions appearing on the face of the documents'' (see 37 CFR 201.17(c)(2)), notices of intention under the section 115 compulsory license without review for ''legal sufficiency,'' ''errors or discrepancies'' (see 37 CFR 201.18(g)), and agent designations made pursuant to section 512(c)(2) without any examination.

[69] While the provision for section 205 documents is technically new, the Office currently already provides similar guidance. *See* U.S. Copyright Office, Compendium of U.S. Copyright Office Practices, sec. 2305 (3d ed. 2017) (''Although the Office will record a document after it has been executed, it does not issue or enforce notices of termination, transfers of ownership, or other documents pertaining to copyright. The Office only serves as an office of public record for such documents. . . . The fact that a document has been recorded is not a determination by the U.S. Copyright Office concerning the validity or the effect of that document. That determination can only be made by a court of law. . . . [T]he Office only examines documents to determine if they comply with the requirements of the Copyright Act and the Office's regulations. The Office will not attempt to interpret the substantive content of any document that has been submitted for recordation. Likewise, the Office will not attempt to determine whether a document satisfies the legal requirements that may be necessary for it to be effective or enforced.'').

Interim Regulations

For the reasons set forth in the preamble, the Copyright Office amends 37 CFR part 201 as follows:

PART 201—GENERAL PROVISIONS

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 17 U.S.C. 702.

■ 2. Revise § 201.4 to read as follows:

§ 201.4 Recordation of transfers and other documents pertaining to copyright.

(a) *General.* This section prescribes conditions for the recordation of transfers of copyright ownership and other documents pertaining to a copyright under 17 U.S.C. 205. A document is eligible for recordation under this section if it meets the requirements of paragraph (d) of this section, if it is submitted in accordance with the submission procedure described in paragraph (e) of this section, and if it is accompanied by the fee specified in § 201.3(c). The date of recordation is the date when all of the elements required for recordation, including a proper document, fee, and any additional required information, are received in the Copyright Office. After recordation the document is returned to the sender with a certificate of recordation. The Office may reject any document submitted for recordation that fails to comply with 17 U.S.C. 205, the requirements of this section, or any relevant instructions or guidance provided by the Office.

(b) *Documents not recordable under this section.* This section does not govern the filing or recordation of the following documents:

(1) Certain contracts entered into by cable systems located outside of the 48 contiguous States (17 U.S.C. 111(e); see § 201.12);

(2) Notices of identity and signal carriage complement, and statements of account of cable systems and satellite carriers and for digital audio recording devices and media (17 U.S.C. 111(d), 119(b), and 1003(c); see §§ 201.11, 201.17, 201.28);

(3) Notices of intention to obtain a compulsory license to make and distribute phonorecords of nondramatic musical works (17 U.S.C. 115(b); see § 201.18);

(4) Notices of termination (17 U.S.C. 203, 304(c) and (d); see § 201.10);

(5) Statements regarding the identity of authors of anonymous and pseudonymous works, and statements relating to the death of authors (17 U.S.C. 302);

(6) Documents pertaining to computer shareware and donation of public domain software (Pub. L. 101–650, sec. 805; see § 201.26);

(7) Notifications from the clerks of the courts of the United States concerning actions brought under title 17, United States Code (17 U.S.C. 508);

(8) Notices to libraries and archives of normal commercial exploitation or availability at reasonable prices (17 U.S.C. 108(h)(2)(C); see § 201.39);

(9) Submission of Visual Arts Registry Statements (17 U.S.C. 113; see § 201.25);

(10) Notices and correction notices of intent to enforce restored copyrights (17 U.S.C. 104A(e); see §§ 201.33, 201.34); and

(11) Designations of agents to receive notifications of claimed infringement (17 U.S.C. 512(c)(2); see § 201.38).

(c) *Definitions.* For purposes of this section:

(1) A *transfer of copyright ownership* has the meaning set forth in 17 U.S.C. 101.

(2) A *document pertaining to a copyright* is any document that has a direct or indirect relationship to the existence, scope, duration, or identification of a copyright, or to the ownership, division, allocation, licensing, or exercise of rights under a copyright. That relationship may be past, present, future, or potential.

(3) An *actual signature* is any legally binding signature, including an electronic signature as defined in 15 U.S.C. 7006.

(4) A *sworn certification* is a statement made in accordance with 28 U.S.C. 1746 that the copy of the document submitted for recordation is, to the best of the certifier's knowledge, a true copy of the original, signed document. A sworn certification must be signed by one of the parties to the signed document, a successor-in-interest to one of the parties to the signed document, or the authorized representative of such a party or successor. Authorized representatives must state who they represent and successors-in-interest must describe their relationship to the document or the original parties to the document. An authorized representative of a successor-in-interest must describe the successor's relationship to the document or the original parties to the document. A sworn certification may be signed electronically.

(5) An *official certification* is a certification, by the appropriate governmental official, that the original of the document is on file in a public office and that the copy of the document submitted for recordation is a true copy of the original. An official certification may be signed electronically.

(d) *Document requirements*—(1) *Original or certified copy.* The remitter must submit either the original document that bears the actual signature(s) of the person(s) who executed it, or a copy of the original, signed document accompanied by a sworn certification or an official certification. Each document submitted for recordation must be certified to either have the actual signature(s) (if it is an original document) or reproduce the actual signature(s) (in the case of a copy of the original document). All documents lacking a handwritten, wet signature (including all documents bearing an electronic signature) are considered to be copies of the original, signed document, and must be accompanied by a sworn certification or an official certification. Where an actual signature on the relevant document is not a handwritten or typewritten name, such as when an individual clicks a button on a Web site or application to indicate agreement to contractual terms, the remitter must submit a description of the nature of the signature and documentation evidencing the existence of the signature (*e.g.,* a database entry or confirmation email showing that a particular user agreed to the terms by clicking ''yes'' on a particular date). Where such description and evidence are provided, the Office will make them available for public inspection and may presume that the signature requirement for recordation has been satisfied, without prejudice to any party claiming otherwise, including before a court of competent jurisdiction.

(2) *Completeness.* Each document submitted for recordation must be, and be certified to be, complete by its terms, but need only include referenced schedules, appendices, exhibits, addenda, or other material essential to understanding the copyright-related aspects of the document.

(3) *Legibility.* Each document submitted for recordation must be, and be certified to be, legible.

(4) *Redactions.* The Office will accept and make available for public inspection redacted documents certified to be redacted in accordance with this paragraph (d)(4), provided that all of the following conditions are satisfied:

(i) The redactions must be limited to financial terms, trade secret information, Social Security or taxpayer-identification numbers, and financial account numbers. Additional types of information may be redacted on a case-by-case basis if the need for any such redactions is justified to the Office in writing and approved by the Office; such written requests should be

included in the remitter's recordation submission to the Office.

(ii) The blank or blocked-out portions of the document must be labeled ''redacted'' or the equivalent.

(iii) Each portion of the document required by paragraph (d)(2) of this section must be included.

(5) *English language requirement.* The Office will accept and record non-English language documents and indexing information only if accompanied by an English translation that is either signed by the individual making the translation or, if a publicly available commercial or consumer translation software product or automated service is used, by the individual using such product or service and accompanied by the name of the product or service. All translations will be made available for public inspection and may be redacted in accordance with paragraph (d)(4) of this section.

(e) *Paper submission procedure*—(1) *Process.* A document may be submitted for recordation by sending it to the appropriate address in § 201.1(b) or to such other address as the Office may specify, accompanied by a cover sheet, the proper fee, and, if applicable, any electronic title list. Absent special arrangement with the Office, the Office reserves the right to not process the submission unless all of the items necessary for processing are received together.

(2) *Cover sheet required.* Submission of a document must include a completed Recordation Document Cover Sheet (Form DCS), available on the Copyright Office Web site. Remitters must follow all instructions provided by the Office in completing Form DCS, including by providing all requested indexing information. Form DCS may be used to provide a sworn certification, if appropriate, and to make any of the other certifications required by this section. Form DCS will not be considered part of the recorded document, but will be used by the Office for examination, indexing, and other administrative purposes. The Office may reject any document submitted for recordation that includes an improperly prepared cover sheet.

(3) *Electronic title list.* (i) In addition to identifying the works to which a document pertains in the paper submission, the remitter may also submit an electronic list setting forth each such work. The electronic list will not be considered part of the recorded document, but will be used by the Office for indexing purposes. Absent special arrangement with the Office, the electronic list must be included in the same package as the paper document to be recorded. The electronic list must be prepared and submitted to the Office in the manner specified by the Copyright Office in instructions made available on its Web site. The Office may reject any document submitted for recordation that includes an improperly prepared electronic title list.

(ii) If a remitter of a recorded document finds that an error or omission in an electronic title list has led to the inaccurate indexing of the document in the public catalog, the remitter may request that the record be corrected by following the instructions provided by the Office on its Web site. Upon receipt of a properly prepared corrective filing and the appropriate fee, the Office will proceed to correct the information in the public catalog, and will make a note in the record indicating that the corrections were made and the date they were made.

(4) *Return receipt.* If a remitter includes two copies of a properly completed Form DCS indicating that a return receipt is requested, as well as a self-addressed, postage-paid envelope, the remitter will receive a date-stamped return receipt attached to the extra copy acknowledging the Copyright Office's receipt of the enclosed submission. The completed copies of Form DCS and the self-addressed, postage-paid envelope must be included in the same package as the submitted document. A return receipt confirms the Office's receipt of the submission as of the date indicated, but does not establish eligibility for, or the date of, recordation.

(5) *Remitter certification.* The remitter must certify that he or she has appropriate authority to submit the document for recordation and that all information submitted to the Office by the remitter is true, accurate, and complete to the best of the remitter's knowledge.

(f) *Reliance on remitter-provided information.* The Copyright Office will rely on the certifications submitted with a document and the information provided by the remitter on Form DCS and, if provided, in an accompanying electronic title list. The Office will not necessarily confirm the accuracy of such certifications or information against the submitted document.

(g) *Effect of recordation.* The fact that the Office has recorded a document is not a determination by the Office of the document's validity or legal effect. Recordation of a document by the Copyright Office is without prejudice to any party claiming that the legal or formal requirements for recordation have not been met, including before a court of competent jurisdiction.

■ 3. Revise § 201.10(f) to read as follows:

§ 201.10 Notices of termination of transfers and licenses.

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(f) *Recordation.* A copy of a notice of termination shall be recorded in the Copyright Office as required by 17 U.S.C. 203(a)(4)(A), 17 U.S.C. 304(c)(4)(A), or 17 U.S.C. 304(d)(1) if it meets the requirements of paragraph (f)(1) of this section, is submitted in compliance with paragraph (f)(2) of this section, and is accompanied by the fee specified in § 201.3(c). The Office may reject any notice submitted for recordation that fails to comply with 17 U.S.C. 203(a), 17 U.S.C. 304(c), 17 U.S.C. 304(d), the requirements of this section, or any relevant instructions or guidance provided by the Office.

(1) *Requirements.* The following requirements must be met before a copy of a notice of termination may be recorded in the Copyright Office.

(i) *What must be submitted*—(A) *Copy of notice of termination.* A copy of a notice of termination submitted for recordation must be, and be certified to be, a true, correct, complete, and legible copy of the signed notice of termination as served. Where separate copies of the same notice were served on more than one grantee or successor-in-title, only one copy need be submitted for recordation.

(B) *Statement of service.* The copy submitted for recordation must be accompanied by a statement setting forth the date on which the notice was served and the manner of service, unless such information is contained in the notice. In instances where service is made by first class mail, the date of service shall be the day the notice of termination was deposited with the United States Postal Service.

(ii) *Timeliness.* (A) The Copyright Office will refuse recordation of a notice of termination as such if, in the judgment of the Copyright Office, such notice of termination is untimely. Conditions under which a notice of termination will be considered untimely include: the effective date of termination does not fall within the five-year period described in section 203(a)(3) or section 304(c)(3), as applicable, of title 17, United States Code; the documents submitted indicate that the notice of termination was served less than two or more than ten years before the effective date of termination; or the date of recordation is after the effective date of termination.

(B) If a notice of termination is untimely, the Office will offer to record the document as a ''document

pertaining to a copyright'' pursuant to § 201.4, but the Office will not index the document as a notice of termination.

(C) In any case where an author agreed, prior to January 1, 1978, to a grant of a transfer or license of rights in a work that was not created until on or after January 1, 1978, a notice of termination of a grant under section 203 of title 17 may be recorded if it recites, as the date of execution, the date on which the work was created.

(2) *Paper submission procedure*—(i) *Process.* A copy of a notice of termination may be submitted for recordation by sending it to the appropriate address in § 201.1(c) or to such other address as the Office may specify, accompanied by a cover sheet, the statement of service, and the proper fee.

(ii) *Cover sheet required.* Submission of a copy of a notice of termination must be accompanied by a completed Recordation Notice of Termination Cover Sheet (Form TCS), available on the Copyright Office Web site. Remitters must follow all instructions provided by the Office in completing Form TCS, including by providing all requested indexing information. Form TCS may be used to provide the statement of service and to make any of the certifications required by this paragraph (f). Form TCS will not be considered part of the recorded notice, but will be used by the Office for examination, indexing, and other administrative purposes. The Office may reject any notice submitted for recordation that includes an improperly prepared cover sheet.

(iii) *Return receipt.* If a remitter includes two copies of a properly completed Form TCS indicating that a return receipt is requested, as well as a self-addressed, postage-paid envelope, the remitter will receive a date-stamped return receipt attached to the extra copy acknowledging the Copyright Office's receipt of the enclosed submission. The completed copies of Form TCS and the self-addressed, postage-paid envelope must be included in the same package as the submitted notice. A return receipt confirms the Office's receipt of the submission as of the date indicated, but does not establish eligibility for, or the date of, recordation.

(iv) *Remitter certification.* The remitter must certify that he or she has appropriate authority to submit the notice for recordation and that all information submitted to the Office by the remitter is true, accurate, and complete to the best of the remitter's knowledge.

(3) *Date of recordation.* The date of recordation is the date when all of the elements required for recordation, including the prescribed fee and, if required, the statement of service, have been received in the Copyright Office. After recordation, the notice, including any accompanying statement, is returned to the sender with a certificate of recordation.

(4) *Effect of recordation.* The fact that the Office has recorded a notice is not a determination by the Office of the notice's validity or legal effect. Recordation of a notice of termination by the Copyright Office is without prejudice to any party claiming that the legal or formal requirements for effectuating termination (including the requirements pertaining to service and recordation of the notice of termination) have not been met, including before a court of competent jurisdiction.

(5) *Reliance on remitter-provided information.* The Copyright Office will rely on the certifications submitted with a notice and the information provided by the remitter on Form TCS and, if provided, in an accompanying statement of service. The Office will not necessarily confirm the accuracy of such certifications or information against the submitted notice.

* * * * *

Dated: October 25, 2017.

Karyn Temple Claggett,

Acting Register of Copyrights and Director of the U.S. Copyright Office.

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2017–24527 Filed 11–9–17; 8:45 am]

BILLING CODE 1410–30–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

[Docket No. 2017–17]

Fees for Electronic Recordation and Notices of Intention To Obtain a Compulsory License

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: The U.S. Copyright Office is publishing a final rule establishing a separate, lower filing fee for recording documents when they are submitted with an electronic title list. Separately, the Office is noting a policy change, effective on the same date as the final rule, to require the payment of fees for the filing of *all* notices of intention to obtain a compulsory license to make and distribute phonorecords, including those that are filed in the Office after failed delivery to the copyright owner.

DATES: Effective December 18, 2017.

FOR FURTHER INFORMATION CONTACT: Sarang V. Damle, General Counsel and Associate Register of Copyrights, by email at *sdam@loc.gov,* or Jason E. Sloan, Attorney-Advisor, by email at *jslo@loc.gov.* Each can be contacted by telephone by calling (202) 707–8350.

SUPPLEMENTARY INFORMATION:

I. New Recordation Fee for Electronic Title Lists

A. Background

This final rule adjusts U.S. Copyright Office fees in accordance with 17 U.S.C. 708. Section 708(a) specifies that ''[f]ees shall be paid to the Register of Copyrights'' for services, including a set of specified services enumerated in paragraphs (1) through (11) of that subsection.[1] This includes, as relevant here, fees for ''the recordation, as provided by section 205, of a transfer of copyright ownership or other document.'' [2] Fees for this service and the other services specifically enumerated in section 708(a)(1)–(9) are to be set forth in a proposed schedule that is sent to Congress 120 days before the adjusted fees can take effect.[3] The fee may go into effect after the end of that period unless ''a law is enacted stating in substance that the Congress does not approve the schedule.'' [4]

Before proposing new fees for the services enumerated in (1) through (9), the Register must conduct a study of the Office's costs and must consider the timing of any fee adjustments and the Office's authority to use the fees consistent with the Office's budget.[5] Section 708(b) further provides that the Register may adjust these fees to ''not more than that necessary to cover the reasonable costs incurred by the Copyright Office for . . . [such services], plus a reasonable inflation adjustment to account for any estimated increase in costs.'' [6] Finally, section 708(b) also mandates that the ''[f]ees [so] established . . . shall be fair and equitable and give due consideration to

[1] 17 U.S.C. 708(a).

[2] *Id.* at 708(a)(4).

[3] *Id.* at 708(b)(5).

[4] *Id.* Section 708(a) also authorizes the Register to fix fees for other services not enumerated in section 708(a)(1)–(9), such as the cost of preparing copies of Office records. *Id.* at 708(a). The fees for these additional Office services, as well as fees for the filing of cable and satellite statements of account under paragraphs (10) and (11) of section 708(a), need not be submitted to Congress, but are instead established by the Register of Copyrights by regulation based on the Office's costs. *Id.*

[5] *Id.* at 708(b)(1).

[6] *Id.* at 708(b)(2).

the objectives of the copyright system.'' [7]

B. Cost Study

Pursuant to section 708, the Office submitted a proposed fee schedule and analysis to Congress on August 18, 2017.[8] That study and this final rule implementing the fee it proposed concern a single Copyright Office service: The recording of documents accompanied by electronic title lists, *i.e.,* lists of certain indexing information about the works to which such documents pertain.[9]

Since 1870, the Copyright Office has recorded documents pertaining to works under copyright, such as assignments, licenses, and grants of security interests. Under the Copyright Act, recordation of such documents is voluntary, but provides certain legal entitlements, such as constructive notice of the facts stated in the recorded document when certain conditions are met.[10] Thus, the Office has an important interest in ensuring that the public record of copyright transactions is as timely, complete, and accurate as possible.

In general, the recordation process is still paper based, and Office staff manually transcribe information from documents into an electronic format to permit indexing in the Office's public catalog. Among the information that must be indexed are the titles of and related information for copyrighted works associated with the document submitted for recordation, which are typically presented in a list appended to the document, referred to informally as a ''title appendix.'' A title appendix associated with a document can include hundreds, or even thousands, of titles.

The manual entry of information from title appendices is a significant contributor to long processing times in the Office's Recordation Section. In 2014, to gain efficiencies, the Office promulgated a new rule permitting documents submitted for recordation to be accompanied by an electronic title list in the form of an Excel spreadsheet.[11] Document recordation fees, however, were last adjusted before the introduction of electronic title lists. Thus, the Office has never set a separate fee for recording documents with such lists, and currently charges the same recordation fee regardless of whether the document has an electronic title list.

As a result, the Office's cost study proposed implementing a separate, reduced filing fee for groups of additional titles provided in an electronic title list that accompanies a document submitted for recordation. The fee adjustment implemented by this final rule only pertains to that fee. The Office is not adjusting the baseline document recordation fee of $105 at this time; that fee will remain the same for recordations made both with and without electronic title lists. Nor is the Office adjusting the fee for groups of additional titles when an electronic title list is not used. Proposals for those fees will be included in a comprehensive study of all Copyright Office costs and fees expected to be submitted to Congress next year.

The fee-setting methodology employed by the study used activity-based costing principles which comply with standards set for federal managerial accounting [12] and with guidance for fee setting as published by the Office of Management and Budget Circular A–25 Revised: User Charges,[13] and the Government Accountability Office.[14] Under the approach, total costs for the entire recordation function were used to develop a time-based multiplier, which was then used to calculate the cost of the individual activities for recording the information contained in electronic title lists. The total cost of completing an electronic title list transaction was determined by aggregating the cost of each individual activity.

Cost studies of this type are typically retrospective, using actual data from a fiscal year that has concluded. This study used actual data from fiscal year 2016, but the methodology was applied prospectively against a planned new service. This prospective approach was used because, concurrent with the effective date of this rule, the Office is implementing a new, more efficient process for providing this service than the one currently employed. This methodology was reviewed and validated by an independent consulting firm.

The new fee for documents submitted with electronic title lists to be implemented by this final rule is as follows:

1 to 50 additional titles: $60
51 to 500 additional titles: $225
501 to 1,000 additional titles: $390
1,001 to 10,000 additional titles: $555
10,001 or more additional titles: $5,550

In the analysis submitted to Congress, the Office determined that while use of electronic title lists can significantly increase the Office's processing efficiency, remitters had little incentive to use them. Thus, the Office proposed, and is now instituting, a fee for using electronic title lists that is generally lower than the current fee for recordations made without them. The lower fee is being adopted primarily to incentivize use of electronic title lists for documents with more than ten additional titles [15] in an effort to increase administrative efficiency and to offer a less expensive avenue to obtaining the benefits of recording a document with the Copyright Office.

In considering the fairness, equity, and objectives of the copyright system, the Office believes that offering recordation services for a lower fee, where remitters have done the work to create an electronic title list, should result in a wider range of remitters submitting documents and may also result in existing remitters submitting additional or updated documents with more frequency than they might otherwise. Receipt of additional recorded documents should result in greater copyright ownership data being incorporated into the Office's records, which furthers the Office's mission and benefits the public at large.

In its analysis, the Office also determined that as compared to manually indexing documents, where more titles generally means more processing time and higher costs, when an electronic title list is used, processing time is typically more constant. However, in further evaluating the fairness, equity, and objectives of the copyright system, the Office has

[7] *Id.* at 708(b)(4).

[8] The study is available on the Office's Web site at *https://www.copyright.gov/policy/feestudy2017/fee-study-2017.pdf.*

[9] Examples of such indexing information can include the types of works, the titles of the works (including alternate titles), their respective registration numbers, and authorship information.

[10] 17 U.S.C. 205(c) (''Recordation of a document in the Copyright Office gives all persons constructive notice of the facts stated in the recorded document, but only if—(1) the document, or material attached to it, specifically identifies the work to which it pertains so that, after the document is indexed by the Register of Copyrights, it would be revealed by a reasonable search under the title or registration number of the work; and (2) registration has been made for the work.'').

[11] *See* 79 FR 55633 (Sept. 17, 2014) (codified at 37 CFR 201.4(c)(4)).

[12] This includes the Federal Accounting Standards Advisory Board's *Managerial Cost Accounting Concepts and Standards for the Federal Government,* which promotes activity-based costing for calculating the cost of providing services. *See* Fed. Accounting Standards Advisory Bd., Statement of Federal Financial Accounting Standards No. 4: Managerial Cost Accounting Concepts and Standards for the Federal Government (1995).

[13] *See* Office of Mgmt. and Budget, *Circular No. A–25 Revised: User Charges, Whitehouse.gov, http://www.whitehouse.gov/omb/circulars_a025* (last visited Aug. 13, 2017).

[14] *See* U.S. Gov't Accountability Office, Federal User Fees: A Design Guide (GAO–08–386SP) (2008).

[15] Though documents with ten or fewer additional titles may be submitted with an electronic title list, the final rule will deliver fee savings to remitters where documents have more than ten additional titles.

decided to adopt a tiered pricing structure based on the number of titles to which the document pertains. Under this scheme, larger filers submitting documents with a larger number of titles pay a higher fee for the added benefit they receive (when the fee is viewed on a per-title basis) to offset the lower total fee for smaller filers with fewer titles. The first four tiers of the proposed schedule increase incrementally based on the total number of additional titles submitted. The reason for the larger jump between the fourth and fifth tiers is because of the significant added costs to the Office to process documents with 10,000 or more titles, caused by current system limitations.

The Office notes that the proposed fee schedule will be revisited as part of a comprehensive study of all Office costs and fees to be completed next year. As discussed above, the goal of the proposed fee schedule is primarily to incentivize use of electronic title lists. To do that, the proposed fee offers a discount from the ordinary recordation fee of $35 per group of ten additional titles. When the full fee study examines all Office costs and evaluates an appropriate fee to record a document without an electronic title list in light of current costs, it is possible that fee will increase, in which case it is also possible that the fee being adopted for using an electronic title list may be adjusted upward as well to ensure adequate cost recovery.

C. Effective Date

Congress's 120-day review period under 17 U.S.C. 708(b)(5) began after the Office submitted the proposed fee schedule and analysis on August 18, 2017. If no law is enacted stating in substance that Congress does not approve of the proposed recordation fee during such time, the fee will be instituted pursuant to this final rule, effective December 18, 2017.

II. Notices of Intention

Though not related to the above-discussed cost study or final rule, the Office is taking this opportunity to provide public notice that it will implement a policy change regarding fees for notices of intention to obtain a compulsory license to make and distribute phonorecords (''NOIs'').

Under the Copyright Act, section 115 establishes a compulsory license, whereby anyone may make and distribute phonorecords of nondramatic musical works, subject to certain terms and conditions, and upon paying royalties when applicable. To obtain a compulsory license, a licensee must serve an NOI on the relevant copyright owner in the form and manner specified by Copyright Office regulations.[16]

In two circumstances, however, an NOI can be filed with the Copyright Office rather than the copyright owner. First, if the public records of the Copyright Office do not identify the copyright owner and include an address at which notice can be served, the NOI can instead be filed with the Office.[17] These ''unidentified NOIs'' can be filed electronically or in paper hard copy, though a discounted fee is offered for electronic submissions.[18]

Second, if the NOI is sent to the last address for the copyright owner shown by the Office's records, but is returned to the sender because the copyright owner was no longer located at that address or refused to accept delivery, the Office's regulations permit the ''original Notice as sent'' to be filed with the Office, along with a ''brief statement that the Notice was sent to the last address for the copyright owner shown by the records of the Copyright Office but was returned,'' and may also ''be accompanied by appropriate evidence that it was mailed to, or that delivery by reputable courier service was attempted at, that address.'' [19] Typically, for these ''returned-to-sender NOIs,'' the Office receives the NOI in the original mailing envelope marked with a return to sender label. The Office does not currently have any mechanism for accepting these NOIs electronically.[20]

The Office's regulations used to explicitly state that no filing fee would be charged for returned-to-sender NOIs, while such a fee *would* be charged for the unidentified NOIs.[21] But in 2001, the Office issued a notice of proposed rulemaking seeking to remove this limitation, as ''[t]he cost to the Office of processing the filing of a Notice of Intention is the same whether the copyright owner is not identified in the records of the Office or the copyright owner is no longer located at the address shown in the records of the Office or has refused to accept delivery.''[22] The Office believed that the same filing fee ''should be charged in both cases.''[23] The final rule, effective in 2004, adopted that proposal, repealing the regulatory language that had expressly prohibited charging a fee.[24] Consistent with this rulemaking, the Copyright Office's fee schedule does not distinguish between different types of NOIs.[25]

In practice, however, and in part due to the extremely low volume of returned-to-sender NOIs the Office received in the years following adoption of the 2004 rule, the Office abstained from imposing the established fee. In recent years, however, the volume of returned-to-sender NOIs has increased sharply. Last year the Office received over 800 such NOIs, and this year the Office has received over 2,000 to date. Each of these NOIs must be individually and manually processed. Because of this increased burden, the Office can no longer afford to forbear from the collection of fees. Accordingly, this document announces a policy change that will be implemented on December 18, 2017: Any returned-to-sender NOIs received in the Office on or after that date *must* be accompanied by the same filing fee applicable to other paper-filed NOIs, which is currently $75 plus $20 per group of one to ten additional titles.[26] The Office is publicly announcing this policy change in advance to give remitters of returned-to-sender NOIs time to adjust their practices.

List of Subjects in 37 CFR Part 201

Copyright, General provisions.

Final Regulations

For the reasons set forth in the preamble, the Copyright Office amends 37 CFR part 201 as follows:

PART 201—GENERAL PROVISIONS

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 17 U.S.C. 702.

■ 2. Amend § 201.3 by revising paragraph (c)(16) to read as follows:

§ 201.3 Fees for registration, recordation, and related services, special services, and services performed by the Licensing Division.

* * * * *

(c) * * *

[16] *See generally* 37 CFR 201.18.

[17] 17 U.S.C. 115(b)(1).

[18] 37 CFR 201.3(e)(1).

[19] *Id.* § 201.18(f)(2).

[20] *See id.*

[21] *Compare* 37 CFR 201.18(e)(1) (2003) (''Notices of Intention submitted for filing shall be accompanied by the fee specified in § 201.3(e).'') *with id.* § 201.18(e)(3) (''No filing fee will be required in the case of Notices filed under this paragraph.'').

[22] 66 FR 45241, 45243 (Aug. 28, 2001); *see also* 69 FR 11566, 11572 (Mar. 11, 2004) (additional, related notice of proposed rulemaking reiterating that ''the Office intends to amend its rules to require a filing fee in each instance where the Notice is filed with the Copyright Office without regard to the licensee's reason for filing the Notice with the Office'').

[23] 66 FR at 45243; *see also* 69 FR at 11572.

[24] 69 FR 34578, 34583 (June 22, 2004).

[25] *See* 37 CFR 201.3(e)(1) (establishing a fee for ''[r]ecordation of a notice of intention to make and distribute phonorecords'' without differentiation).

[26] *See id.*

Registration, recordation and related services	Fees ($)
* * * * * * *	
(16) Recordation of a document, including a notice of intention to enforce	.....
Single title	105
Additional titles (per group of 1 to 10 titles)	35
Additional titles provided in an electronic title list	
1 to 50 additional titles	60
51 to 500 additional titles	225
501 to 1,000 additional titles	390
1,001 to 10,000 additional titles	555
10,001 or more additional titles	5,550
Correction of online Public Catalog data due to erroneous electronic title submission (per title)	7
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Dated: October 24, 2017.

Karyn Temple Claggett,

Acting Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2017–24526 Filed 11–9–17; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 202

[Docket No. 2017–8]

Secure Tests

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Interim rule with request for comments.

SUMMARY: The U.S. Copyright Office is issuing an update to its interim rule, issued June 12, 2017, governing registration of secure tests. Based on the initial comments received on that interim rule, the Office has determined that there is an immediate need to establish a new group registration option for secure test questions and answers and other related materials (referred to as ''test items'') that are stored in an electronic database, test bank, or other medium of expression. This interim rule incorporates most of the same procedures that the Office adopted in its recent interim rule on secure tests and adds additional procedures for group registration. To seek a group registration, applicants will be required to submit an online application, upload a redacted copy of the individual test items to the electronic registration system, and complete and submit a brief questionnaire. If, based on the answers to the questionnaire, the test items appear to be eligible for the group registration option, the Office will contact the applicant and schedule an appointment to deliver these materials to the Office in person. On the appointed date, the applicant must bring a copy of the application and a complete unredacted copy of the actual test items. In addition, the applicant must bring a redacted copy of the test items, and a signed declaration confirming that this copy is identical to the redacted copy that was uploaded to the electronic registration system. The Office will examine each test item to determine if it contains sufficient copyrightable authorship. If the Office registers the claim, the registration will cover each test item as a separate work of authorship, and the registration will be effective as of the date the Office initially received the application, filing fee, and the redacted copy of the test items in proper form through the electronic registration system. To be clear, the previous interim rule otherwise remains in effect, and applicants may continue to use that rule to register individual secure tests. The Office welcomes public comment on both this interim rule and the June 12, 2017 interim rule.

DATES: Effective November 13, 2017. Comments on this interim rule and the interim rule published on June 12, 2017 (82 FR 26850), must be made in writing and must be received by the U.S. Copyright Office no later than December 11, 2017.

ADDRESSES: For reasons of government efficiency, the U.S. Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments are on the U.S. Copyright Office Web site at *http://copyright.gov/rulemaking/securetests/.* If electronic submission of comments is not feasible due to lack of access to a computer and/or the internet, please contact the Office for special instructions using the contact information below.

FOR FURTHER INFORMATION CONTACT: Robert J. Kasunic, Associate Register of Copyrights and Director of Registration Policy and Practice; Sarang Vijay Damle, General Counsel and Associate Register of Copyrights; Erik Bertin, Deputy Director of Registration Policy and Practice; or Abioye Ella Mosheim, Attorney-Advisor, by telephone at 202–707–8040 or by email at *rkas@loc.gov, sdam@loc.gov, ebertin@loc.gov,* and *abmo@loc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. General Provisions Regarding Copyright Registration

Under the Copyright Act of 1976, the U.S. Copyright Office (the ''Copyright Office'' or ''Office'') is responsible for registering copyright claims. *See* 17 U.S.C. 408. In doing so, the Office has a statutory obligation to confirm that the legal and formal requirements for registration have been met, such as confirming fixation and examining the work for copyrightable authorship. *See* 17 U.S.C. 410(a) (obligating the Register of Copyrights (the ''Register'') ''after examination'' to ''determine[ ] that . . . the material deposited constitutes copyrightable subject matter and that the other legal and formal requirements of this title have been met'').

The Office has the further obligation to obtain a registration deposit that is sufficient to verify the scope of the claim, and to provide an adequate archival record of what was examined and registered. *Id.* 408(b) (generally requiring a ''complete'' copy of works deposited for registration); *id.* 705(a) (requiring the Register to ''ensure that

records of deposits . . . are maintained''); *id.* 705(b) (requiring the Register to make ''the articles deposited in connection with completed copyright registrations and retained under the control of the Copyright Office . . . open to public inspection''). In the case of unpublished works, the Office is statutorily required to keep the deposit for the full term of copyright protection. 17 U.S.C. 704(d).

B. Secure Test Registration Procedures

In 1978, as part of the regulations implementing the 1976 Copyright Act, the Office issued a regulation that established a special procedure to exempt ''secure tests'' from some of the otherwise applicable rules for registration, deposit, and examination. The Office explained that this procedure was specifically designed for tests ''used in connection with admission to educational institutions, high school equivalency, placement in or credit for undergraduate and graduate course work, awarding of scholarships, and professional certification'' and that it was intended to protect the confidential nature of these works. *See* 42 FR 59302, 59304 & n.1 (Nov. 16, 1977) (noting correspondence from the Educational Testing Service, American College Testing Program, The College Entrance Examination Board, The American Council on Education, the Law School Admission Council, the National Board of Medical Examiners, the Federation of State Medical Boards, and the National Conference of Bar Examiners, among others). In establishing this special procedure, the Office adopted a definition of ''secure tests'' that it believed would best identify the kinds of tests that raised special confidentiality concerns.[1]

Furthermore, the Office observed that ''although secure tests should be deposited in the Copyright Office for examination incident to registration under section 408, their retention by the Office and availability for public inspection could severely prejudice the future utility, quality, and integrity of the materials.'' *Id.* Accordingly, the Office adopted a regulation providing that ''[i]n the case of any secure test the Copyright Office will return the deposit to the applicant promptly after examination.'' 37 CFR 202.20(c)(2)(vi) (1978). At the same time, the Office recognized the need to retain some evidence of the work that had been examined and registered. Accordingly, the regulation required that ''sufficient portions, description[s], or the like [be] retained so as to constitute a sufficient archival record of the deposit.'' *Id.* In promulgating this regulation, the Office also offered that ''[a]s a matter of practice, special arrangements can be made for the examination of such materials under strict conditions of security and in the presence of a representative of a copyright owner.'' 42 FR at 59304.

Initially, this procedure was used to register secure tests administered with physical booklets, as that was the type of ''work'' the Office had in mind when the regulation was adopted. Beginning in the 1990's, the Office expanded its procedures—without altering the underlying regulation—to permit secure registration of tests administered in a machine-readable format and secure tests administered with physical booklets containing questions taken from an automated database. This procedure mirrored the procedure described above, with the exception of the deposit requirement. Specifically, applicants could bring an unredacted copy of the entire test to the in-person appointment, or alternatively, they could bring 50 unredacted pages from the test or the database of test questions. With respect to the redacted copy of the test, applicants could use the same procedure used to examine physical test booklets, or alternatively, they could submit 50 redacted pages from the test or the underlying database of test questions. Still later, the Office modified this procedure—again without revisiting the regulation—stating that applicants could submit the title page of the test, a redacted copy of the last page of the test, and 50 pages from the test or database of test questions (either in redacted or unredacted form). While the Office described these procedures in a circular (*Copyright Registration of Secure Tests* (*Circular 64*)), they were never incorporated into the Office's regulations and were never the subject of a formal rulemaking.

While these post-1978 changes to the secure test procedure were an attempt to be responsive to developments in the marketplace—as the testing industry moved from using static test booklets to randomized or adaptive tests delivered by a computer—they did not ensure, among other things, an adequate deposit that could serve as a long-term record of what material was examined and registered. As a result, over time the Office's special procedures for registration of secure tests came into increasing tension with the general rules governing copyright registration.

As a result, on June 12, 2017, the Office issued an interim rule that memorialized certain aspects of its secure test procedure, and adopted new procedures to increase the efficiency of its examination of secure tests. *See* 82 FR 26850 (June 12, 2017). In addition, the interim rule brought secure test registration procedures back into alignment with the underlying statutory and regulatory framework for copyright registration. In particular, the Office made clear that only those works that satisfy the regulatory definition of a ''secure test'' would be eligible for the secure test procedure. *Id.* at 26851. In addition, the Office noted that, under its longstanding regulation, the redacted copy must contain a sufficient archival record of what was submitted for registration, and that its prior practices allowing for the registration of test item banks were in considerable tension with that requirement. *Id.* at 26851. The Office therefore declined to permit registration of test item banks under those prior practices.

The Office issued the June 12, 2017 rule on an interim basis and before receiving public comments, in part, because it memorialized most of the Office's longstanding procedures for examining secure tests, and because the improvements in that process were expected to provide immediate benefits for test publishers. *See* 82 FR 26853. The Office invited comment on the interim rule and provided a generous amount of time for public input before issuing a final rule to give applicants and the Office an opportunity to evaluate the new procedures based on actual experience.

II. Group Registration of Secure Test Items

Although the deadline for submitting comments does not expire until December 11, 2017, many commenters have expressed significant concerns about the June 12, 2017 interim rule, contending that it restricts their ability to register, in a secure manner, test items (*i.e.,* sets of questions and answers) stored in or pulled from electronic databases and test banks.[2]

[1] The regulation defined a ''secure test'' as ''a nonmarketed test administered under supervision at specified centers on specific dates, all copies of which are accounted for and either destroyed or returned to restricted locked storage following each administration. For these purposes a test is not marketed if copies are not sold but it is distributed and used in such a manner that ownership and control of copies remain with the test sponsor or publisher.'' 37 CFR 202.20(b)(4) (1978).

[2] *See e.g.,* PSI Comments at 7–8; Am. Board of Fam. Med., Inc., Comments at 2; NBCRNA Comments at 2. In addition, many comments called for updates to the longstanding regulatory definition of ''secure test,'' which is defined as ''a nonmarketed test administered under supervision at specified centers on scheduled dates, all copies of which are accounted for and either destroyed or returned to restricted locked storage following each administration.'' 37 CFR 202.13(b)(1). Although the

Continued

The Office appreciates the commenters bringing these issues to our attention.

The Office recognizes that secure tests serve an important societal function, and that providing a secure method for registering copyright claims in those tests furthers the public good. Although the June 12, 2017 interim rule was aimed to better align secure test registration procedures with the Office's statutory obligations and general good practices for copyright registration, the Office also recognizes that the interim rule did not provide secure test publishers with a means for registering individual test items that are stored in a database or test bank without disclosing the content of these works. To address these legitimate concerns, the Office has decided to issue another interim rule as part of this rulemaking, and to make that rule effective immediately.

A. Group Registration Generally

This interim rule establishes a new group registration option for test items prepared for use in a secure test.

When Congress enacted the Copyright Act, it authorized the Register to specify by regulation the administrative classes of works for the purpose of seeking a registration and the nature of the deposit for each such class. Congress also gave the Register the discretion to allow groups of related works to be registered with one application and one filing fee. *See* 17 U.S.C. 408(c)(1). This procedure is known as group registration. Pursuant to this authority, the Office issued regulations creating group registrations for certain limited categories of works, provided that certain conditions have been met. *See generally* 37 CFR 202.3(b)(1)–(10), 202.4.

As the legislative history explains, allowing ''a number of related works to be registered together as a group represent[ed] a needed and important liberalization of the law.'' H.R. Rep. No. 94–1476, at 154 (1976), *reprinted in* 1976 U.S.C.A.N.N. 5659, 5770; S. Rep. No. 94–473, at 136 (1975). Congress recognized that requiring applicants to submit separate applications for certain types of works may be so burdensome and expensive that authors and copyright owners may forgo registration altogether, since copyright registration is not a prerequisite to copyright protection. *Id.* If copyright owners do not submit their works for registration under this permissive system, the public record will not contain any information concerning those works. This creates a void in the record that diminishes the value of the Office's database.

Allowing a number of related works to be submitted on one application, however, is not without its issues. When large numbers of works are grouped together in one application, information about the individual works may not be adequately captured. Group registration options, therefore, require careful balancing of the need for an accurate public record and the need for an efficient method of facilitating the examination of those works.

The new procedure will be known as the ''group registration option for secure test items'' or ''GRSTQ''. The rule will allow a group of test items that are derived from a test bank or database to be registered using the same basic procedure for registering an individual secure test.[3] The test items must be prepared for use in a ''secure test,'' as defined in § 202.13(b)(1) of the earlier interim rule. And if certain requirements have been met, the test items may be registered by submitting a redacted copy of the works and presenting an unredacted copy of these materials to the Office for an in-person examination.

Under this interim rule, each individual test item may constitute one work if the item is determined to be copyrightable in itself. While there is no limit to the number of test items that may be included in each submission, each work must share certain traits. Specifically, the test items contained in a single group must all be either published or unpublished. They must all be created by the same author or co-authors, and the copyright claimant(s) must be the same for each item. Because an overwhelming majority of secure tests are works made for hire, the Office is considering whether to limit these registrations to works made for hire, although it did not include this restriction in this interim rule. The Office welcomes public comments on whether this requirement should be included in the final rule.

A group registration for secure test items will cover each work in the group, *i.e.,* each test item will be deemed to be registered as a separate work. Claims in the selection, coordination, or arrangement of the group as a whole will not be permitted.[4] Each of these requirements is discussed below.

A. Eligibility Requirements

1. Test Items That May Be Included in the Group

To qualify for the GRSTQ option, all the test items in the group must be prepared for use in a secure test, as defined in § 202.13(b)(1) of the earlier interim rule. A database or test bank does not qualify as a ''secure test'' in and of itself. But the Office recognizes that when test items are selected from a test bank and assembled together to form an actual secure test, they share the same security concerns that prompted the Office to create the special accommodation for individual secure tests. For this reason, test items that are prepared for use in a secure test will be eligible for the GRSTQ option.

For the purposes of registration, a ''test item'' is a question (or ''stem''), the correct answer to that question, any incorrect answer choices (or ''distractors''), and any associated material, such as a narrative passage or diagram. A single narrative or diagram followed by multiple related questions and correct and incorrect answers will together be considered a single test item. Under this interim rule, each test item will be considered one work. Thus, if an applicant submits one textual passage followed by a question and four answers related to that passage, this would be considered one work for purposes of registration. A single narrative or diagram followed by multiple sets of related questions and answers will also be considered one work. The Office believes this definition will be broad enough to encompass many different kinds of test items. It nonetheless welcomes public comments on whether that definition could be clarified or otherwise improved.

2. The Number of Test Items That May Be Included in the Group

Under this interim rule, the Office will allow an unlimited amount of works to be included with each group registration, and will examine each individual test item for copyrightable authorship. Applicants should note, however, that an extremely large number of test items may take a

Office is not in a position to amend that regulatory definition at this time, it acknowledges that the administration of secure tests has changed in many ways since this definition was first promulgated in 1978, and it is continuing to consider those comments that have asked the Office to update this definition to account for these changes.

[3] To be clear, the interim rule issued on June 12, 2017 otherwise remains in effect, and may continue to be used to register individual secure tests. 37 CFR 202.13(b)(1).

[4] Because of the confusion surrounding the treatment of test items stored in databases under the June 12, 2017 interim rule, the Office intends to apply this interim rule to pending registration applications, but where applicable, the Office will request a revised application and deposit materials. If these requirements are met, the Office will assign an effective date of registration based on the date that the initial application and deposit were received.

significant amount of time—in some cases, several days—to examine. Moreover, applicants will be required to pay an hourly fee for the time spent examining these test items during the in-person appointment.

Over time, allowing an unlimited number of works to be registered with one application may reduce the quality of the registration record, or it may impose an unreasonable administrative burden on the Office. Therefore, the Office will monitor this process for several months following the issuance of this interim rule, and will evaluate what effect, if any, allowing an unlimited amount of tests items per registration may have on the Office's business processes to determine whether the number should be limited under the final rule.

When completing the electronic application, the applicant must reasonably identify the total number of test items that are included in the application. The applicant should provide this information on the questionnaire and by numbering each test item that appears in the deposit. The Office will use this information to plan for the in-person examination. Numbering the test items will also help the Office identify and examine the relevant works in the deposit.

3. Publication

Under this interim rule, an applicant will be allowed to register a group of unpublished test items, or a group of test items that are published within a three-calendar-month period. Applicants will not be allowed to combine published and unpublished test items in the same claim.

If an applicant submits a group of published test items, and if the items were published on the same date, the applicant should provide that date in the application. If the test items were published on different dates, the applicant must identify the first date that the items were published. Claims with a range of publication dates outside of a three-calendar–month period will be refused.

4. Title of the Group

To register a group of test items prepared for use in a secure test, the applicant must provide a title for the group as a whole. In addition, the applicant must append the term ''GRSTQ'' at the beginning of the title of the group, so that the Office can more easily assign the claim to an appropriate member of the Registration Program. Upon request, the examiner will remove this term from the title field before the claim is approved.

Applicants must provide additional descriptive information in the title that, at a minimum, identifies the name of the secure test that the items are intended for. The title may also include any relevant dates. For example, applicants can identify the specific test where the test items will be used (*e.g.* ''GRSTQ: Test items for February 2017 LSAT''), the test bank or database from which the test items were derived (*e.g.* ''GRSTQ: Test items added to the FINRA Series 7 Exam item bank in the 3rd quarter of 2017''), or the subject matter of the test items (*e.g.* ''GRSTQ: SAT reading comprehension test items'').

5. Author and Claimant

Under this interim rule, all the test items in the group must be authored by the same person or organization. Likewise, the copyright claimant(s) for each work must be the same person or organization. If the author(s) and claimant(s) are different, the application must contain an appropriate transfer statement explaining how the claimant obtained all of the exclusive rights in the works.

B. The Application Process

The application process described in this interim rule is essentially identical to the process described in the interim rule announced on June 12, 2017. *See* 82 FR 26852–53. To register a group of test items, applicants must complete and submit an application through the electronic registration system using the Standard Application, and they must pay the $55 filing fee. Prior to scheduling an examination appointment, applicants must complete and upload a brief questionnaire about the test items, which may be obtained from the Office's Web site at *https://www.copyright.gov/forms/securetest-questionnaire.pdf,* and they must upload a redacted copy of all the test items being registered. The Office will use this information to determine if the works are eligible for the GRSTQ option.

The copy uploaded to the electronic registration system should contain a redacted copy of each test item, and, as mentioned above, each test item should be numbered. Most of the content that appears on each page may be blocked out, provided that the redacted copy contains a sufficient amount of visible content that may be used to identify each item. For instance, the applicant may leave a narrow vertical or diagonal strip of visible content across each page. Alternatively, the applicant may redact the content of each test item, except for a small number of identifiable words. The Office has provided representative examples of acceptable redaction methods in the most recent version of *Circular 64* (posted on the Office's Web site on November 13, 2017.

The questionnaire and the redacted copy containing all of the test items must be contained in separate electronic files, and they must be uploaded to the electronic registration system in Portable Document Format (PDF). The file name for the questionnaire should include the word ''Questionnaire'' and the case number assigned to the claim. (This eleven-digit number is automatically generated by the electronic registration system, and it appears near the top of each screen of the online application.) The file name for the redacted copy should match the title provided on the questionnaire.

Once the application, filing fee, questionnaire and the redacted copy have been received, the Office will assign the claim to a Literary Division examiner who will examine the claim in the date order of the Literary Division's pending overall workload. The examiner will review these items to determine if the works appear to be eligible for the GRSTQ option. If so, the examiner will contact the applicant and schedule an in-person appointment to examine the works under secure conditions. The fact that the examiner schedules an appointment, however, does not necessarily mean that the test items are eligible for the GRSTQ option or that they will be registered. As discussed below, the in-person examination may reveal that individual test items or the group as a whole is ineligible for registration under these procedures or in general.[5]

C. The In-Person Examination

On the day of the in-person examination appointment, the applicant must bring the following materials to the Office:

(i) A copy of the completed application.

(ii) The nonrefundable examination fee.[6] This fee will be based on the amount of time that it takes to examine each item during the in-person appointment; it is in addition to the filing fee mentioned above. Both the

[5] If the examiner determines that the test items are not eligible for registration under secure test procedures, but are eligible under normal (*i.e.,* non-secure test) examination procedures, the examiner will ask the applicant to upload a complete unredacted copy of the items, and he or she will change the effective date of registration to match the date that the unredacted copy is received.

[6] The Office will charge the same hourly examination rate regardless of whether an applicant is seeking to register a secure test or a group of test items prepared for use in a secure test. *See* 37 CFR 201.3(d)(5).

filing fee and the examination fee are nonrefundable, regardless of whether the Office issues a certificate of registration for the test items.

(iii) A copy of the redacted test items that were uploaded to the electronic registration system.

(iv) A signed declaration confirming that this redacted copy is identical to the redacted copy that was uploaded to the electronic registration system. Applicants may obtain a copy of this declaration from the Office's Web site at *https://www.copyright.gov/forms/securetest-declaration.pdf.*

(v) An unredacted copy of the test items submitted for registration.

Applicants must bring a copy of the unredacted test items, with the entire content completely visible so that they may be examined. The test items in the unredacted copy should be numbered, should appear in the same order as the redacted copy, and should precisely match the test items as they appear in the redacted copy.

The examiner will review the redacted and unredacted copies in a secure location in the presence of the applicant or the applicant's representative. Because the Office will examine each test item for copyrightable authorship, and because the Office is not currently placing a limit on the number of items, the examination may require more time and may result in a higher total examination fee than an examination involving an individual secure test. If the examiner determines that one or more of the test items are not copyrightable, he or she will require the applicant to exclude that material from the claim in order to continue the examination, or will refuse the claim altogether. Face-to-face disputes with the examiner about the sufficient creativity of an item will not be allowed and will result in refusal of the claim. If an applicant does not agree that an individual test item should be excluded, the applicant may seek to register that test item or test items alone and appeal the subsequent refusal.

When the examination is complete, the examiner(s) will stamp the date of the appointment on the redacted and unredacted copies and will return them to the applicant. The signed declaration and the redacted copy that was uploaded to the electronic system will be retained by the Office; this redacted copy will constitute the deposit.

If the examiner determines that the legal and formal requirements have been met, he or she will register the claim(s) and will add an annotation to the certificate indicating that the test items were registered under this interim rule in accordance with the eligibility requirements for this group registration option. The registration will be effective as of the date that the Office originally received the application, filing fee, and the redacted copy that was uploaded to the electronic registration system.

D. The Scope of Registration

Under this interim rule, a group registration will cover each test item in the group, and each test item will be registered as a separate work. *See* 37 CFR 202.4(m). The group is merely an administrative classification created solely for the purpose of registering multiple works with one application and one filing fee. *See* 17 U.S.C. 408(c)(1) (''Th[e] administrative classification of works has no significance with respect to the subject matter of copyright or the exclusive rights provided by this title.''). Therefore, the Office will not consider the group as a whole to be a compilation or a collective work under sections 101, 103(b), or 504(c)(1) of the Copyright Act. By contrast, when an applicant registers a secure test under the June 12, 2017 interim rule, the applicant must assert a claim in the test as a whole, or in the individual test items and the selection, coordination, and/or arrangement of those items. *See* 86 FR at 26852.

IV. Request for Comments

This interim rule will go into effect immediately upon the publication of this document in the **Federal Register**. As was the case with the June 12, 2017 interim rule, this is a non-substantive rule that is not subject to the restriction in 5 U.S.C. 553(d). *See* 82 FR 26853. In addition, there is ''good cause'' for this rule to go into immediate effect because it restores to secure test publishers a method of registering test items that existed prior to the issuance of the June 12, 2017 interim rule but was not provided under that rule. *See* 5 U.S.C. 553(d)(3). And, finally, the Copyright Office prepared this interim rule based upon its experience in administering other group registrations, and its review of comments received in response to the June 12, 2017 interim rule.

Comments will be due on December 11, 2017 (the same deadline for submitting comments on the June 12, 2017 interim rule). The Office decided to issue this rule without publishing an initial notice of proposed rulemaking for several reasons:

First, the interim rule addresses concerns expressed by interested parties in comments filed in response to the earlier interim rule on secure tests. Second, the procedures for scheduling an in-person appointment, submitting an unredacted copy of the works, and providing a redacted copy for the Office's records are consistent with the Office's longstanding practices for examining secure tests.

Finally, issuing the rule on an interim basis affords both the Office and interested parties an opportunity to evaluate how these procedures work in conjunction with the procedures announced in the June 12, 2017 interim rule, to determine whether these procedures should be modified in any respect, and whether the number of test items that may be included in each claim should be adjusted before the Office issues a final rule. *See* 5 U.S.C. 553(b)(3)(B).

List of Subjects in 37 CFR Part 202

Copyright, Preregistration and registration of claims to copyright.

Interim Regulation

In consideration of the foregoing, the U.S. Copyright Office amends 37 CFR part 202 as follows:

PART 202—PREREGISTRATION AND REGISTRATION OF CLAIMS TO COPYRIGHT

■ 1. The authority citation for part 202 continues to read as follows:

Authority: 17 U.S.C. 408(f), 702.

■ 2. Amend § 202.4 as follows:

■ a. Revise paragraph (b).

■ b. Redesignate paragraphs (k) through (m) as paragraphs (l) through (n), respectively.

■ c. Add new paragraph (k).

■ d. In newly redesignated paragraph (n), remove ''paragraph (g)'' and add in its place ''paragraph (g) or (k)''.

The revision and addition read as follows:

§ 202.4 Group registration.

* * * * *

(b) *Definitions.* For purposes of this section, unless otherwise specified, the terms used have the meanings set forth in §§ 202.3, 202.13, and 202.20.

* * * * *

(k) *Secure test items.* Pursuant to the authority granted by 17 U.S.C. 408(c)(1), the Register of Copyrights has determined that a group of test items may be registered in Class TX with one application, one filing fee, and identifying material, if the conditions set forth in § 202.13(c) and (d) have been met.

* * * * *

■ 3. Amend § 202.13 as follows:

■ a. Revise paragraph (a).

■ b. Add paragraph (b)(5).

■ c. Revise paragraphs (c) introductory text and (c)(2).

■ d. Remove paragraph (c)(3).
■ e. Redesignate paragraphs (c)(4) and (5) as paragraphs (c)(3) and (4), respectively.
■ f. Revise newly redesignated paragraphs (c)(3)(iii), (iv), and (v) and the first sentence in newly redesignated paragraph (c)(4).
■ g. Add paragraph (d).

The additions and revisions read as follows:

§ 202.13 Secure tests.

(a) *General.* This section prescribes rules pertaining to the registration of secure tests or a group of test items prepared for use in a secure test.

(b) * * *

(5) A *test item* is comprised of a question (or ''stem''), the correct answer to that question, any incorrect answer choices (or ''distractors''), and any associated material, such as a narrative passage or diagram, and each item shall be considered one work. A single narrative, diagram, or other prefatory material, followed by multiple sets of related questions and correct or incorrect answers shall together be considered one item.

(c) *Deposit requirements.* Pursuant to the authority granted by 17 U.S.C. 408(c)(1), the Register of Copyrights has determined that a secure test or a group of test items prepared for use in a secure test may be registered with identifying material, and the filing and examination fees required by § 201.3(c) and (d), if the following conditions are met:

* * * * *

(2) In the case of a secure test, the applicant must submit a redacted copy of the entire test. In the case of a group of test items prepared for use in a secure test, the applicant must submit a redacted copy of each test item. In all cases the redacted copy must contain a sufficient amount of visible content to reasonably identify the work(s). In addition, the applicant must complete and submit the secure test questionnaire that is posted on the Copyright Office's Web site. The questionnaire and the redacted copy must be contained in separate electronic files, and each file must be uploaded to the electronic registration system in Portable Document Format (PDF). The Copyright Office will review these materials to determine if the work(s) qualify for an in-person examination. If they appear to be eligible, the Copyright Office will contact the applicant to schedule an appointment to examine an unredacted copy of the work(s) under secure conditions.

(3) * * *

(iii) A copy of the redacted version of the work(s) that was uploaded to the electronic registration system.

(iv) A signed declaration confirming that the redacted copy specified in paragraph (c)(3)(iii) of this section is identical to the redacted copy that was uploaded to the electronic registration system.

(v) In the case of a secure test, the applicant must bring an unredacted copy of the entire test. In the case of a group of test items prepared for use in a secure test, the applicant must bring an unredacted copy of all the test items.

(4) The Copyright Office will examine the copies specified in paragraphs (c)(3)(iii) and (v) of this section in the applicant's presence. * * *

(d) *Group registration requirements.* The Copyright Office may register a group of test items if the following conditions have been met:

(1) All the test items must be prepared for use in a secure test, and the name of the secure test must be identified in the title of the group.

(2) The group may contain an unlimited amount of works, but the applicant must identify the individual works included within the group by numbering each test item in the deposit.

(3) The applicant must provide a title for the group as a whole, and must append the term ''GRSTQ'' to the beginning of the title.

(4) The group must contain only unpublished works, or works published within the same three-calendar-month period and the application must identify the earliest date that the works were published.

(5) All the works in the group must have the same author or authors, and the copyright claimant for each work must be the same. Claims in the selection, coordination, or arrangement of the group as a whole will not be permitted on the application. Each item in the group must be separately copyrightable or must be excluded from the group.

Dated: November 6, 2017.

Karyn Temple Claggett,

Acting Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2017–24532 Filed 11–9–17; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket DOT–OST–2016–0189]

RIN 2105–AE58

Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Addition of Certain Schedule II Drugs to the Department of Transportation's Drug-Testing Panel and Certain Minor Amendments

AGENCY: Office of the Secretary of Transportation (OST), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The Department of Transportation is amending its drug-testing program regulation to add hydrocodone, hydromorphone, oxymorphone, and oxycodone to its drug-testing panel; add methylenedioxyamphetamine as an initial test analyte; and remove methylenedioxyethylamphetamine as a confirmatory test analyte. The revision of the drug-testing panel harmonizes DOT regulations with the revised HHS Mandatory Guidelines established by the U.S. Department of Health and Human Services for Federal drug-testing programs for urine testing. This final rule clarifies certain existing drug-testing program provisions and definitions, makes technical amendments, and removes the requirement for employers and Consortium/Third Party Administrators to submit blind specimens.

DATES: This rule is effective on January 1, 2018.

FOR FURTHER INFORMATION CONTACT: Patrice M. Kelly, Acting Director, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone number 202–366–3784; *ODAPCWebMail@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Purpose

The Department of Transportation (DOT or the Department) issued a notice of proposed rulemaking (NPRM) on January 23, 2017. 82 FR 7771 (Jan. 23, 2017). The NPRM proposed to revise Part 40 of Title 49 of the Code of Federal Regulations (CFR) to harmonize with certain parts of the revised the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (HHS Mandatory Guidelines), which was published on

the same day. 82 FR 7920 (Jan. 23, 2017). DOT currently requires urine testing for safety-sensitive transportation industry employees subject to drug testing under Part 40.

There are two changes to the HHS Mandatory Guidelines with which the NPRM proposed to harmonize Part 40. First, the revised HHS Mandatory Guidelines, in part, allow Federal agencies with drug-testing responsibilities to test for four additional Controlled Substances Act (CSA) Schedule II prescription medications: Hydrocodone, hydromorphone, oxycodone, and oxymorphone. Second, the HHS Mandatory Guidelines remove methylenedioxyethylamphetamine (MDEA) as a confirmatory test analyte from the existing drug-testing panel and add methylenedioxyamphetamine (MDA) as an initial test analyte. In addition to harmonizing with pertinent sections of the HHS Mandatory Guidelines for urine testing, the NPRM proposed to clarify certain existing Part 40 provisions; to remove provisions that no longer are necessary (such as obsolete compliance dates); to move the content of certain provisions out of Part 40 and onto the Office of Drug and Alcohol Policy and Compliance's (ODAPC) Web site; and to update definitions and web links where necessary. The Department also proposed to remove existing Part 40 requirements related to blind specimen testing.

The Department received 69 comments on the proposed rulemaking. The comments were from multiple sources including transportation industry associations, drug and alcohol testing industry companies and associations, doctors and medical groups, labor organizations, and individuals.

II. Authority for This Rulemaking

This rule is promulgated pursuant to the Omnibus Transportation Employee Testing Act (OTETA) of 1991 (Pub. L. 102–143, Title V, 105 Stat. 952). OTETA sets forth the requirements for DOT reliance on the HHS Mandatory Guidelines for scientific testing issues. Section 503 of the Supplemental Appropriations Act, 1987 (Pub. L. 100–71, 101 Stat 391, 468), 5 U.S.C. 7301, and Executive Order 12564 establish HHS as the agency that directs scientific and technical guidelines for Federal workplace drug-testing programs and standards for certification of laboratories engaged in such drug testing. While DOT has discretion concerning many aspects of the regulations governing testing in the transportation industries' regulated programs, we must follow the HHS Mandatory Guidelines for the categories of drugs for which we will require testing.

III. Background

Relevant History of the DOT Drug-Testing Program Regulation

The Department first published its drug testing program regulation, 49 CFR part 40 (Part 40) on November 21, 1988 as an interim final rule (53 FR 47002). We based the rule on the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (See 53 FR 11970, April 11, 1988), which, in part, required cocaine and marijuana to be screened by Federal agencies. HHS based this requirement on the incidence and prevalence of the abuse of these two substances in the general population and on the experiences, at the time, of the Departments of Defense and Transportation in screening their workforces (53 FR 11973–11974). The 1988 HHS Mandatory Guidelines also authorized Federal agencies to test their employees for the use of phencyclidine, amphetamines, and opiates. The DOT published a final rule on December 1, 1989 (54 FR 49854), which incorporated several provisions from the 1988 HHS Mandatory Guidelines. Among these provisions was a 5-panel test that included all of the drugs for which HHS authorized testing. In 1991, Congress passed the Omnibus Transportation Employee Testing Act (OTETA) which, in part, required the Department and DOT Agencies to look to the HHS for the scientific and technical guidelines regarding the drugs for which we test and specimens we collect.

The Department made comprehensive revisions to Part 40 on August 19, 1994 (59 FR 42996), December 19, 2000 (65 FR 79462), and August 16, 2010 (75 FR 49850). The 2010 revision again harmonized our DOT drug-testing program, where necessary, with the HHS Mandatory Guidelines effective October 1, 2010 (73 FR 7185; 75 FR 22809). Specifically, we required initial and confirmatory testing for methylenedioxymethamphetamine (MDMA); confirmatory testing for MDA and MDEA; and initial testing for 6-acetylmorphine (6–AM). We also lowered the initial and confirmatory test cutoff concentrations for amphetamines and cocaine.

Just as we have revised Part 40 in the past, we are revising Part 40 to harmonize, in pertinent part, with the most recently revised HHS Mandatory Guidelines that have an effective date of October 1, 2017. See 82 FR 7920.

Changes Relevant to the HHS Mandatory Guidelines

HHS monitors drug abuse trends and reviews information on new drugs of abuse from sources such as Federal regulators, researchers, the drug-testing industry, and public and private sector employers. In its May 15, 2015 ''Notice of Proposed Revisions'' (See 80 FR 28103), HHS indicated that, since its original HHS Mandatory Guidelines were published in 1988, a number of recommendations had been made for additional drugs to be included in Federal workplace drug-testing programs. According to HHS, recommendations for adding the four semi-synthetic drugs were based on a review of scientific information and on input from the Drug Testing Advisory Board (DTAB) [1] on the methods necessary to detect the analytes of drugs and on drug abuse trends. With the DTAB recommendations, private sector experience findings, and analysis of current drug abuse trends, HHS concluded that the additional semi-synthetic opioids, oxycodone, oxymorphone, hydrocodone, and hydromorphone, should be added in the Federal program.

In its Final Rule dated January 23, 2017, HHS acknowledged that, while it had proposed MDA and MDEA as initial test analytes, three commenters disagreed with the addition of MDA and MDEA as target analytes. HHS indicated that the commenters stated that this change would require modification of current immunoassay reagents, laboratory processes, or both. The commenters noted that this would impose an unnecessary burden for compounds with such low incidence in workplace testing. HHS determined that the number of positive MDEA specimens reported by HHS-certified laboratories does not support testing all specimens for MDEA in Federal workplace drug testing programs. Based on the comments and its own studies, HHS removed MDEA from its Mandatory Guidelines. HHS indicated that it understands MDA and some other analytes also have a low incidence of testing positive, but believes the continued testing for these analytes is warranted in a deterrent program. In particular, inclusion of MDA as an initial and confirmatory test analyte is warranted according to HHS because, in

[1] The Drug Testing Advisory Board provides advice to HHS (the Administrator of SAMHSA) based on an ongoing review of the direction, scope, balance, and emphasis of the Agency's drug-testing activities and the drug testing laboratory certification program. See *http://www.samhsa.gov/about-us/advisory-councils/drug-testing-advisory-board-dtab/board-charter.*

addition to being a drug of abuse, it is a metabolite of MDEA and MDMA.

Harmonizing Changes to the DOT Drug-Testing Program Regulation

In keeping with our obligations under OTETA to follow the HHS Mandatory Guidelines for the drugs for which we test, our NPRM proposed to add and remove the drugs adopted in the revised HHS Mandatory Guidelines for urine testing. Inclusion of these four semi-synthetic opioids is intended to help address the nation-wide epidemic of opioid abuse. Also, adding these four drugs, which are already tested for in many transportation employers' non-DOT testing programs because of their widespread use and potentially impairing effect, will allow the DOT to detect a broader range of drugs being used illegally. This will enhance the safety of the transportation industries and the public they serve. The Department's final rule makes these harmonizing amendments to Part 40.

IV. Main Policy Issues

A. Modification of the Drug Testing Panel

The NPRM

The Department proposed to add the four semi-synthetic opioids to the DOT panel (*i.e.,* hydrocodone, hydromorphone, oxycodone, and oxymorphone) to maintain consistency with the HHS Mandatory Guidelines. Such consistency is mandated by Federal statute, OTETA, and applies not only to the drugs tested but also to specimen testing validity values and initial and confirmatory testing values. To cover these substances, as well as those previously in the opiate category (*i.e.,* codeine, morphine, 6–AM), the NPRM proposed to rename the category from ''opiates'' to ''opioids.''

As we mentioned in the NPRM preamble, opioid abuse and related problems are a major national concern. Transportation industries are not immune to this trend and the safety issues it raises. Consequently, the Department proposed including these substances in its testing panel not only for consistency with the HHS Mandatory Guidelines but as a response to a national problem that can affect transportation safety.

In addition, to be consistent with changes to the HHS Mandatory Guidelines, the Department proposed to remove MDEA from the testing panel and add MDA as an initial test analyte.

Comments

There were 52 comments addressing the addition of the specified semi-synthetic opioids to the DOT testing panel. Of those comments, 41 supported the NPRM's proposal. Supporters generally recognized the need for the Department to act consistently with the HHS Mandatory Guidelines and agreed that addressing opioid abuse issues in the context of transportation safety is important. Of the other 11 comments, several expressed concerns that adding these substances would increase circumstances in which drivers innocently using opioids (*e.g.,* via a prescription for pain medication) would be unfairly treated as drug abusers, with consequent positive tests harming their careers. A few comments suggested adding other substances, such as methadone or synthetic cannabinoids, to the panel.

Other commenters, including some labor organizations, were concerned that employees would have to compromise their medical privacy in order to avoid results being verified positive by medical review officers (MROs). One comment suggested raising the cutoff levels to make it less likely that an employee using a legitimate prescription medication would receive a positive laboratory result. Other comments raised concerns about how adding these opioids to the testing panel would impact other aspects of Part 40, such as MRO determinations about whether a prescription is legitimate or when it is appropriate for an MRO to inform an employer of a safety concern after verifying a negative result based on an employee's legitimate use of prescription medication. Other comments recommended additional rules or guidance concerning MRO practice, such as additional opioids training and directing MROs not to second-guess the prescription judgments of an employee's physician.

DOT Response

We acknowledge the 41 comments that supported adding the four semi-synthetic opiates to the DOT drug testing panel. We agree that this is an important safety improvement. In addition, we appreciate that so many commenters recognized that we must follow the HHS Mandatory Guidelines for the drugs for which we test.

Although a commenter suggested adding other substances and raising the HHS established cut-off levels, we are not permitted to make such changes. As noted above, OTETA requires the Department to conform with the HHS Mandatory Guidelines with respect to the drugs for which we test and their cutoff levels. The Department does not have the discretion to decline to include drugs that are included in the HHS Mandatory Guidelines or to change the cutoff levels that HHS has established. Furthermore, HHS conducted a full notice and comment period regarding these aspects of the HHS Mandatory Guidelines and that time would have been the appropriate point for commenters to request HHS to consider their concerns. To further ensure that our regulated public was kept informed about this opportunity to comment on HHS rulemakings that could potentially affect them, on May 15 and 19, 2015, ODAPC sent notices to the ODAPC list-serve informing subscribers about the HHS proposal so that interested parties could submit comments to the HHS docket. See *http://content.govdelivery.com/accounts/USDOT/bulletins/1047858* and *http://content.govdelivery.com/accounts/USDOT/bulletins/1051d3e.* Once HHS reaches a final determination on the drugs and their cutoff levels, the DOT cannot depart from HHS's decisions on these matters.

Similarly, DOT does not have the authority to add substances such as methadone or synthetic cannabinoids to our drug testing panel without the scientific and technical expertise of the HHS, as expressed in the HHS Mandatory Guidelines. In addition, HHS is limited to testing for drugs under Schedules I and II of the CSA. Parties interested in having additional drugs in those CSA Schedules tested as part of the Federal or DOT program should discuss the matter with HHS.

The Department received comments regarding the relationship between the Department's drug panel and the HHS Mandatory Guidelines during past rulemaking activities. The Department's position, described above, affirms its past responses. (See 75 FR 49850, 49850–49853).

In other sections of this preamble, the Department will discuss comments related to MRO practice issues that could arise when the four new semi-synthetic opioids in our testing panel are introduced. Examples of these issues include an employee's medical privacy, legitimacy of prescriptions, MROs not questioning the treating physician's prescription judgment, and safety concerns.

B. Blind Specimens

The NPRM

The NPRM proposed to remove from Part 40 the requirements for blind specimen testing. The purpose of this proposal was to relieve unnecessary costs and administrative burdens on employers, C/TPAs, and other parties.

The blind specimen requirement has been part of the Department's drug testing program since its inception. The requirement for employers and C/TPAs to submit blinds was intended to help ensure the accuracy of the laboratory testing process. Under the current regulation, an employer will send a blind specimen to an HHS-certified laboratory, accompanied by a Federal Drug Testing Custody and Control Form (CCF) with the name of a fictitious donor, for quality control purposes to see if the laboratory's results match the known contents of that particular blind specimen.

Over the years, as the accuracy of the laboratory testing process was consistently established, DOT reduced the number of blind specimens that employers were required to send to laboratories to reduce cost and administrative burdens associated with the process. As we stated in the NPRM, not one false positive result was found through the testing of the blind specimens in more than 25 years of drug testing.

As the NPRM noted, laboratories are subject to thorough biannual inspections and quarterly proficiency testing through the HHS National Laboratory Certification Program (NLCP). In addition, if an employee has questions about the accuracy of the positive, adulterated, or substituted test result of his or her own specimen, the employee has the right to request the test of his or her split specimen. Believing that the blind specimen testing requirement was no longer necessary to ensure the accuracy and integrity of the testing process, we proposed eliminating this requirement and sought public comment on the subject.

Comments

Twenty-five comments addressed this proposal. Fifteen supported removing the requirement, while ten asked to retain it. Proponents of removal, principally some testing industry associations and employer groups, generally agreed that there were sufficient safeguards on the accuracy and integrity of the system and that blind specimens were unnecessary. They commented that it was, consequently, a good idea to eliminate the costs and burdens associated with the requirement. They said that the accuracy and integrity of the system will not be compromised by eliminating blind specimen testing. One employer association noted that the requirement only affected the largest companies in its industry, and not small businesses.

Opponents of removing the requirement, including labor organizations and some laboratory-related entities, made several arguments. More than one commenter stated that, while the Department may not have been aware of any false positives resulting from blind specimen tests, there was no information presented about the incidence of false negatives. False negatives, they said, could be as damaging to the integrity and safety objectives of the drug testing programs as false positives. Some commenters said the existence of blind specimen testing could provide an incentive to laboratories to maintain the accuracy of their procedures, somewhat analogous to the deterrent effect of random testing on employee behavior. In its absence, laboratories might relax their standards. Other commenters said that, even if blind specimen testing did not reveal any false positives, the existence of the process of blind specimens added to, or at least increased the appearance of, fairness to employees.

In addition, some commenters noted that because laboratories will begin testing for new substances proposed under the NPRM (*i.e.,* the semi-synthetic opioids), it would be useful to maintain blind specimen testing to help to ensure that errors did not occur in the testing of these newly added drugs. Also, some of the commenters believed that it would be better to keep blind specimen testing in place as a safeguard, as opposed to relying wholly on split specimens and the NLCP. One commenter noted that NLCP's oversight of laboratories could be weakened by future decreases in HHS budgets and this could lead to the reduction of the effectiveness of that program.

DOT Response

The history of the blind specimen testing requirement shows decreasing reliance on this process as a safeguard. Laboratories have accumulated a record of accuracy spanning more than 25 years. Years ago, the DOT reduced the amount of blind specimen testing from three percent to one percent, with no known ill effects on the integrity of the process.

We disagree with the commenters who implied that elimination of the blind specimen testing would cause laboratories to change the way they do business and, thereby lower their standards. Given the continuing rigorous HHS oversight and the business necessity of maintaining accuracy, it is not likely that laboratories would relax their standards simply because the relatively small number of blind specimen tests now required has been eliminated.

While commenters who favor retaining the requirement expressed concern about the possibility of false negatives, or the potential loss of a deterrent effect on laboratories by eliminating blind specimen testing, these concerns are speculative. None of the laboratories or blind specimen manufacturers who commented provided data to support any assertions of false negatives. Without data to support these assertions, the Department has no basis on which to substantiate that there are false negatives indicative of systemic laboratory problems. Instead of identifying laboratory problems, false negatives, if they exist, could be attributed to problems with the manufacture of the blind specimens or employers and C/TPAs not adhering to the manufacturer's instructions on the use or expiration date of their product. The Department retention of the blind specimen testing requirement would exacerbate, not reduce, those problems.

The Department and the transportation industries rely upon the NLCP certification and oversight processes, as well as the split specimen testing process, to ensure that the accuracy of the laboratory testing is up to NLCP certification standards. In OTETA, Congress directed the Department to rely on HHS-certified laboratories, without any reference to the additional process of blind specimen testing. Moreover, there have been no false positive results for blind specimens reported to the Department, as required by the current Part 40, either before or after the NPRM was issued. The Department will continue to rely on HHS for laboratory certification because now more than 25 years of blind specimen testing has shown that there have been no false positive blind specimen results.

Given the rigorous HHS oversight of the laboratories, as well as the business necessity for the laboratories to maintain a reliable record of accuracy, it is not likely that laboratories would relax their standards simply because the relatively small number of blind specimen tests now required was eliminated. Consequently, the Department is adopting its proposal to remove blind specimen testing requirements from part 40.

C. The DOT List-Serve

The NPRM

The NPRM proposed requiring key personnel in the drug and alcohol testing process—collectors, Breath

Alcohol Technicians (BATs), Screening Test Technicians (STTs), Medical Review Officers (MROs), Substance Abuse Professionals (SAPs)—to subscribe to the Office of Drug and Alcohol Policy and Compliance (ODAPC) list-serve. That list-serve is a very useful source of information for: The DOT drug and alcohol testing rules and programs; guidance for handling issues that have arisen in the implementation of the program; relevant antidrug information from Federal partners; and updates concerning the program. Subscriptions are free to users. Currently, there are more than 40,000 ODAPC list-serve subscribers.

Comments

Everyone who commented thought that the list-serve is a very useful tool that many of them subscribe to and support. Nine of the 13 comments on this proposal expressed full or qualified support for the proposal to make the ODAPC list-serve mandatory for key persons who have currency requirements included in their part 40 qualification requirements. Opponents of requiring subscription to the list-serve said that the proposed change was unnecessarily prescriptive and could impose compliance costs (*e.g.,* time spent signing up and reading the material) that were not considered in the regulatory evaluation. One commenter stated that subscribing to the list-serve served no safety purpose. In addition, they asked how the requirement could be monitored, documented, or enforced. One commenter offered that the proposal would work better as a ''best practice'' than a mandate. Some commenters supported the proposal because of the useful information the list-serve provides, but had questions and concerns about its implementation. One commenter suggested that supervisors of BATs, STTs, and collectors should be required to subscribe instead of the BATs, STTs, and collectors themselves. This commenter believed that their supervisors should make sure that they learned relevant information conveyed by the list-serve. Another supporter of the proposal was concerned that monitoring staff members' compliance could be burdensome for parties like C/TPAs. Another expressed concern about how the mandate would work given, the rapid turnover of collectors and BATs.

DOT Response

The Department is appreciative that the commenters recognized the value of the list-serve, and that a number of industry organizations expressed their commitment to publicizing the service and encouraging their members to take advantage of it. We want to extend our gratitude to all who have spread the word about the usefulness of the list-serve and to the more than 40,000 subscribers.

As noted in the NPRM, we believe that the cost and burdens of additional drug and alcohol program workers subscribing to the list-serve would likely be minimal, and that there would be benefits to everyone receiving the useful information it contains. While some commenters expressed concern about potential costs, we note that the service is free. Reading information on the list-serve is unlikely to be time-consuming and no different than if the service agent were to receive the information from a different source. Signing up for the list-serve merely requires one to enter one's email address on the Office of Drug and Alcohol Policy and Compliance's Web page at *www.transportation.gov/odapc.* No comments attempted to provide data regarding potential costs.

Since the plain language rewrite of 49 CFR part 40, 65 FR 79462 (December 19, 2000), collectors, MROs and SAPs have been required to ''keep current on any changes to . . . [the applicable regulations and guidelines].'' This applies to collectors in § 40.33(a); Medical Review Officers (MROs) in § 40.151(b)(3); Substance Abuse Professionals (SAPs) in § 40.281(b)(3) [SAPs]. Similarly; § 40.213(a) requires Breath Alcohol Technicians (BATs) and Screening Test Technicians (STTs) to ''be knowledgeable about the alcohol testing procedures in this part and the current DOT guidance.''

DOT agency auditors, inspectors and investigators who inspect the service agents listed above currently ask the individual collector/BAT/STT/MRO or SAP whether that individual is current on 49 CFR part 40 and the applicable guidelines, to ensure the requirements for currency are met. The individual service agent would need to produce a 101-page copy of 49 CFR part 40 and the applicable guidelines in hard copy. After the list-serve requirement becomes effective, the individual service agent may demonstrate currency by showing the most recent list-serve—most likely by displaying it on the service agent's smart phone or other computer. Proving one's subscription to the list-serve will show the DOT auditor/inspector/investigator that the individual is subscribed to a system that provides an opportunity to stay current with the latest information about the program. Unequivocally, this would be a cost savings, would help to improve compliance by getting the relevant and timely information into the hands of the specified service agents, and would demonstrate the DOT's commitment to making information available electronically.

Even when a service agent subscribes to the list-serve, it is a best business practice for that service agent to keep a paper copy of Part 40 and applicable guidelines for easy reference and for when electronic retrieval of these documents is not possible. Certainly, service agents can view these documents on-line at ODAPC's Web site, but Internet accessibility is not always possible, especially during transportation operations in remote areas.

While we would welcome the subscription to the list-serve by management personnel, it would not make sense to put the requirement of a list-serve subscription upon the collection site supervisor or other management personnel because they are not necessarily the individuals responsible for complying with the qualification requirement under the existing Part 40 to remain current in his or her knowledge. A collector/BAT/STT/MRO or SAP is the individual with the requirement for training, remaining current and maintaining his or her own documentation.

The Department disagrees with the comment that subscribing to the list-serve serves no safety purpose. Over the years, we have used the list-serve to inform the DOT-regulated industry about various important program-related information. For example, list-serves have included: Public Interest Exclusion decisions against fake MROs; changes to the Federal Drug Testing Custody and Control Form (CCF) and authorization for use of the electronic CCF (eCCF); updated guidance documents such as: The Urine Specimen Collector Guidelines; What Employers Need to Know About DOT Drug and Alcohol Testing; FAA's Designated Employer Representative videos; FTA's Annual National Drug and Alcohol Conference; Official ODAPC Interpretations of Part 40; and the FMCSA's National Drug and Alcohol Testing Clearinghouse. Each of these notices touched on topics directly related to the DOT's drug and alcohol testing program. The list-serves communicate information that is related to the integrity and safety aspect of the program.

D. MRO Practice Issues

The NPRM

The NPRM proposed to amend existing § 40.141(b) to say that ''prescription,'' for purposes of MRO

verification determinations, means ''a legally valid prescription under the Controlled Substances Act [CSA].'' This same language was used in § 40.135(e), in the context of informing third parties about potential safety implications of an employee's use of a controlled substance. The intent of the proposal was to harmonize the language of these sections for clarity and consistency.

It has always been the intent of this program to follow the CSA regarding what constitutes a legally valid prescription. The term ''prescription'' has become more loosely used in recent years. Under the Internal Revenue Code, individuals can be reimbursed for over-the-counter medications and some services, if the taxpayer has a ''prescription'' from their doctors for these things that are not controlled substances under the CSA. In addition, some state laws allowing marijuana use the term ''prescription,'' even though a recommendation for someone to use marijuana under state law is not a prescription consistent with the Controlled Substances Act.

The NPRM also proposed to allow MROs to conduct additional testing (*i.e.,* for D,L stereoisomers of amphetamine and methamphetamine isomers and/or tetrahydrocannabivarin (THC–V)) of a specimen, if doing so is necessary to verify a test result. The testing for D,L stereoisomers of amphetamine and methamphetamine can be useful to an MRO in distinguishing whether a methamphetamine positive resulted from use of a legitimate over-the counter product. An MRO can order a test for THC–V to be conducted to determine whether the laboratory reported marijuana result was due to the smoking of marijuana. The THC–V differential testing can distinguish whether a THC positive is due to the smoking of marijuana, a CSA Schedule I illegal drug, or is due to the use of Marinol, a CSA Schedule III prescribed pharmaceutical. Because of this regulatory change, MROs do not need to obtain DOT consent to order such tests. However, MROs can use only laboratories that meet NLCP criteria for conducting these additional tests.

Comments

There were only nine comments on these specific proposals. All of them supported the authorization of MROs to order the laboratory to test for D,L stereoisomers of amphetamine and methamphetamine or THC–V. One comment, from a testing industry association, suggested that the Department issue more detailed guidance to MROs concerning when it is appropriate to order these tests. Another comment suggested making the testing for D,L stereoisomers of amphetamine and methamphetamine mandatory in all methamphetamine positives to avoid delays in reporting final verification results to employers.

With respect to the definition of ''prescription,'' eight of the nine commenters supported the NPRM. The ninth suggested that this was a matter better left to medical organizations. Another commenter suggested that the rule specify that there could never be a legally valid prescription for marijuana, to reinforce that state ''medical marijuana'' laws do not have validity for the purposes of the DOT program, which is bound to follow Federal law. One commenter specifically noted that the word ''prescription'' is not specifically defined in the CSA.

As noted earlier in the ''Modification to the Drug Testing Panel'' section, commenters to the proposal to add the four semi-synthetic opioids raised a number of issues concerning MRO practice. One issue of concern to several commenters was whether a prescription should still be considered by the MRO as a legitimate medical explanation if it had been filled a long time before the positive test result (*e.g.,* six months, a year, two years before the drug test that an MRO is being asked to verify). They said this is an important inquiry because the semi-synthetic opioids proposed to be added to the DOT testing panel are Schedule II drugs that are frequently prescribed and may be retained and used by the donor long after the prescription was filled. Some commenters were concerned that MROs' decisions have been and will continue to be inconsistent regarding the age of a prescription considered to be grounds for declaring a legitimate medical explanation for a positive result.

A related comment asked that DOT clarify that an MRO could not question a prescribing physician's decision to issue a prescription. That is, an MRO should not ''second guess'' the prescribing physician's determination that it was medically appropriate to prescribe one of the four semi-synthetic opioids and verify a test as positive notwithstanding the existence of the prescription.

Other commenters recommended that MROs should receive more frequent training than currently required (*e.g.,* requalification training every three years rather than every five years), with special emphasis on issues concerning the semi-synthetic opioids added to the DOT panel. One of these comments suggested that MROs should not be authorized to make determinations about these drugs until they had received specific training concerning the semi-synthetic opioids. This commenter also asked that legal review of MRO decisions be permitted under the regulations and that MROs and collectors themselves be subject to drug testing.

Another area of comment focused upon the provision of § 40.327(a) that directs MROs to report to employers and third parties when safety concerns remain after a non-negative test laboratory-confirmed result is downgraded to a negative due to the existence of a prescription. Some commenters believed that the downgraded non-negative results are still likely to result in the medical disqualification of the employee (§ 40.327(a)(1)), for those positions that require medical qualification, such as airline pilots, Coast Guard mariners and Commercial Driver's License (CDL) drivers. For those without medical certification requirements, these commenters believed that the MRO would report a ''safety concern'' under § 40.327(a)(2) when, in the MRO's medical judgment, the employee's continued performance of his or her safety-sensitive function is likely to pose a significant safety risk. These commenters' concern was that, absent further regulatory language or guidance from DOT, some MROs might report information to employers (*e.g.,* information about a semi-synthetic opioid that an employee was legally taking) from which an employer could infer an employee's medical condition. These commenters believed that release of information would not only compromise the employee's medical privacy but could threaten the employee's job. One commenter thought that paragraph (a)(2) should be deleted altogether. Commenters suggested that, before reporting a safety concern under § 40.327(a)(1), an MRO should be required to contact the employee's prescribing physician to determine whether the physician was aware of the employee's safety-sensitive duties and, if so, whether the prescribing physician believed the prescribed drug would not impair the employee's ability to perform those duties safely.

DOT Response

The Department is adopting the NPRM's proposal to authorize MROs to conduct testing for D,L stereoisomers of amphetamine and methamphetamine and THC–V. Most commenters agreed that these proposals had merit. We do not believe it necessary to make the testing for D,L stereoisomers of amphetamine and methamphetamine mandatory in methamphetamine cases,

believing it better to leave this decision to MROs' discretion. Neither is it necessary to make THC–V testing mandatory. To make these requirements would be unnecessary in most cases and would, therefore, cause needless expense with no additional safety benefit. In response to those who thought additional guidance is necessary, we will provide it in the future on the basis of demonstrated need.

We will also adopt, with a slight change, the NPRM's language saying that a prescription means a legally valid prescription within the overall meaning of the CSA. While, as one commenter pointed out, the CSA does not contain an explicit definition of ''prescription,'' the Drug Enforcement Administration (DEA), which is designated by statute to carry out the CSA, has regulations and guidance regarding prescriptions. Therefore, we are changing the proposed language to say that a prescription must be ''consistent with'' and not simply ''under'' the CSA. The proposed language was already present in § 40.135(e), so we will make a technical amendment to that language for consistency. In addition, we have added the same language to § 40.137(a) to provide clarity to MROs when verifying laboratory-confirmed positive test results.

The key point of the phrase we have added is to make sure that a prescription is legally valid. For example, regardless of any state ''medical marijuana'' laws, there cannot be a legally valid prescription for marijuana, since it remains a Schedule I substance under the CSA.

The issues concerning restricting an MRO's judgment about how long a prescription may be considered to be legitimate are complex and not appropriate for this rulemaking. The Department is concerned that establishing a ''bright line'' cutoff date for the valid use of a prescription—*i.e.,* that an otherwise legally valid prescription would be regarded as no longer providing a legitimate medical explanation for a laboratory positive after a certain amount of time had passed—would be a too-facile substitute for the individualized inquiry that we expect an MRO to make in such cases. It could also result in an unintended hardship on an employee who is not intentionally abusing a prescription medication but who unintentionally runs afoul of a standardized expectation for how quickly he or she will use medication prescribed.

The DEA has not set a maximum duration for the length of time a prescription can be considered to be legally used by the person to whom it was prescribed. Consequently, it would not be appropriate for the Department to substitute its judgment for that of the DEA, which is the Federal agency with the authority for determining what constitutes a valid prescription under the CSA.

The MROs are highly qualified individuals who Part 40 requires to make judgment calls. MROs must take into account differences in medications, and other case-specific factors. While some commenters characterize this as ''inconsistent'' across the breadth of a national program, it carries out the intention that MROs will make individualized determinations for each donor. Although it might be less work and superficially ''consistent'' for MROs to make decisions on the basis of a ''bright line'' standard, doing so would not advance the objectives of the program. Consequently, the Department will not create a time limit on the use of a legally valid prescription.

Some commenters also suggested that the final rule prohibit an MRO from questioning whether the prescribing physician should have prescribed the substance. That is, the MRO should not be allowed to say, in effect, ''yes, the employee has a legally valid prescription issued by his or her physician, but I think that the physician should not have issued that prescription in the first place, or the prescription was for too high a dosage of a drug, so I won't treat the prescription as a legitimate medical explanation for a laboratory positive.'' This situation could arise, for example, with respect to prescriptions for the opioids added to the DOT panel by this rule (or for any other legally prescribed drug identified in our drug panel), if an MRO thought an employee's doctor had been too liberal in prescribing pain medications.

We agree that it is inappropriate for an MRO to question an employee's legally valid prescription in this way. Even if the employee's physician's prescription practices are inconsistent with an MRO's understanding of good standards of medical practice, employees are entitled to rely on their physicians' prescriptions as authorization to use the legally prescribed substance as a legitimate medical explanation. To say otherwise would place an unfair burden on the employee to judge the appropriateness of his or her physician's conduct. As a logical outgrowth of this issue raised by commenters, we have added language to § 40.137 of the final rule to prohibit MROs from denying a legitimate medical explanation because the MRO thinks the prescribing physician should not have prescribed the medication to the donor. However, it is important to note that a valid concern about whether the employee can continue performance safely may be present and the prescribing physician may still be asked to reconsider the employee's use of the prescription in accordance with § 40.135(e).

MROs with a concern about a physician's prescribing practices can address this with the prescribing physician or raise the issue with the appropriate state licensing agency for the prescribing physician. For example, an MRO can choose to file a complaint with a local DEA office, a medical licensing board, or other oversight organization regarding the practices of a prescribing physician who the MRO believes is violating standards of care. That approach remains a more direct way to address the possible malfeasance of the prescribing physician, instead of denying the legitimacy of the safety-sensitive employee's prescription.

The issue of states or nations (*i.e.,* Canada and Mexico) that allow recommendations or state-recognized ''prescriptions'' for ''medical marijuana'' presents a completely different consideration. Marijuana is a Schedule I drug and, therefore, regardless of the prescribing physician's intent, it cannot be the basis of a legitimate medical explanation. Consistent with longstanding DOT regulatory language and guidance (*e.g.,* §§ 40.137(e)(2), 40.151(e), and DOT ''Medical Marijuana'' Notice *https://www.transportation.gov/odapc/medical-marijuana-notice;* DOT ''Recreational Marijuana'' Notice *https://www.transportation.gov/odapc/dot-recreational-marijuana-notice*), MROs must not treat medical marijuana authorizations under state law as providing a legitimate medical explanation for a DOT drug test that is positive for marijuana.

We agree with commenters that MROs should receive appropriate information concerning issues that may arise with respect to the semi-synthetic opioids added to the DOT panel in this final rule. The Department will issue guidance, as needed, highlighting opioid issues that may arise.

We believe that shortening the MRO re-training interval to three years would impose a cost and burden that is unnecessary. Since we already have opiates in the DOT-regulated drug testing panels, adding semi-synthetic opioids to the panel is not a radical change for these highly trained Medical Doctors and Doctors of Osteopathy. Likewise, requiring special training concerning opioids for MROs, or

limiting their ability to verify opioid positive test results unless they had received such training, is likely to unnecessarily delay implementation of the addition of these controlled substances to the program without a justifiable reason to require the training. There was no showing by commenters that, absent such specialized training outside the normal training process, MROs would be incapable of assessing whether there were legitimate medical explanations for opioid positive results. Thus, we believe that additional training is not needed to ensure that MROs are familiar with semi-synthetic opioid issues.

As noted above, commenters were concerned that, as applied to commonly prescribed substances like the semi-synthetic opioids covered by this rule, § 40.327(a)(2) could lead to adverse outcomes for employees such as compromising the employee's medical privacy or employment. For example, an MRO might note that an employee had a legally valid prescription for an opioid, which provided a legitimate explanation for a laboratory positive result, but then decide that the employer should be told that the employee's use of that opioid poses a significant safety risk, endangering the employee's continued employment. Given the apparent frequency with which opioids are prescribed, commenters feared that the occurrence of issues of this kind could increase.

Although we did not propose any new language to § 40.327, we believe this section warrants a discussion and a slight amendment to the existing language of § 40.135 as a logical outgrowth of the commenter's concerns as to the frequency with which medical information would be reported because of adding the four semi-synthetic opioids. It may not be necessary for the MRO to report medical information to third parties in every case where the MRO receives substantiated evidence that an employee has a valid prescription that merits downgrading a result from a positive to a negative.

Under § 40.327, an MRO must report drug test results and medical information the MRO learns as part of the verification process to third parties without the employee's consent if the MRO determines, in his or her reasonable medical judgement, that either of two concerns is triggered. First, the MRO is required to disclose to third parties information when the information obtained during the verification interview is likely to render the employee medically unqualified under an applicable DOT agency regulation (*e.g.,* a fitness for duty requirement). Second, the MRO must report the information to third parties if the ''information indicates that continued performance by the employee of his or her safety-sensitive function is likely to pose a significant safety risk.'' The third parties to whom this information can be disclosed are: The employer; a DOT agency; a SAP; or an examiner who determines whether the employee is medically qualified under an applicable DOT agency safety regulation.

We understand, and the commenters were concerned, that MROs already apply the procedures of §§ 40.135 and 40.327 to commonly prescribed medications that can cause a laboratory-confirmed positive result. Thus, adding the semi-synthetic opioids would pose a similar, but certainly not a new, scenario of a laboratory-confirmed positive that would be downgraded to a negative result because of a legally valid prescription, and this medical information would be reported to a third party, when appropriate.

This concern, however, should not be overstated. There is not an automatic requirement for an MRO to report medical information to third parties for every downgraded drug test result. There are and will continue to be cases where the MRO would not need to report medical information to a third party. We leave the determination of the significant safety risk to the ''reasonable medical judgment'' of the MRO, recognizing that every downgraded test result is not the same and needs the individualized professional judgment of the MRO.

The MROs have a serious safety duty when verifying the prescription an employee provides to the MRO. Under § 40.141(b), the MRO (and not the MRO's staff) must ''review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides.'' With the advancement of photography manipulation and enhancement software easily available through the Internet, MROs should speak with the pharmacy and not simply rely on a photograph of the prescription label. That contact with the pharmacy can also shed light on whether there is a significant safety risk posed in the particular situation the MRO is assessing.

To ensure that the employee is not caught by surprise by an MRO's decision to report the medical information regarding a legally valid prescription to a third party, we have amended § 40.135(e). Specifically, we will direct the MRO to first provide the employee with up to five business days after the reporting the verified negative result to have the prescribing physician contact the MRO to determine if the medication(s) can be changed to one that does not make the employee medically unqualified or that does not pose a significant safety risk before reporting the safety concern. If the MRO does not receive such information from the prescribing physician, the MRO would then report to third parties as provided in § 40.327. The provision of giving the employee five days to have his/her prescribing physician contact the MRO is not new. In fact, it has been in part 40 since the year 2000. The only difference is that previously, the MRO would first report the medical information and then wait for the prescribing physician to respond. We have no reason to believe this process is not effective. However, in response to the commenters' concerns, we are changing this process to provide the employee the opportunity to allay any MRO safety risk concerns by having his or her prescribing physician change the medication immediately, discuss other ways to eliminate or mitigate the MRO's concerns, or both change the medication and discuss alternatives. This should also reduce the number of reports MROs would make. We do not anticipate this change will increase costs because there is no new collection of information, we are simply directing the MRO to pause for five days before reporting the medical information to third parties. In fact, this pause may reduce costs because we anticipate that it should reduce the number of reports to employers under § 40.135(e).

Although we are creating a pause before the MRO reports the information so that the employee can have time to communicate with the employee's own physician, the part 40 requirement for the MRO to report the downgraded test result as a verified negative immediately remains unchanged. With this final rule, the employer will receive a negative result first and medical information, if necessary, will come later.

There may be cases where the MRO is contacted by the employee's physician before the end of the five days, but the communication between the doctors does not alleviate the significant safety risk that the MRO has identified. In such cases, the MRO can report the medical information to third parties after the discussion with the employee's physician; the MRO is not required to allow five days to elapse.

Comments that MRO decisions should be legally reviewed and that MROs and collectors should be subject to drug testing are outside the scope of this

rulemaking. Thus, they will not be addressed.

E. Fatal Flaws and Questionable Specimens

The NPRM

The NPRM proposed to add three fatal flaws to the existing list of four flaws that would cause a test to be cancelled. Each fatal flaw is an error that cannot be subsequently corrected because of the potential for each of the flaw to affect the accuracy and integrity of that specimen. The existing fatal flaws are listed in §§ 40.83 and 40.199. The proposed additional flaws were listed in a September 2016 revision of the HHS NLCP Manual. Specifically, the flaws proposed to be added were: (1) There is no CCF; (2) two separate collections were performed using one CCF; and (3) there was no specimen submitted to the laboratory with the CCF.

The NPRM also addressed a situation when there is an initial ''questionable'' specimen (*e.g.,* one calling for an immediate recollection under direct observation because the temperature was out of range or there were signs of tampering), but there was no second specimen provided (*e.g.,* because the donor was unable to provide the second specimen under direct observation, even after waiting three hours and drinking fluids). The current regulation does not provide clear instructions to the collector regarding what to do with the initial specimen in this scenario. The NPRM proposed that the collector discard the initial specimen in this case, leaving the MRO to determine whether there was a sufficient medical explanation for the ''shy bladder.''

Comments

One commenter noted that the changes to fatal flaws by the NLCP, the source of the Department's proposed changes, had not earlier been the subject of public comment before HHS changed the HHS Mandatory Guidelines in this respect. This commenter also noted that there could be inconsistencies between HHS and DOT criteria for fatal flaws.

Another commenter raised a technical point with respect to the proposed § 40.83(c)(2), requesting clarification to say that a CCF without an accompanying specimen would become a fatal flaw only when an actual specimen had been collected. The commenter explained that, in a shy bladder or collection site refusal situation, a collector might mistakenly send a CCF to the laboratory, even when there was no specimen to send. If the test were cancelled by the laboratory, then there would be no shy bladder evaluation and, what may have been a refusal would result in a cancelled test. Two other commenters, also referred to this same situation, saying that the solution would be to clarify that this fatal flaw exists only when a specimen was actually collected.

With respect to the ''questionable specimen'' scenario on what to do with a first specimen that was collected and was out of temperature range or showed signs of tampering, but then a sufficient second specimen was not collected under direct observation, we received ten comments. All of these comments on the proposal supported it.

DOT Response

Three commenters who were concerned about a fatal flaw cancelling a test in the ''insufficient specimen'' scenario raised a good point related not only those scenarios, but also for collection site walk-away refusals. The Department will adopt these commenters' suggestions that a fatal flaw will exist in cases where a CCF is sent to the laboratory without a specimen, as long as there a specimen was actually collected. This will avoid a situation in which, for example, there was a CCF filled out for an original specimen, a shy bladder situation occurred, no second specimen was collected, but the CCF was mistakenly sent to the laboratory. The ultimate result of this process—a determination by the MRO about whether there was a sufficient medical explanation for the employee's failure to provide a full specimen—could be confused by a laboratory decision that there was a fatal flaw, even though the fatal flaw has no impact upon the MRO's determination of a refusal. Accordingly, we have amended §§ 40.83 and 40.199, both of which deal with this particular fatal flaw.

Otherwise, the Department is adopting its proposal with respect to fatal flaws without change. Commenters had the opportunity to comment on these proposed changes in context of the DOT NPRM, whether or not HHS provided such an opportunity concerning its changes to the HHS Mandatory Guidelines.

Regarding the ''questionable specimen'' scenario, the DOT is adopting the proposed amendment to Part 40 without change. All commenters agreed that, when a second specimen in a situation calling for a recollection under direct observation cannot be obtained for ''shy bladder'' reasons, it made sense to discard the first questionable specimen and rely on the insufficient specimen process for a result. In the insufficient specimen process, an MRO with advice from a referral physician determines whether there was a refusal to test or not. This approach of discarding the insufficient specimen is simple and direct, and should reduce opportunities for confusion. It is also a cost-relieving provision.

V. Section-by-Section Analysis

This portion of the preamble discusses each of the provisions of Part 40 amended by this final rule, including responses to comments on matters that have not previously been discussed under ''Main Policy Issues.''

A. Sections Concerning the Addition of Four Opioids to the DOT Drug Testing Panel

In the ''Main Policy Issues'' portion of the preamble, we discussed the proposal to add four semi-synthetic opioids to the DOT drug testing panel and responded to comments on that proposal. As noted there, the Department is adopting this proposal. The primary section in which the Department's decision to add these substances is carried out is § 40.87, which lists each substance that is part of the DOT panel, including the additions made by this final rule, together with the initial test and confirmatory test cutoffs. There are parallel changes in § 40.85(d) and Appendices B and C, in each case changing the term ''opiates'' to ''opioids.'' A commenter suggested rewording the proposed language in § 40.87, footnote 3, to match the language in the HHS Mandatory Guidelines. After discussing this point with HHS, we changed the wording from what was proposed to a more accurate and plain language version, with no intended change in meaning. In §§ 40.137 and 40.139, a slightly different term, ''semi-synthetic opioids,'' is used in the contexts of differing standards for MRO verification of ''natural'' opioid laboratory positives (*e.g.,* codeine) and the newly added semi-synthetic opioids to the DOT drug testing panel (*e.g.,* hydrocodone).

B. Definitions

The final rule, like the NPRM, clarifies the definition of ''The Department, DOT Agency'' and ''Drugs.'' The main change in the latter is to use the broader term ''opioids'' in place of ''opiates,'' to encompass the substances that the rule adds to the DOT drug panel. There were few comments on the proposed changes to this section.

One commenter requested that we clarify that NASA or its contractors were not DOT agencies. As readers of the existing and new versions of this

section will note, NASA is not listed as a DOT agency. As a Federal agency, NASA is subject to the Federal employee program that uses the HHS Mandatory Guidelines. Contractors to or employees of NASA or other Federal agencies who are subject to DOT regulations in their own right (*e.g.,* because they perform safety-sensitive functions as pilots, drivers or mariners who would be covered by the respective applicable DOT agency regulations) would be covered by applicable DOT rules.

We also included a technical amendment to this section based on a recent official interpretation. Specifically, we are clarifying that the USCG is only a DOT agency for the drug testing component of Part 40 since its regulation (46 CFR part 16) incorporates Part 40 for drug testing and not for alcohol testing.

C. Three Provisions Related to Urine Specimens

Fatal Flaws

The rationale for the Department's decision to add new items to the list of ''fatal flaws'' and our response to comments on the proposal to do so, are found in the ''Main Policy Issues'' portion of this preamble. The affected provisions are §§ 40.83(c) (concerning fatal flaws detected by a laboratory as it processes a specimen) and 40.199 (concerning the MRO's responsibility to cancel tests in which fatal flaws have been found).

Shy Bladder Process—''Questionable Specimens''

As discussed under the Fatal Flaws and Questionable Specimens heading in the Main Policy Issues portion of this preamble, after considering the comments on the subject, the Department will require the collector to discard any initial collection that was questionable (*e.g.,* out of temperature range, showing signs of tampering). The MRO would then evaluate a ''shy bladder'' situation that developed if the employee was unable to provide a sufficient specimen for the direct observation recollection. This provision has been incorporated into § 40.193(b)(4).

Only Urine Specimens Are Authorized for Testing

The NPRM proposed to add a new section, § 40.210, clarifying, that Part 40 authorizes drug testing of only urine specimens screened and confirmed at HHS-certified laboratories. This means that point-of-collection instant tests, hair tests, and oral fluid tests are not presently allowed under Part 40 for DOT drug testing. There were four comments on this proposal, all of which agreed with it.

The Department is aware that a rulemaking that would authorize oral fluid testing under the HHS Mandatory Guidelines is currently in progress at HHS. If HHS authorizes this method of testing, DOT could follow on with its own rulemaking to conform Part 40 to the revision of the HHS Mandatory Guidelines, as long as the HHS final rule is in accordance with OTETA's other requirements.

Likewise, it is our understanding that HHS is considering whether to authorize hair testing as part of the HHS Mandatory Guidelines. As in the case of oral fluids, and given the Department's statutory obligation to remain consistent with the HHS Mandatory Guidelines and with OTETA's other obligations, if HHS authorizes the use of hair testing in a manner consistent with OTETA requirements, then the Department would follow suit in its own rulemaking to amend Part 40.

We are also aware that there are unusual circumstances in which testing other than urine testing can take place. For example, Federal Railroad Administration (FRA) post-accident testing, under the authority of 49 CFR part 219 (not Part 40), can involve blood testing and the testing of other body fluids and tissues. Likewise, the USCG, under the authority of 46 CFR part 4, may require other bodily fluids or tissues be chemically tested to determine the presence or drugs or alcohol for post-accident events. Part 40 recognizes certain situations when a clinical evaluation performed under the direction of the MRO is appropriate, and in those events the MRO may choose to use another testing methodology (49 CFR 40.195(a)(3)). The MRO may use another testing methodology in these narrow situations for the purpose of being able to clarify that a donor is not using drugs, but not to show a positive test result. However, these situations are not inconsistent with the new § 40.210, which states that for drug tests required by Part 40, only urine testing is authorized.

D. Removing the Blind Specimen Testing Requirement

The rationale for the Department's decision to remove the blind specimen testing requirement, and our response to comments on the proposal to do so, are found in the ''Main Policy Issues'' portion of this preamble. As a result of this decision, sections, or references in sections, pertaining to the former blind testing requirement have been removed. The affected provisions are in §§ 40.03, 40.29, 40.37, 40.103, 40.105, 40.123, 40.169, and 40.189.

E. Prohibition on DNA Testing of Urine Specimens

The NPRM proposed adding a sentence to paragraph (f) of this section further emphasizing the existing DOT prohibition on the use of DNA testing on DOT drug testing specimens (§ 40.13(e)). The five commenters who spoke to the proposal supported it. Several comments supported the Department's long-standing grounds for its position (*e.g.,* that the CCF process provides sufficient evidence of the identity of a specimen; that DNA testing would show only that an original specimen and a reference specimen that the donor provided behind closed doors were different, not that a donor's specimen was misidentified). Some commenters added that the prohibition would preclude further intrusions into an employee's privacy and potential discrimination by employers against drivers whose DNA test revealed a potential medical condition. The new language states that DNA testing is not authorized and ODAPC will not give permission for such testing. The Department is adopting the proposed language without change.

F. Legal Prescriptions and Additional Testing

As discussed under the MRO Practice Issues heading in the Main Policy Issues portion of this preamble, the Department proposed to add a reference to legal prescriptions under the CSA to this section, as well as to authorize MROs to obtain THC–V testing and testing for D,L stereoisomers of amphetamine and methamphetamine at their discretion. After considering the comments, almost all of which were supportive, as discussed above, the Department has adopted this proposal with the slight modification of ''consistent with'' instead of ''under,'' and incorporated these changes in §§ 40.137(b) and 40.135(e) for consistency.

G. Minor Modification to Certain Section Headings

The NPRM proposed to modify the section heading of §§ 40.137 and 40.139 to incorporate the addition of the four new semi-synthetic opioids. There were 10 comments on this proposal, all of which agreed with it. The Department is adopting the proposed language without change. Also, as commenters correctly pointed out, and as is discussed under the MRO Practice Issues heading in the ''Main Policy Issues'' portion of this

preamble, the proposed § 40.139(c)(3) should be rephrased. This paragraph should provide that, in a situation where there is a laboratory positive for morphine or codeine (in the absence of a finding of 6–AM) below 15,000 ng/mL, and the employee admits to unauthorized use of one of the semi-synthetic opioids, the MRO does not verify the test as positive. The final rule makes this correction.

H. Subscribing to the ODAPC List-Serve

The rationale for the Department's decision to require key persons in the DOT testing process to subscribe to the ODAPC, and our response to comments on the proposal do so, are found in the ''Main Policy Issues'' portion of this preamble. The Department is adopting the proposed language without change. The affected provisions are §§ 40.33 (collectors), 40.121 (MROs), 40.213 (BATs/STTs), and 40.281 (SAPs).

I. Listing SAP Certification Organizations on ODAPC's Web Site

The NPRM proposed moving organizations who provide SAP credentialing listed in § 40.281(a)(6) out of Part 40 and onto the ODAPC Web site. We proposed this change to provide greater flexibility for changes to the list and quicker updates. There were four comments to the proposal, all of which supported it. The final rule adopts the proposal without change.

One commenter asked for clarification regarding whether there is a ''grace'' period when an organization is removed from the list and what the timeline would be for a SAP to be 're-qualified' under one of the approved organizations. When a certifying organization is added or removed from the list, the Department intends to notify the list-serve subscribers of the change. Since all SAPs will be required to subscribe to the list-serve, each SAP would receive this important notification. However, specific details regarding ''grace periods for requalification'' would depend upon the facts of each situation and would, therefore, be guidance that ODAPC would provide at the relevant times.

J. Prohibition From Using the DOT or DOT Agency Name, Logos, or Other Official Branding

The Department is concerned that some service agents misrepresented themselves as approved, certified, or endorsed by the Department, by means including, but not limited to, the use of a DOT or DOT agency logo, title, or emblem. Where we have found these misuses of DOT or DOT agency names, logos, or other official branding, ODAPC has taken action under the Public Interest Exclusion provisions to issue Notices of Corrective Actions.

The Department does not approve, certify, or endorse service agents or their activities. We regard the use of such symbols or other means as implying approval, certification or endorsement. When a service agent makes such a representation, the Department views it as false and deceptive holding-out by a party not part of the Federal Government. For this reason, the NPRM proposed to specifically add such false representations to the grounds on which the Department could initiate a PIE proceeding against the offender.

Five of the six comments on this subject supported this proposal and its rationale. The sixth disagreed, on the basis that DOT did not articulate a safety basis for the proposal and that it could impose an unnecessary burden on companies using agency ''brands'' to distinguish tests.

The basis for the proposal is to prevent false and deceptive representations by organizations marketing to DOT employers. Such misrepresentations are at least misleading and at worst deliberately deceptive. When a private party misrepresents that it is part of or that it is certified, approved or endorsed by the DOT or a DOT agency, this can have safety implications for an employer that relies on the holding out of an endorsement if the service agent does not provide services in accordance with DOT requirements. The Department and the DOT Agencies are not ''brands,'' and their names should not be used as if they were.

One of the commenters who supported the proposal noted that training materials should be able to include materials that may contain screen shots or references to DOT Web sites, and publications that contain DOT logos, titles, etc. We agree. We appreciate that employers and service agents reproduce our publications and other materials containing the DOT logos and this regulatory change would not prohibit members of the public from using and/or reproducing the materials that are produced by ODAPC and/or the DOT Agencies. The non-deceptive use of such training materials is not something that we would view as violating our rules because it does not indicate approval or certification by the Department or a DOT agency.

K. Removing Obsolete Compliance Dates

The NPRM proposed removing obsolete compliance dates from several sections. For example, former § 40.33(d) established compliance dates for training then-existing collectors in 2001–2003. Similar training deadlines, all of which were established as part of the transition to the 1999 revision of Part 40 from previous editions, were found in §§ 40.121 (MROs), 40.213 (BATs/STTs), and 40.281 (SAPs). In addition, §§ 40.45 and 40.203 contained a 2011 date to complete a transition to a revised custody and control form. There were four comments on these changes, all of which supported them. These proposed changes are adopted in the final rule. In § 40.121(d), we also eliminated, as a commenter suggested, a reference to continuing education units tied to one of the obsolete compliance dates.

L. Editorial Corrections

In drafting the NPRM, we noted a few sections in which editorial corrections would be helpful for purposes of clarification. In § 40.67(n), we changed ''collector'' to ''service agent'' to clarify that all service agents had a responsibility to ensure that a directly observed collection was conducted when necessary. In § 40.162(c) a reference to § 40.159(f) was corrected to cite paragraph (g) of that section. In § 40.233(b)(4), a reference to § 40.333(a)(2) was corrected to cite paragraph (a)(3) of that section. There were three comments on these proposals, all of which agreed with the proposed changes. These changes are adopted in the final rule.

M. Updating Specified Appendices to Part 40

The NPRM proposed to update the following appendices: Appendices B and C, to add the four semi-synthetic opioids to the drugs listed and remove MDEA; Appendix D, to update a web link; and Appendix H, to remove the instruction sheet for the Management Information System Data Collection from our regulations and move it to our guidance material located on our Web site. The reason for proposing to move the MIS instruction sheet to the ODAPC Web site was to provide greater flexibility for changes and/or updates to this document. There were seven comments to the proposal to update the appendices, all of which supported it. The final rule adopts this proposal without change.

N. Updating Web Links

The Department proposed to update web links in the rule text that have changed on our DOT Web site. There were four comments to this proposal, all of which supported the proposal. In several sections, the Department updated the ODAPC Web address to the

current *http://www.transaportation.gov/odapc.* The affected sections are §§ 40.33, 40.45, 40.105, 40.121, 40.205, 40.213, 40.225, 40.281, and 40.401. In addition, in Appendix D, the Department updated the Web link for reporting split specimens failing to reconfirm to *https://www.transportation.gov/content/split-specimen-cancellation-notification-49-cfr-part-40187-appendix-d.* These updates are adopted in the final rule.

O. Alcohol Testing Device Web Links

Though not among the originally proposed changes, we are making a technical amendment to make it easier to permit employers to use alcohol testing devices approved by the National Highway Traffic Safety Administration (NHTSA), which are the only devices permitted to be used for DOT alcohol testing. Since 1994, the regulation has required employers and service agents to only us a device once the device was approved by NHTSA and appeared on NHTSA's conforming products lists (CPLs) for alcohol screening devices (ASDs) and Evidential Breath Testing Devices (EBTs). NHTSA used the CPLs to add approved devices and remove devices as appropriate. Because there was no regular schedule with which the CPLs were published, employers and alcohol technicians were prohibited by the regulation from using newly approved devices because a new CPL was not published. To permit employers and alcohol technician the ability to use a device as soon possible after NHTSA approves it, we will now list the NHTSA-approved ASDs on a new ODAPC Web page entitled ''Approved Screening Devices to Measure Alcohol in Bodily Fluids'' and we will now list the NHTSA approved EBTs on new ODAPC Web page for ''Approved Evidential Breath Measurement Devices.'' Although, we will no longer require regulated parties to check the actual CPL, we will continue to rely on NHTSA for approval and removal of the devices. ODAPC will take responsibility for creating and continuing to keep the Web pages updated whenever NHTSA notifies us that a device has been approved and added to the list, or removed from the list. This is purely an administrative change as to where to find the list of approved devices. There are no costs associated with this technical change and it should be burden-reducing because it will avoid confusion that has been occurring for DOT-regulated parties and for the product manufacturers. Accordingly, we have made changes to §§ 40.3; 40.229; 40.231; 40.233 and 40.235.

VI. Other Comments

There were two comments concerning the cost-benefit analysis. Those comments are addressed in the regulatory analysis section titled Executive Order 12866 and 13563 and DOT's Regulatory Policies and Procedures.

There were a number of comments that were outside the scope of the NPRM, such as including (or not including) hair or oral fluid testing in the DOT program, reducing the subject matter of refresher training for BATs/STTs, including additional drugs (*e.g.,* benzodiasepines) in the drug testing panel, providing more oversight of MRO decisions, changing some criteria for testing in the Federal Transit Administration rules (49 CFR part 655), broadening the use of electronic signatures in the program, allowing laboratories to use their own protocols for substituted specimen situations, reporting from laboratories to MROs through a third party, and criteria for determining when a test is considered to have been refused. While these and other matters may be worth consideration at a later time, they are outside the scope of the present rulemaking.

VII. Regulatory Analyses and Notices

Changes to Federal regulations are subject to a number of regulatory requirements, which are identified and discussed below. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 601 *et seq.,* requires agencies to analyze the economic impact of regulatory changes on small entities. The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that DOT consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from OMB for each collection of information it conducts, sponsors, or requires through regulations. Section (a)(5) of division H of the Fiscal Year 2005 Omnibus Appropriations Act, Public Law 108–447, 118 Stat. 3268 (Dec. 8, 2004) and section 208 of the E-Government Act of 2002, Public Law 107–347, 116 Stat. 2889 (Dec. 17, 2002) requires DOT to conduct a Privacy Impact Assessment (PIA) of a regulation that will affect the privacy of individuals. Finally, the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) requires DOT to analyze this action to determine whether it will have an effect on the quality of the environment. This portion of the preamble summarizes the DOT's analyses of these impacts with respect to this rule.

Executive Order 12866 and 13563 and DOT's Regulatory Policies and Procedures

This final rule is not a significant regulatory action under Executive Order 12866 and 13563, as well as the Department's Regulatory Policies and Procedures (44 FR 11034). It proposes to harmonize specific Part 40 procedures with recently mandated HHS Guidelines and, in the interest of improving efficiency, make certain program modifications. As such, this proposal would not impose any major policy changes and would not impose any significant new costs or burdens.

Costs

The NPRM

As noted in the Department's NPRM, the HHS Mandatory Guidelines addressed the burdens associated with the addition of new drugs to the drug-testing panel (82 FR 7920, January 23, 2017). The cost impact of drug testing for oxycodone, oxymorphone, hydrocodone, and hydromorphone would be minimal because HHS determined that all HHS-certified laboratories testing specimens from Federal agencies are currently conducting tests for one or more of these analytes on non-regulated urine specimens. HHS further indicated in its analysis that laboratory personnel currently are trained to test for the additional drugs and test methods already have been implemented. Many HHS-certified laboratories conduct non-regulated tests for transportation employers who already include the four semi-synthetic opioids in their non-regulated testing programs. For those employers, therefore, shifting the four drugs from non-regulated tests to regulated tests would not increase testing costs.

HHS determined that the costs associated with implementation of testing for the four additional semi-synthetic opioids would be approximately $0.11–$0.30 per test. Once the testing has been implemented, the cost per specimen for initial testing for the added analytes would range from $.06 to $0.20 due to reagent costs. Current costs for each confirmatory test range from $5.00 to $10.00 for each specimen reported as positive due to

costs of sample preparation and analysis. HHS indicated that based on information from non-regulated workplace drug testing for these analytes in 2012 and testing performed on de-identified federally regulated specimens in 2011, approximately 1% of the submitted specimens is expected to be confirmed as positive for the added analytes. Therefore, HHS indicates that the added cost for confirmatory testing will be $0.05 to $0.10 per submitted specimen.

Approximately 6.3 million DOT-regulated tests occur per year. DOT considered the maximum ranges HHS provided in its analysis. Therefore, with the projected maximum implementation cost per specimen of $0.30, the maximum cost per specimen of initial testing at $0.20, and the maximum cost per specimen of confirmation testing at $0.10, the additional cost per urine test would be an additional $0.60. Under the new HHS Mandatory Guidelines, and based on an estimated 6.3 million DOT tests conducted annually, a cost of approximately $3,800,000 would be realized by employers subject to DOT-regulated testing ($0.60 × 6,300,000 DOT tests annually = $3,780,000).

HHS indicated that there will be minimal costs associated with adding MDA as an initial test analyte because the current immunoassays can be adapted to test for this analyte. According to HHS, before a lab is allowed to test regulated specimens for MDA, HHS must test three groups of performance test, or ''PT'' samples. HHS provides the PT samples at no cost to its certified laboratories but HHS estimates that the laboratory costs to conduct the PT testing would range from $900 to $1,800 for each certified laboratory. There are approximately 27 HHS-certified laboratories who process DOT drug tests. With the maximum cost estimate of $1,800 for each certified laboratory, a cost of approximately $48,600 would be realized for DOT ($1,800 × 27 laboratories = $48,600.)

Testing for additional drugs would result in new MRO costs, as MROs would have additional review and verification to conduct. Based on the positivity rates from non-regulated workplace drug testing and the additional review of specimens with a laboratory confirmed positive for prescription medications, HHS estimates that MRO costs would increase by approximately 3%. The additional costs for testing and MRO review would be incorporated into the overall cost for the Federal agency submitting the specimen to the laboratory. HHS bases the estimation of costs incurred on overall cost to the Federal agency affected because cost is usually based on all specimens submitted from an agency, rather than individual specimen testing costs or MRO review of positive specimens. Based on this analysis, therefore, DOT projects an additional MRO cost of $189,000 (.03 projected increase × 6,300,000 DOT tests annually).

Comments

There were two comments on our cost estimates. One questioned the projected cost savings of the proposal to eliminate the blind specimen testing requirement. Specifically, the commenter said that the cost savings were inflated because we did not take into consideration the 50-blind specimen limit per quarter and that blinds are not required to be submitted for employers with fewer than 2,000 employees. The same commenter also questioned why DOT did not factor in increased potential costs that were mentioned by commenters in the HHS rulemaking such as, increased estimated MRO costs of 10% and start-up costs to laboratories to implement testing for the additional analytes. Another commenter requested that we further explain the analysis for the costs associated with confirmation testing. Specifically, the commenter wanted us to adjust the cost-benefit analysis to address confirmation test costs for the four prescription drug initial positive tests, not just the projected 1% of the specimens that are confirmed positive. The commenter suggested that, when making this calculation, DOT consider using laboratory data for the percentage of positive test results that will require a confirmation test.

DOT Response

Regarding the blind specimen costs, our response is included in the 'cost-savings' paragraph of this section. As for the comment about not factoring in potential costs that were mentioned by commenters in the HHS rulemaking, we did not see the need to address them since HHS already responded to those comments (82 FR 7931). In short, HHS assumed the start-up costs for testing the four semi-synthetic opioids, and changes to the amphetamines would be de minimis given that laboratories could use existing immunoassays.

To further explain the costs associated with verifying test results for the additional semi-synthetic opioids, we agree with the commenters that the 3% estimated by HHS may not be sufficient for calculating the costs to the DOT-regulated industries. We have added the full cost of the MRO review of the non-negative results for the four semi-synthetic opioids instead of just the additional 3% estimated by HHS. As we understand it, the upper limit cost of a MRO review for non-negatives is approximately $60. Given the estimated 1% (63,000) of specimens confirming for the semi-synthetic opioids, the estimated additional costs for MRO reviews resulting from this final rule would be $3,780,000 ($60 × 63,000).

Regarding the specific comment for DOT to consider the confirmation test costs for the four prescription drug initial positive tests, not just the projected 1% of the specimens that are confirmed positive, the Department has no basis to conclude that there will be an additional cost to DOT-regulated employers for specimens that screen positive but do not confirm as positive. Furthermore, the commenters did not provide any data to support their assertion. As we understand it and as explained in our ''What Employers Need to Know About DOT Drug and Alcohol Testing'' handbook, employers may choose one of two pricing structures, bundled and unbundled. Bundled pricing means that one-price-fits-all. The price of the bundle is dependent on various factors like volume and positive rate. In unbundled pricing, it is 'a la carte' pricing for each test the laboratory has to run. Our projected costs assume a bundled pricing structure since it appears to be widely used.

We also want to address two issues related to information we provided in our NPRM. First, we incorrectly associated the full cost of the Proficiency Testing (PT) to only the cost of testing for MDA. However, based on HHS final rule [82 FR 7931], the cost for PT testing ($48,600) is for all the semi-synthetic opioids and MDA, not just MDA. Accordingly, our cost analysis now correctly articulates that the cost of PT is for all the compounds as outlined in HHS' final rule. This does not change the quantified cost of the rule. Second, we estimated that the per specimen cost would be an additional $0.60 (implementation cost of $0.30 and a maximum screening and confirmation testing cost of $0.30) for a total cost of $3,780,000 ($0.60 × 6,300,000). As we mentioned earlier, HHS assumed the start-up costs would be de minimis. DOT agrees that the start-up costs are expected to be de minimis. Therefore, we have removed the implementation costs (approximately an additional $0.30 per specimen) that were originally proposed. Thus, a cost of $1,890,000 ($0.30 × 6,300,000) would be realized by employers subject to DOT-regulated testing and not the $3,780,000 we originally estimated.

On a final note, we acknowledge potential costs that were not discussed in the NPRM for those employees with positive test results that would potentially go through the return-to-duty process. As we mentioned earlier, we estimated that 1% (63,000) of the specimens will be confirmed for one or more of the semi-synthetic opioids. Based on MRO's experiences in non-DOT testing that 80% of the semi-synthetic results will be downgraded to 'negative' due to legitimate medical explanations (*e.g.,* valid prescriptions), we estimate that only 12,600 of the 63,000 laboratory confirmed positives will be reported by the MRO as verified positive. We further estimate that, of the 12,600 verified positive results, approximately 25% (3,150) will participate in the return-to-duty process. The other individuals will not return to positions that require DOT testing or will continue working at their non-DOT positions. With the mandatory Substance Abuse Professional (SAP) evaluation costing approximately $400, the return-to-duty test costing approximately $50, and the minimum of six follow-up tests costing approximately $300 (6 × $50), the return-to-duty cost would be approximately $750 per employee. Altogether, the Department estimates the total return-to-duty costs to be approximately $2,362,500 (3,150 × $750).

This estimate does not include costs associated with education or treatment that the employee completes before taking the required return-to-duty test. A verified positive result merely identifies that the individual needs to seek treatment. The positive result does not create the employee's condition. By seeking treatment sooner than later, the potential costs associated with education and treatment for an individual that tests positive could be less than if the employee did not test positive.

Cost-Savings

The NPRM

In the NPRM, DOT estimated a cost-savings of at least $3.1 million per year from the elimination of the requirement for employers to submit blind specimen testing to laboratories (estimated at approximately $50 per test). This estimate of cost-savings is based on the regulatory analysis performed when DOT reduced blind specimen testing in 2000 (65 FR 79462, 79517, Dec. 19, 2000), adjusted for inflation. Based on the blind specimen requirements made effective in 2000 for employers to submit 1% of 6,300,000 DOT tests for blind testing conducted annually at a cost of approximately $50 per test yields a cost-savings of $3,150,000 (63,000 × $50).

Comments

One commenter suggested that the savings from the elimination of blind specimen testing had been overestimated, because the cost-benefit analysis did not take into account the 50-specimen maximum and the requirement that only employers with more than 2,000 covered employees were required to submit blind specimens.

DOT Response

We revised our calculation to take into consideration the commenter's concerns. Our revised calculation takes into account: The estimated number of DOT-regulated employers (728,324) and employees (5,192,065); the known number of employers (175) with employee counts from 2,000 to 50,000; an estimated number of C/TPAs (2,158) with an employee count of 2,000; the 25% random testing rate and estimated number of other tests; the 1% blind specimen rate; and an estimated cost of $50 per blind specimen test. The estimated number of C/TPAs is based on the assumption that the smaller employers (employers with less than 2,000 employees), would join a C/TPA to administer their random testing pools and other aspects of the DOT program and include them in their consortium. Accordingly, we project annual cost-savings from eliminating the blinds would be $1,298,016. We have placed in the docket for this rulemaking a document describing the basis for this estimate and calculation in greater detail.

Net Economic Impact

The DOT believes the projected cost to the DOT of implementing testing for the additional drugs being added to the drug-testing regimen will be minimal. The projected $1,938,600 for the four semi-synthetic opioid drugs and PT testing ($1,890,000 and $48,600 respectively) and the $3,780,000 projected MRO costs would result in total projected costs of $5,718,600. The projected cost savings from eliminating the blind specimen testing requirement would be $1,298,016. The estimated net cost impact of this proposal, therefore, would be $4,420,584 ($5,718,600 − $1,298,016) per year. This rule will not have an economically significant impact under Executive Order 12866 because it would not have an annual effect on the economy of $100 million or more, nor do we have any basis to conclude that it would adversely affect any sector of the economy.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354, ''RFA''), 5 U.S.C. 601 *et seq.,* establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed rule would have a significant economic impact on a substantial number of small entities. If the agency determines that it would, the agency must prepare a regulatory flexibility analysis. However, if an agency determines that it is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) provides that the head of the agency may so certify, and a regulatory flexibility analysis would not be required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This final rule conforms the existing DOT drug-testing panel to recently issued HHS Mandatory Guidelines and, with certain minor amendments (mostly editorial), to improve the efficiency of the DOT drug-testing program. The net costs of this rule do not constitute a significant burden to any entity, small or otherwise. Consequently, the DOT certifies, under the RFA, that this rule will not have a significant economic impact on a substantial number of small entities.

Federalism

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This rule does not include requirements that (1) have substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government, (2) impose substantial direct compliance costs on State and local governments, or (3)

preempt State law. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

Paperwork Reduction Act/Privacy Act

The Paperwork Reduction Act requires that the DOT consider the impact of paperwork and other information collection burdens imposed on the public. Information collections for Part 40 currently are approved under OMB Control No. 2105–0529. The Privacy Act provides safeguards against invasion of personal privacy through the misuse of records by Federal Agencies. It establishes controls over what personal information is collected, maintained, used and disseminated by agencies in the executive branch of the Federal government.

This rule does not create any new paperwork or other information collection burdens needing approval, nor would it require any further protections under the Privacy Act.

National Environmental Policy Act

The Department has analyzed the environmental impacts of this action pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). See 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, Federal agencies also must consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. This rule does not meet any of these criteria. The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) does not require a written statement for this final rule because the rule does not include a Federal mandate that may result in the expenditure in any one year of $155,000,000 or more by State, local, and tribal governments, or the private sector.

Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 titled ''Reducing Regulation and Controlling Regulatory Costs,'' directs that, unless prohibited by law, whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation, it shall identify at least two existing regulations to be repealed. In addition, any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

List of Subjects in 49 CFR Part 40

Administrative practice and procedures, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

The Final Rule

For reasons discussed in the preamble, the Department of Transportation is amending part 40 of Title 49 Code of Federal Regulations, as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

■ 1. The authority citation for 49 CFR part 40 is revised to read as follows:

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

■ 2. Amend § 40.3 as follows:
■ a. Revise the definition of ''*Alcohol screening device (ASD)*'';
■ b. Remove the definition ''*Blind specimen or blind performance test specimen*'';
■ c. Revise and reorder (in correct alphabetical order) the definition ''*DOT, the Department, DOT Agency*'';
■ d. Revise the definition ''*Drugs*''; and
■ e. Revise the definition of ''*Evidential breath testing device (EBT)*''.

The revisions read as follows:

§ 40.3 What do the terms used in this part mean?

* * * * *

Alcohol screening device (ASD). A breath or saliva device, other than an EBT, that is approved by the National Highway Traffic Safety Administration (NHTSA) and appears on ODAPC's Web page for ''Approved Screening Devices to Measure Alcohol in Bodily Fluids'' because it conforms to the model specifications from NHTSA.

* * * * *

DOT, The Department, DOT Agency. These terms encompass all DOT agencies, including, but not limited to, the Federal Aviation Administration (FAA), the Federal Railroad Administration (FRA), the Federal Motor Carrier Safety Administration (FMCSA), the Federal Transit Administration (FTA), the National Highway Traffic Safety Administration (NHTSA), the Pipeline and Hazardous Materials Safety Administration (PHMSA), and the Office of the Secretary (OST). For purposes of this part, the United States Coast Guard (USCG), in the Department of Homeland Security, is considered to be a DOT agency for drug testing purposes only since the USCG regulation does not incorporate Part 40 for its alcohol testing program. These terms include any designee of a DOT agency.

* * * * *

Drugs. The drugs for which tests are required under this part and DOT agency regulations are marijuana, cocaine, amphetamines, phencyclidine (PCP), and opioids.

* * * * *

Evidential Breath Testing Device (EBT). A device that is approved by the National Highway Traffic Safety Administration (NHTSA) for the evidential testing of breath at the .02 and .04 alcohol concentrations, and appears on ODAPC's Web page for ''Approved Evidential Breath Measurement Devices'' because it conforms with the model specifications available from NHTSA.

* * * * *

■ 3. Revise § 40.26 to read as follows:

§ 40.26 What form must an employer use to report Management Information System data to a DOT agency?

As an employer, when you are required to report MIS data to a DOT agency, you must use the U.S. Department of Transportation Drug and Alcohol Testing MIS Data Collection Form to report that data. You must use the form at appendix H to this part. You may view and download the instructions on the Department's Web site (*https://www.transportation.gov/odapc*). You must submit the MIS report in accordance with rule requirements (*e.g.,* dates for submission, selection of companies required to submit, and method of reporting) established by the DOT agency regulating your operation.

§ 40.29 [Amended]

■ 4. Amend § 40.29 by removing the entry ''§§ 40.103–40.105—Blind specimen requirements.''

■ 5. Amend § 40.33 by revising paragraphs (a) and (d) to read as follows:

§ 40.33 What training requirements must a collector meet?

* * * * *

(a) *Basic information.* You must be knowledgeable about this part, the current ''DOT Urine Specimen Collection Procedures Guidelines,'' and DOT agency regulations applicable to the employers for whom you perform collections. DOT agency regulations, the DOT Urine Specimen Collection Procedures Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington DC, 20590, 202–366–3784, or on the ODAPC Web site (*https://www.transportation.gov/odapc*). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at: *https://www.transportation.gov/odapc/get-odapc-email-updates.*

* * * * *

(d) You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

* * * * *

§ 40.37 [Amended]

■ 6. Amend § 40.37 by removing the entry ''§ 40.103—Processing blind specimens.''

§ 40.45 [Amended]

■ 7. Amend § 40.45(a) by removing the parenthetical ''(*http://www.dot.gov/odapc*)'' and adding, in its place ''(*http://www.transportation.gov/odapc*)'' and § 40.45(b) by removing the parenthetical ''(*e.g.,* that after November 30, 2011, they must not use an expired CCF for DOT urine collections)''

■ 8. Amend § 40.67 by revising paragraph (n) to read as follows:

§ 40.67 When and how is a directly observed collection conducted?

* * * * *

(n) As a service agent, when you learn that a directly observed collection should have been collected but was not, you must inform the employer that it must direct the employee to have an immediate recollection under direct observation.

■ 9. Amend § 40.83 by revising paragraph (c) to read as follows:

§ 40.83 How do laboratories process incoming specimens?

* * * * *

(c) You must inspect each specimen and CCF for the following ''fatal flaws:''

(1) There is no CCF;

(2) In cases where a specimen has been collected, there is no specimen submitted with the CCF;

(3) There is no printed collector's name and no collector's signature;

(4) Two separate collections are performed using one CCF;

(5) The specimen ID numbers on the specimen bottle and the CCF do not match;

(6) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (h) of this section);

(7) There is an insufficient amount of urine in the primary bottle for analysis, unless the specimens can be redesignated (see paragraph (h) of this section).

* * * * *

■ 10. Revise § 40.85 to read as follows:

§ 40.85 What drugs do laboratories test for?

As a laboratory, you must test for the following five drugs or classes of drugs in a DOT drug test. You must not test ''DOT specimens'' for any other drugs.

(a) Marijuana metabolites.

(b) Cocaine metabolites.

(c) Amphetamines.

(d) Opioids.

(e) Phencyclidine (PCP).

■ 11. Amend § 40.87 by revising paragraph (a) to read as follows:

§ 40.87 What are the cutoff concentrations for drug tests?

(a) As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmatory drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites (THCA) [2]	50 ng/mL [3]	THCA	15 ng/mL.
Cocaine metabolite (Benzoylecgonine)	150 ng/mL [3]	Benzoylecgonine	100 ng/mL.
Codeine/ Morphine	2000 ng/mL	Codeine	2000 ng/mL.
		Morphine	2000 ng/mL.
Hydrocodone/ Hydromorphone	300 ng/mL	Hydrocodone	100 ng/mL.
		Hydromorphone	100 ng/mL.
Oxycodone/ Oxymorphone	100 ng/mL	Oxycodone	100 ng/mL.
		Oxymorphone	100 ng/mL.
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL.
Amphetamine/ Methamphetamine	500 ng/mL	Amphetamine	250 ng/mL.
		Methamphetamine	250 ng/mL.
MDMA [4]/MDA [5]	500 ng/mL	MDMA	250 ng/mL.
		MDA	250 ng/mL.

[1] For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):

Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

[2] An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

[3] *Alternate technology (THCA and Benzoylecgonine):* When using an alternate technology initial test for the specific target analytes of THCA and Benzoylecgonine, the laboratory must use the same cutoff for the initial and confirmatory tests (i.e., 15 ng/mL for THCA and 100ng/mL for Benzoylecgonine).

[4] Methylenedioxymethamphetamine (MDMA).

[5] Methylenedioxyamphetamine (MDA).

* * * * *

§ 40.103 [Removed]

■ 12. Remove § 40.103.

§ 40.105 [Removed]

■ 13. Remove § 40.105.

■ 14. Amend § 40.121 by revising paragraphs (b)(3) and (c)(3), and the paragraph (d) introductory text to read as follows:

§ 40.121 Who is qualified to act as an MRO?

* * * * *

(b) * * *

(3) You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at *https://www.transportation.gov/odapc/get-odapc-email-updates.* DOT agency regulations, DOT MRO Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–3784), or on the ODAPC Web site (*http://www.transportation.gov/odapc*).

(c) * * *

(3) You must meet the requirements of paragraphs (a), (b), and (c) of this section before you begin to perform MRO functions.

(d) *Requalification training.* During each five-year period from the date on which you satisfactorily completed the examination under paragraph (c)(2) of this section, you must complete requalification training.

* * * * *

■ 15. Amend § 40.123 by revising paragraph (e) to read as follows:

§ 40.123 What are the MRO's responsibilities in the DOT drug testing program?

* * * * *

(e) You must act to investigate and correct problems where possible and notify appropriate parties (*e.g.,* HHS, DOT, employers, service agents) where assistance is needed, (*e.g.,* cancelled or problematic tests, incorrect results).

* * * * *

■ 16. Amend § 40.135 by revising paragraph (e) to read as follows:

§ 40.135 What does the MRO tell the employee at the beginning of the verification interview?

* * * * *

(e) You must also advise the employee that, before informing any third party about any medication the employee is using pursuant to a legally valid prescription consistent with the Controlled Substances Act, you will allow 5 business days from the date you report the verified negative result for the employee to have the prescribing physician contact you to determine if the medication can be changed to one that does not make the employee medically unqualified or does not pose a significant safety risk. If, in your reasonable medical judgment, a medical qualification issue or a significant safety risk remains after you communicate with the employee's prescribing physician or after 5 business days, whichever is shorter, you must follow § 40.327. If, as the MRO, you receive information that eliminates the medical qualification issue or significant safety risk, you must transmit this information to any third party to whom you previously provided information under § 40.327.

■ 17. Amend § 40.137 by revising the section heading and paragraph (a) to read as follows:

§ 40.137 On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, semi-synthetic opioids, or PCP?

(a) As the MRO, you must verify a confirmed positive test result for marijuana, cocaine, amphetamines, semi-synthetic opioids (*i.e.,* hydrocodone, hydromorphone, oxycodone, and oxymorphone), and/or PCP unless the employee presents a legitimate medical explanation for the presence of the drug(s)/metabolite(s) in his or her system. In determining whether an employee's legally valid prescription consistent with the Controlled Substances Act for a substance in these categories constitutes a legitimate medical explanation, you must not question whether the prescribing physician should have prescribed the substance.

* * * * *

■ 18. Amend § 40.139 by revising the section heading and paragraphs (c) introductory text and (c)(3) to read as follows:

§ 40.139 On what basis does the MRO verify test results involving 6-acetylmorphine, codeine, and morphine?

* * * * *

(c) For all other codeine and morphine positive results, you must verify a confirmed positive test result only if you determine that there is clinical evidence, in addition to the urine test, of unauthorized use of any opium, opiate, or opium derivative (*i.e.,* morphine, codeine, or heroin).

* * * * *

(3) To be the basis of a verified positive result for codeine or morphine, the clinical evidence you find must concern a drug that the laboratory found in the specimen. (For example, if the test confirmed the presence of codeine, and the employee admits to unauthorized use of hydrocodone, you must not verify the test positive for codeine. The admission must be for the substance that was found through the actual drug test.)

* * * * *

■ 19. Amend § 40.141 by revising paragraph (b) to read as follows:

§ 40.141 How does the MRO obtain information for the verification decision?

* * * * *

(b) If the employee asserts that the presence of a drug or drug metabolite in his or her specimen results from taking prescription medication (*i.e.,* a legally valid prescription consistent with the Controlled Substances Act), you must review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides. You may contact the employee's physician or other relevant medical personnel for further information. You may request an HHS-certified laboratory with validated protocols (see § 40.81(c)) to conduct testing for D,L stereoisomers of amphetamine and methamphetamine or testing for tetrahydrocannabivarin (THC- V) when verifying lab results, as you determine necessary.

■ 20. Amend § 40.162 by revising paragraph (c) to read as follows:

§ 40.162 What must MROs do with multiple verified results for the same testing event?

* * * * *

(c) As an exception to paragraphs (a) and (b) of this section, as the MRO, you must follow procedures at § 40.159(g) when any verified non-negative result is also invalid.

§ 40.169 [Amended]

■ 21. Amend § 40.169 by removing the entry ''§ 40.105—Notification of discrepancies in blind specimen results.''

§ 40.189 [Amended]

■ 22. Amend § 40.189 by removing the entry ''§ 40.103—Blind split specimens.''

■ 23. Amend § 40.193 by revising paragraph (b)(4) to read as follows:

§ 40.193 What happens when an employee does not provide a sufficient amount of urine for a drug test?

* * * * *

(b) * * *

(4) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the ''Remarks'' line of the CCF (Step 2), and immediately notify the DER. You must also discard any specimen the employee previously provided to include any specimen that is ''out of temperature range'' or shows signs of tampering. In the remarks section of the CCF that you will distribute to the MRO and DER, note the fact that the employee provided an ''out of temperature range specimen'' or ''specimen that shows signs of tampering'' and that it was discarded because the employee did not provide a second sufficient specimen.

* * * * *

■ 24. Amend § 40.199 by revising paragraph (b) to read as follows:

§ 40.199 What problems always cause a drug test to be cancelled?

* * * * *

(b) The following are ''fatal flaws'':

(1) There is no CCF;

(2) In cases where a specimen has been collected, there is no specimen submitted with the CCF;

(3) There is no printed collector's name and no collector's signature;

(4) Two separate collections are performed using one CCF;

(5) The specimen ID numbers on the specimen bottle and the CCF do not match;

(6) The specimen bottle seal is broken or shows evidence of tampering (and a split specimen cannot be re-designated, see § 40.83(h)); or

(7) Because of leakage or other causes, there is an insufficient amount of urine in the primary specimen bottle for analysis and the specimens cannot be re-designated (see § 40.83(h)).

* * * * *

■ 25. Amend § 40.203 by revising paragraph (d)(3) to read as follows:

§ 40.203 What problems cause a drug test to be cancelled unless they are corrected?

* * * * *

(d) * * *

(3) The collector uses a non-Federal form or an expired CCF for the test. This flaw may be corrected through the procedure set forth in § 40.205(b)(2), provided that the collection testing process has been conducted in accordance with the procedures in this part in an HHS-certified laboratory.

■ 26. Add § 40.210 to subpart I to read as follows:

§ 40.210 Are drug tests other than urine permitted under the regulations?

No. Drug tests other than on urine specimens are not authorized for testing under this part. Only urine specimens screened and confirmed at HHS certified laboratories (see § 40.81) are allowed for drug testing under this part. Point-of-collection urine testing or instant tests are not authorized.

■ 27. Amend § 40.213 by revising paragraphs (a), (d), and (e) to read as follows:

§ 40.213 What training requirements must STTs and BATs meet?

* * * * *

(a) You must be knowledgeable about the alcohol testing procedures in this part and the current DOT guidance. Procedures and guidance are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, 202–366–3784, or on the ODAPC Web site, *http://www.transportation.gov/odapc*). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at (*https://www.transportation.gov/odapc/get-odapc-email-updates*).

* * * * *

(d) You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform STT or BAT functions.

(e) *Refresher training.* No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c) of this section.

* * * * *

§ 40.225 [Amended]

■ 28. Amend § 40.225(a) by removing the parenthetical ''(*http://www.dot.gov/dapc*)'' and adding, in its place ''(*http://www.transportation.gov/odapc*)''

■ 29. Revise § 40.229 to read as follows:

§ 40.229 What devices are used to conduct alcohol screening tests?

ASDs listed on ODAPC's Web page for ''Approved Screening Devices to Measure Alcohol in Bodily Fluids'' and EBTs listed on ODAPC's Web page for ''Approved Evidential Breath Measurement Devices'' are the only devices you are allowed to use to conduct alcohol screening tests under this part. You may use an ASD for DOT alcohol tests only if there are instructions for its use in this part. An ASD can be used only for screening tests for alcohol, and must not be used for confirmation tests.

■ 30. Amend § 40.231 by revising paragraph (a) to read as follows:

§ 40.231 What devices are used to conduct alcohol confirmation tests?

(a) EBTs on ODAPC's Web page for ''Approved Evidential Breath Measurement Devices'' that meet the requirements of paragraph (b) of this section are the only devices you may use to conduct alcohol confirmation tests under this part.

* * * * *

■ 31. Amend § 40.233 by revising paragraphs (a) introductory text and (c)(4) to read as follows:

§ 40.233 What are the requirements for proper use and care of EBTs?

(a) As an EBT manufacturer, you must submit, for NHTSA approval, a quality assurance plan (QAP) for your EBT before ODAPC places the EBT on its Web page for ''Approved Evidential Breath Measurement Devices.''

* * * * *

(c) * * *

(4) You must maintain records of the inspection, maintenance, and calibration of EBTs as provided in § 40.333(a)(3).

* * * * *

■ 32. Amend § 40.235 by revising paragraph (a) to read as follows:

§ 40.235 What are the requirements for proper use and care of ASDs?

(a) As an ASD manufacturer, you must submit, for NHTSA approval, a QAP for your ASD before NHTSA approves it and ODAPC places the device on its Web page for ''Approved Screening Devices to Measure Alcohol in Bodily Fluids''. Your QAP must specify the methods used for quality control checks, temperatures at which the ASD must be stored and used, the shelf life of the device, and environmental conditions (*e.g.,* temperature, altitude, humidity) that may affect the ASD's performance.

* * * * *

■ 33. Amend § 40.281 by revising paragraphs (a)(6), (b)(3), and (c)(3) to read as follows:

§ 40.281 Who is qualified to act as a SAP?

* * * * *

(a) * * *

(6) You are a drug and alcohol counselor certified by an organization listed at *https://www.transportation.gov/odapc/sap.*

(b) * * *

(3) You must be knowledgeable about this part, the DOT agency regulations applicable to the employers for whom you evaluate employees, and the DOT

SAP Guidelines. You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at *https://www.transportation.gov/odapc/get-odapc-email-updates.* DOT agency regulations, DOT SAP Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington DC, 20590 (202–366–3784), or on the ODAPC Web site (*http://www.transportation.gov/odapc*).

(c) * * *

(3) You must meet the requirements of paragraphs (a), (b), and (c) of this section before you begin to perform SAP functions.

* * * * *

■ 34. Amend § 40.331 by revising paragraph (f) to read as follows:

§ 40.331 To what additional parties must employers and service agents release information?

* * * * *

(f) Except as otherwise provided in this part, as a laboratory you must not release or provide a specimen or a part of a specimen to a requesting party, without first obtaining written consent from ODAPC. DNA testing and other types of identity testing are not authorized and ODAPC will not give permission for such testing. If a party seeks a court order directing you to release a specimen or part of a specimen contrary to any provision of this part, you must take necessary legal steps to contest the issuance of the order (*e.g.,* seek to quash a subpoena, citing the requirements of § 40.13). This part does not require you to disobey a court order, however.

* * * * *

■ 35. Amend § 40.365 by revising paragraph (b)(10) to read as follows:

§ 40.365 What is the Department's policy concerning starting a PIE proceeding?

* * * * *

(b) * * *

(10) For any service agent, falsely representing that the service agent or its activities is approved or certified by the Department or a DOT agency (such representation includes, but is not limited to, the use of a Department or DOT agency logo, title, or emblem).

* * * * *

§ 40.401 [Amended]

■ 36. Amend § 40.401(a) by removing the parenthetical ''(*http://www.dot.gov/ost/dapc*)'' and adding, in its place ''(*http://www.transportation.gov/odapc*)''

■ 37. Revise Appendix B to Part 40 to read as follows:

Appendix B to Part 40—DOT Drug-Testing Semi-Annual Laboratory Report to Employers

The following items are required on each laboratory report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
Employer Identification: (name; may include Billing Code or ID code)
C/TPA Identification: (where applicable; name and address)
1. Specimen Results Reported (total number)
By Test Reason
(a) Pre-employment (number)
(b) Post-Accident (number)
(c) Random (number)
(d) Reasonable Suspicion/Cause (number)
(e) Return-to-Duty (number)
(f) Follow-up (number)
(g) Type of Test Not Noted on CCF (number)
2. Specimens Reported
(a) Negative (number)
(b) Negative and Dilute (number)
3. Specimens Reported as Rejected for Testing (total number)
By Reason
(a) Fatal flaw (number)
(b) Uncorrected Flaw (number)
4. Specimens Reported as Positive (total number) By Drug
(a) Marijuana Metabolite (number)
(b) Cocaine Metabolite (number)
(c) Opioids (number)
(1) Codeine (number)
(2) Morphine (number)
(3) 6–AM (number)
(4) Hydrocodone (number)
(5) Hydromorphone (number)
(6) Oxycodone (number)
(7) Oxymorphone (number)
(d) Phencyclidine (number)
(e) Amphetamines (number)
(1) Amphetamine (number)
(2) Methamphetamine (number)
(3) MDMA (number)
(4) MDA (number)
5. Adulterated (number)
6. Substituted (number)
7. Invalid Result (number)

■ 38. Revise Appendix C to Part 40 to read as follows:

Appendix C to Part 40—DOT Drug-Testing Semi-Annual Laboratory Report to DOT

Mail, fax, or email to:
U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, W62–300, 1200 New Jersey Avenue SE., Washington, DC 20590, *Fax:* (202) 366–3897, *Email: ODAPCWebMail@dot.gov.*

The following items are required on each report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
1. DOT Specimen Results Reported (total number)
2. Negative Results Reported (total number)
Negative (number)
Negative-Dilute (number)
3. Rejected for Testing Results Reported (total number)
By Reason
(a) Fatal flaw (number)
(b) Uncorrected Flaw (number)
4. Positive Results Reported (total number)
By Drug
(a) Marijuana Metabolite (number)
(b) Cocaine Metabolite (number)
(c) Opioids (number)
(1) Codeine (number)
(2) Morphine (number)
(3) 6–AM (number)
(4) Hydrocodone (number)
(5) Hydromorphone (number)
(6) Oxycodone (number)
(7) Oxymorphone (number)
(d) Phencyclidine (number)
(e) Amphetamines (number)
(1) Amphetamine (number)
(2) Methamphetamine (number)
(3) MDMA (number)
(4) MDA (number)
5. Adulterated Results Reported (total number)
By Reason (number)
6. Substituted Results Reported (total number)
7. Invalid Results Reported (total number)
By Reason (number)

■ 39. Revise Appendix D to Part 40 to read as follows:

Appendix D to Part 40—Report Format: Split Specimen Failure To Reconfirm

Mail, fax, or submit electronically to:

U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, W62–300, 1200 New Jersey Avenue SE., Washington, DC 20590, *Fax: (202) 366–3897.* Submit Electronically: *https://www.transportation.gov/content/split-specimen-cancellation-notification-49-cfr-part-40187-appendix-d*

The following items are required on each report:

1. MRO name, address, phone number, and fax number.

2. Collection site name, address, and phone number.

3. Date of collection.

4. Specimen I.D. number.

5. Laboratory accession number.

6. Primary specimen laboratory name, address, and phone number.

7. Date result reported or certified by primary laboratory.

8. Split specimen laboratory name, address, and phone number.

9. Date split specimen result reported or certified by split specimen laboratory.

10. Primary specimen results (*e.g.,* name of drug, adulterant) in the primary specimen.

11. Reason for split specimen failure-to-reconfirm result (*e.g.,* drug or adulterant not present, specimen invalid, split not collected, insufficient volume).

12. Actions taken by the MRO (*e.g.,* notified employer of failure to reconfirm and requirement for recollection).

13. Additional information explaining the reason for cancellation.

14. Name of individual submitting the report (if not the MRO)

■ 40. Amend Appendix H to Part 40 by:
■ a. Revising the introductory text; and
■ b. Removing the instruction sheet entitled: ''U.S. DEPARTMENT OF

TRANSPORTATION DRUG AND ALCOHOL TESTING MIS DATA COLLECTION FORM INSTRUCTION SHEET''.

The revision reads as follows:

Appendix H to Part 40—DOT Drug and Alcohol Testing Management Information System (MIS) Data Collection Form

The following form is the MIS Data Collection form required for use to report calendar year MIS data.

* * * * *

Issued in Washington, DC on November 3, 2017.

Elaine L. Chao,

Secretary of Transportation.

[FR Doc. 2017–24397 Filed 11–9–17; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 121004518–3398–01]

RIN 0648–XF815

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; 2017 Commercial Accountability Measure and Closure for Gulf Gray Triggerfish

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements accountability measures for commercial gray triggerfish in the exclusive economic zone (EEZ) of the Gulf of Mexico (Gulf) through this temporary rule. NMFS projects commercial landings for gray triggerfish will reach the commercial annual catch target (ACT)(commercial quota) by November 18, 2017. Therefore, NMFS is closing the commercial sector for gray triggerfish in the Gulf EEZ on November 18, 2017. This closure is necessary to protect the gray triggerfish resource.

DATES: This rule is effective 12:01 a.m., local time, November 18, 2017, until January 1, 2018.

FOR FURTHER INFORMATION CONTACT: Kelli O'Donnell, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *kelli.odonell@noaa.gov.*

SUPPLEMENTARY INFORMATION: The reef fish fishery of the Gulf includes gray triggerfish and is managed under the Fishery Management Plan for Reef Fish Resources of the Gulf (FMP). The FMP was prepared by the Gulf Fishery Management Council and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. All gray triggerfish weights discussed in this temporary rule are in round weight.

On August 4, 2008, NMFS established gray triggerfish accountability measures as well as commercial quotas for gray triggerfish through Amendment 30A to the FMP (73 FR 38139). On May 9, 2013, NMFS issued a final rule to implement Amendment 37 to the FMP (78 FR 27084). In part, Amendment 37 revised gray triggerfish commercial annual catch limits (ACLs) and ACTS.

Under 50 CFR 622.41(b)(1), NMFS is required to close the commercial sector for gray triggerfish when the commercial quota is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS has determined that the commercial quota for Gulf gray triggerfish of 60,900 lb (27,624 kg) will be reached by November 18, 2017. Accordingly, the commercial sector for Gulf gray triggerfish is closed effective 12:01 a.m., local time, November 18, 2017, until the start of the next commercial fishing season on January 1, 2018.

The operator of a vessel with a valid commercial vessel permit for Gulf reef fish having gray triggerfish onboard must have landed and bartered, traded, or sold such gray triggerfish prior to 12:01 a.m., local time, November 18, 2017. During the closure, the sale or purchase of gray triggerfish taken from the Gulf EEZ is prohibited. The prohibition on the sale or purchase does not apply to gray triggerfish that were harvested, landed ashore, and sold prior to 12:01 a.m., local time, November 18, 2017, and were held in cold storage by a dealer or processor.

The recreational sector for gray triggerfish is also closed through December 31, 2017. Therefore all harvest or possession of gray triggerfish is prohibited until the start of the new fishing year (50 CFR 622.39(b)). The commercial and recreational sectors for gray triggerfish will reopen on January 1, 2018, the beginning of the 2018 gray triggerfish fishing year.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of gray triggerfish and the Gulf reef fish fishery and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.41(b)(1) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best scientific information available. The NOAA Assistant Administrator for Fisheries (AA), finds that the need to immediately implement this action to close the commercial sector for gray triggerfish constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(B), as such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the final rule implementing Amendment 37 (78 FR 27084; May 9, 2013), which established the closure provision for commercial gray triggerfish, have already been subject to notice and comment, and all that remains is to notify the public of the closure. Such procedures are contrary to the public interest because of the need to immediately implement this action to protect gray triggerfish since the capacity of the fishing fleet allows for rapid harvest of the commercial quota. Prior notice and opportunity for public comment would require time and could potentially result in a harvest well in excess of the established commercial quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: November 7, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–24519 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 151130999–6594–02]

RIN 0648–XF807

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfer

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 North Carolina is transferring a portion of its 2017 commercial bluefish quota to the State of Rhode Island. This quota adjustment is necessary to comply with the Atlantic Bluefish Fishery Management Plan quota transfer provisions. This announcement informs the public of the revised commercial quotas for North Carolina and Rhode Island.

DATES: Effective November 7, 2017, through December 31, 2017.

FOR FURTHER INFORMATION CONTACT: Cynthia Hanson, Fishery Management Specialist, (978) 281–9180.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. The 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 are described in § 648.162 and the initial 2017 allocations were published on March 13, 2017 (82 FR 13402).

The final rule implementing Amendment 1 to the Bluefish Fishery Management Plan published in the **Federal Register** on July 26, 2000 (65 FR 45844), and provided a mechanism for transferring bluefish 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 of a transfer of bluefish commercial quota under § 648.162(e)(1)(i) through (iii). The Regional Administrator must first approve any such transfer based on the criteria in § 648.162(e).

North Carolina is transferring 100,000 lb (45,359 kg) of Atlantic bluefish commercial quota to Rhode Island. This transfer was requested by state officials in Rhode Island to ensure their 2017 commercial bluefish quota would not be exceeded. Both states have agreed to the transfer and certified that it meets all pertinent state requirements. The revised bluefish quotas for calendar year 2017 are now: North Carolina, 2,638,704 lb (1,196,896 kg); and Rhode Island, 681,563 lb (309,152 kg); based on the initial quotas published in the 2016–2018 Atlantic Bluefish Specifications and subsequent transfers.

Classification

This action is taken under 50 CFR part 648 and is exempt from review under Executive Order 12866.

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

Dated: November 7, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–24534 Filed 11–7–17; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 82, No. 217
Monday, November 13, 2017

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

7 CFR Part 3419

RIN 0524–AA68

Matching Funds Requirements for Agricultural Research and Extension Capacity Funds at 1890 Land-Grant Institutions and 1862 Land-Grant Institutions in Insular Areas

AGENCY: National Institute of Food and Agriculture

ACTION: Proposed rule and withdrawal of proposed rule.

SUMMARY: The National Institute of Food and Agriculture (NIFA) withdraws the Notice of Proposed Rulemaking (RIN 0524–AA25) published on April 29, 2003. In addition, NIFA proposes to revise its regulations for the purpose of implementing the statutory amendments applicable to the matching requirements for Federal agricultural research and extension capacity (formula) funds for 1890 land-grant institutions (LGUs), including Central State University, Tuskegee University, and West Virginia State University, and 1862 land-grant institutions in insular areas, and to remove the term ''qualifying educational activities.'' These matching requirements were amended by the Farm Security and Rural Investment Act; the Food, Conservation, and Energy Act of 2008; and the Agricultural Act of 2014.

DATES: As of November 13, 2017, the proposed rule published April 29, 2003, at 68 FR 23013, is withdrawn. Submit comments on the proposed rule on or before January 12, 2018.

ADDRESSES: You must submit comments, identified by 7 CFR part 3419, electronically through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions online for submitting comments.

FOR FURTHER INFORMATION CONTACT: Maggie Ewell, Senior Policy Advisor, 202–401–0222.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

The National Institute of Food and Agriculture (NIFA) is revising part 3419 of Title 7, subtitle B, chapter XXXIV of the Code of Federal Regulations which implements the matching requirements provided under section 1449 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (NARETPA) for agricultural research and extension capacity (formula) funds authorized for the 1890 land-grant institutions, including Central State University, Tuskegee University, and West Virginia State University and 1862 land-grant institutions in insular areas. This revision is required due to the statutory amendments of sections 7212 of the Farm Security and Rural Investment Act of 2002 (FSRIA); section 7127 of the Food, Conservation, and Energy Act of 2008; and section 7129 of the Agricultural Act of 2014. Additionally, NIFA is making changes to the Definitions and Use of Matching Funds sections to provide clarity on allowable uses of matching funds. NIFA rescinds the previous, not yet finalized, Notice of Proposed Rulemaking published in the **Federal Register** on April 29, 2003, RIN 0524–AA25 (68 FR 23013).

§ 3419.1 Definitions. The definition of eligible institution was updated to include West Virginia State University (formerly West Virginia State College) and Central State University. Section 753 of the Agricultural, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2002 (Pub. L. 107–76) restored 1890 land-grant institution status to West Virginia State College. In 2004, the West Virginia Legislature approved West Virginia State College's transition to University status. Central State University was recognized as an 1890 land-grant institution under section 7129 of the Agricultural Act of 2014.

In 2014, NIFA re-branded its formula grant programs as ''capacity grants.'' Therefore, the definition of formula funds is changed to reflect this terminology, capacity funds, and the words ''by formula'' were inserted to clarify that capacity funds are provided by formula to eligible institutions.

The term and definition for qualifying educational activities was removed due to the fact that this term has caused confusion regarding what constitutes an allowable qualifying educational activity. NIFA follows the authorized uses of funds in NARETPA, codified at 7 U.S.C. 3221 and 3222, for extension and research programs. Research funds are for conducting agricultural research, printing, disseminating the results of research, administration, planning and direction, purchase and rental of land, and the construction, acquisition, alteration, or repair of buildings necessary for conducting agricultural research. Extension funds are for the expenses of conducting extension programs and activities. 7 U.S.C. 3221(e) expressly prohibits extension funds from being spent on college course teaching or lectures in college.

NARETPA also contains definitions that explain the difference between education in conjunction with extension programs and education and teaching. Extension education is defined as ''informal'' while teaching and education is defined as ''formal classroom instruction,'' which is expressly prohibited under 7 U.S.C. 3221(e).

Because the authorized uses related to education expenses are clearly outlined in NARETPA and in 7 U.S.C. 3221 and 3222, NIFA does not see value in including the term ''qualifying educational activity'' as a term in regulation and, further, wants to ensure there is no conflict between its regulatory authorizations and the law. Therefore, NIFA is removing the term ''qualifying educational activity'' and will allow only informal educational activities, as authorized by statute.

§ 3419.2 Matching funds requirements. Revisions to this section were required due to statutory amendments of sections 7212 of FSRIA; section 7127 of the Food, Conservation, and Energy Act of 2008; and section 7129 of the Agricultural Act of 2014. The information regarding Fiscal Years 2000, 2001, and 2002 were removed as they are outdated and no longer applicable. NIFA proposes replacing this text with the matching requirements for 1862 land-grant institutions in insular areas for the Smith-Lever 3(b) and (c) program (7

U.S.C. 343(e)(4)(A)) and the Hatch Act program (7 U.S.C. 361c(d)(4)(A)), which state that insular areas will provide matching funds from non-Federal sources in an amount equal to not less than 50 percent of the formula funds distributed by NIFA to each of the 1862 land-grant institutions in insular areas, respectively. NIFA proposes replacing existing text with the matching requirement to the Evans Allen/Section 1445 fund program (7 U.S.C. 3222d) and Extension/Section 1444 fund programs (7 U.S.C. 3221) which state that the State will provide equal matching funds from non-Federal sources.

§ 3419.3 Limited Waiver Authority. The section entitled, ''Determination of non-Federal sources of funds,'' § 3419.3, has been removed, because it reiterated a statutory requirement to submit, in the year 1999, a report on non-Federal funds used as match to be submitted. There is no further statutory requirement or authority to submit reports on the sources of non-Federal funds, therefore NIFA proposes the removal of this section. Section 3419.4 Limited Waiver Authority will be re-designated as § 3419.3 and modified to include the provisions of 7 U.S.C. 3222d(d): Authorization of a 50% waiver of matching funds authority for 1890 land-grant institutions. Additionally, § 3419.3 includes the authority to waive up to 100% of the required match for 1862 land-grant institutions in insular areas that is present in 7 U.S.C. 343(e)(4)(B).

NIFA also proposes to add to this section a description of the criteria a land-grant institution must demonstrate in order to be eligible for a waiver. The three criteria are: Impacts from natural disaster, flood, fire, tornado, hurricane, or drought; State and/or Institution facing a financial crisis; or lack of matching funds after demonstrating a good faith effort to obtain funds.

§ 3419.4 Application for waivers for both 1890 land-grant institutions and 1862 land-grant institutions in insular areas. NIFA proposes to add § 3419.4 to outline how 1890 land-grant institutions and 1862 land-grant institutions in insular areas may request a matching waiver. To request a waiver, the president of the institution must submit in writing a request for a waiver of the matching requirements. The request must include the name of the eligible institution, the type of capacity funds, which would include Section 1444 Extension, Section 1445 Research; Smith-Lever; or Hatch Act; the fiscal year of the match; and the basis of the request, *i.e.,* one or more of the criteria identified in 3419.3. Requests for waivers may be submitted with the application for funds or at any time during the period of performance of the award. Additionally, NIFA includes a requirement for current supporting documentation, where current is defined as within the past two years from the date of the letter requesting the waiver. It is critical that NIFA base its decisions for matching waivers on the current state of affairs within the State and institution. Using older data does not provide adequate rationale for NIFA to waive the statutorily required match for capacity programs.

§ 3419.5 Certification of matching funds. The only proposed change in this section is changing the word ''formula'' to ''capacity,'' consistent with the current terminology used by NIFA.

§ 3419.6 Use of matching funds. NIFA proposes minor technical changes to this section, use of the term ''capacity'' in place of ''formula'' and ''must'' in place of ''shall.'' These technical changes have no impact on the requirements from the existing to the proposed regulation. Additionally, NIFA proposes to add clarifying language that matching funds must be used for the same purpose as Federal dollars as well as a specific prohibition on the use of tuition dollars and student fees as match.

The intent of the proposed rule is to clarify two requirements. First, the revised proposed rule clarifies that matching funds must be used by an eligible institution for the same purpose as Federal award dollars: Agricultural research and extension activities that have been approved in the plan of work. Second, the revised proposed rule removes the end phrase: ''or for approved qualifying educational activities.'' As discussed in § 3419.1 Definitions, the use of the phrase ''qualifying educational activities'' has caused confusion regarding what constitutes an allowable qualifying educational activity. NIFA supports the position, as required under 2 CFR 200.306, that all matching funds must be necessary and reasonable for accomplishment of project or program objectives. In other words, to be allowable as a match, the costs must be allowable under the Federal award. This principle applies to matching funds 1890 land-grant institutions receive for Research and Extension programs, as well as the funds received by 1862 land-grant institutions in insular areas for Smith-Lever and Hatch programs.

NIFA follows the authorized uses of funds in the authorizing statutes for determining what is allowable under the Federal award. For 1862 land-grant institutions in insular areas, this would be the authorized uses under 7 U.S.C. 343 for Smith-Lever programs and 7 U.S.C. 361a for Hatch Act programs.

For 1890 Extension and Research programs, NIFA follows the authorizations included in NARETPA, codified at 7 U.S.C. 3221 and 3222. Research funds are for conducting agricultural research; printing; disseminating the results of research, administration, planning and direction; purchase and rental of land; and the construction, acquisition, alteration, or repair of buildings necessary for conducting agricultural research. Extension funds are for the expenses of conduction extension programs and activities. 7 U.S.C. 3221(e) expressly prohibits extension funds from being spent on college course teaching or lectures in college.

NARETPA also contains definitions that explain the difference between education in conjunction with extension programs versus education and teaching. Extension education is defined as ''informal'' while teaching and education is defined as ''formal classroom instruction,'' which is expressly prohibited under 7 U.S.C. 3221(e).

Because the authorized uses related to education expenses are clearly outlined in NARETPA and 7 U.S.C. 3221 and 3222, NIFA does not see value in including the term ''qualifying educational activity'' as a term in regulation and further, wants to ensure there is no conflict between its regulatory authorizations and the law. Therefore, NIFA is removing the term ''qualifying educational activity;'' however, the removal is intended to prohibit expenditures related to formal education activities. NIFA will allow only informal education activities, as authorized by statute.

Under 7 U.S.C. 3221(a)(3), funds appropriated for extension must be used for the expenses of conducting extension programs and activities, and for contributing to the retirement of employees subject to the provisions of 7 U.S.C. 331. 7 U.S.C. 3222(e) expressly prohibits extension funds from being spent on college course teaching and lectures in college. Section 1404(7) of NARETPA defines the term extension to mean informal education programs conducted in the States in cooperation with the Department of Education. Therefore, NIFA has determined that the current authorizations allow for informal education programs to be conducted with extension funding, but not for formal classroom instruction.

7 U.S.C. 3222(a)(3) states that: ''research funding must be used for the expenses of conducting agricultural research, printing, disseminating the

results of such research, contributing to the retirement of employees subject to the provisions of 7 U.S.C. 331 of this title, administrative planning and direction, and purchase and rental of land and the construction, acquisition, alteration, or repair of buildings necessary for conducting agricultural research.''

Because the authorizing statutes so clearly identify authorized uses and prohibitions, NIFA believes that no further explanation or inclusion of qualifying educational activities is needed in this regulation.

§ 3419.7 Reporting of matching funds. The revised proposed rule adds a section on reporting of matching funds to clarify an existing requirement that 1890 land-grant institutions and 1862 land-grant institutions in insular areas report all capacity funds expended on an annual basis using Standard Form (SF) 425, in accordance with 7 CFR part 3430. This ensures that the information on matching funds is reported to NIFA.

§ 3419.8 Redistribution of funds. The revised proposed rule removes the first sentence of the existing provision as the timing of reapportionment may vary. Removing this sentence does not change the statutory requirements for reapportionment. The only significance of the deletion is to remove the July 1 date for action.

Additionally, one other technical correction is changing ''shall'' to ''must,'' consistent with the plain English provisions relating to rulemaking.

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying the costs and benefits of simplifying and harmonizing rules, and of promoting flexibility. This rulemaking has been determined to be not significant for purposes of Executive Order 12866.

Executive Order 13771

This proposed rule is not expected to be an EO 13771 regulatory action because this rulemaking is not significant under EO 12866.

Regulatory Flexibility Act

This revised proposed rule has been reviewed in accordance with the Regulatory Flexibility Act of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, (5 U.S.C. 601–612). The Director of the NIFA certifies that this proposed regulation will not have a significant economic impact on a substantial number of small entities. This proposed regulation will affect institutions of higher education receiving Federal funds under this program. The U.S. Small Business Administration Size Standards define institutions as ''small entities'' if they are for-profit or nonprofit institutions with total annual revenue below $5,000,000 or if they are institutions controlled by governmental entities with populations below 50,000. The rulemaking does not involve regulatory and informational requirements regarding businesses, organizations, and governmental jurisdictions subject to regulation.

Catalogue of Federal Domestic Assistance

The programs affected by this revised proposed rule are listed in the Catalogue of Federal Domestic Assistance under 10.500, Cooperative Extension Service; and 10.205, Payments to 1890 Land-Grant Colleges and Tuskegee University.

Paperwork Reduction Act

The Department certifies that this revised proposed rule has been assessed in accordance with the requirements of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*. The Department concludes that this proposed rule does not impose any new information collection requirements or change the burden estimate on existing information collection requirements. In addition to the SF–424 form families (*i.e.,* Research and Related and Mandatory) and the SF–425 Federal Financial Report (FFR) No. 0348–0061, NIFA has three currently approved OMB information collections associated with this rulemaking: OMB Information Collection No. 0524- 0042, NIFA REEport; No. 0524–0041, NIFA Application Review Process; and No. 0524–0026, Organizational Information.

Unfunded Mandates Reform Act of 1995 and Executive Order 13132

The Department has reviewed this revised proposed rule in accordance with the requirements of Executive Order No. 13132 and the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.,* and has found no potential or 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. As there is no Federal mandate contained herein that could result in increased expenditures by State, local, or tribal governments, or by the private sector, the Department has not prepared a budgetary impact statement.

Clarity of This Regulation

Executive Order 12866 and the President's Memorandum of June 1, 1998, require each agency to write all rulemaking in plain language. The Department invites comments on how to make this proposed rule easier to understand.

List of Subjects in 7 CFR Part 3419

Agricultural extension, Agricultural research; 1890 land-grant institutions; insular areas; 1862 land-grant institutions in insular areas; matching funds.

For the reasons stated in the preamble, the National Institute of Food and Agriculture rescinds the previous Notice of Proposed Rulemaking RIN–0524–AA25 issued April 29, 2003 (68 FR 23013) and proposes to amend 7 CFR part 3419 as follows:

PART 3419—MATCHING FUNDS REQUIREMENT FOR AGRICULTURAL RESEARCH AND EXTENSION CAPACITY FUNDS AT 1890 LAND-GRANT INSTITUTIONS, AND 1862 LAND-GRANT INSTITUTIONS IN INSULAR AREAS

■ 1. The authority citation for part 3419 is revised to read as follows:

Authority: 7 U.S.C. 3222d; 7 U.S.C. 343(e); 7 U.S.C. 361c; Pub. L. 107–171; Pub. L. 110–234; Pub. L. 113–79

■ 2. Amend § 3419.1 as follows:

■ a. Add a definition for ''*Capacity funds*'';

■ b. Revise the definition of ''*Eligible institution*'';

■ c. Remove the definition of ''*Formula funds*'';

■ d. Revise the definition of ''*Matching funds*'';

■ e. Remove the definition of ''*Qualifying educational activities*''

The addition and revisions read as follows:

§ 3419.1 Definitions.

As used in this part:

Capacity funds means agricultural extension and research funds provided by formula to the eligible institutions under sections 1444 and 1445 of the National Agricultural Research, Extension, and Teaching Policy Act of

1977 (NARETPA), as amended, or under sections 3(b) and (c) of the Smith-Lever Act, 7 U.S.C. 343(b) and (c) or under section 3 of the Hatch Act of 1887, 7 U.S.C. 361c.

Eligible institution means a college or university eligible to receive funds under the Act of August 30, 1890 (7 U.S.C. 321 *et seq.*) (commonly known as the Second Morrill Act), including Central State University, Tuskegee University, and West Virginia State University (1890 land-grant institutions), and a college or university designated under the Act of July 2, 1862 (7 U.S.C. 301, *et seq.*) (commonly known as the First Morrill Act) and located in the Commonwealth of Puerto Rico and the insular areas of American Samoa, Guam, Micronesia, Northern Marianas, and the Virgin Islands (1862 land-grant institutions in insular areas).

Matching funds means funds from non-Federal sources, including those made available by the State to the eligible institutions, for programs or activities that fall within the purposes of agricultural research and cooperative extension under: sections 1444 and 1445 of NARETPA; the Hatch Act of 1887; and the Smith-Lever Act.

* * * * *

■ 2. Amend § 3419.2 as follows:
■ a. Remove the introductory text;
■ b. Revise Paragraphs (a) and (b).

The revisions read as follows:

§ 3419.2 Matching funds requirement.

(a) 1890 land-grant institutions: The distribution of capacity funds are subject to a matching requirement. Matching funds will equal not less than 100% of the capacity funds to be distributed to the institution.

(b) 1862 land-grant institutions in insular areas: The distribution of capacity funds are subject to a matching requirement. Matching funds will equal not less than 50% of the capacity funds to be distributed to the institution.

* * * * *

§ 3419.3 [Removed]

■ 3. Remove § 3419.3

§ 3419.4 [Redesignated as § 3419.3]

■ 4. Redesignate § 3419.4 as § 3419.3 and revise it to read as follows:

§ 3419.3 Limited waiver authority.

(a) *1890 land-grant institutions:* The Secretary may waive the matching funds requirement in 7 CFR 3419.2 above the 50% level for any fiscal year for an eligible institution of a State if the Secretary determines that the State will be unlikely to satisfy the matching requirement.

(b) *1862 land-grant institutions in insular areas:* The Secretary may waive up to 100% of the matching funds requirements in 7 CFR 3419.2 for any fiscal year for an eligible institution in an insular area.

(c) The criteria to waive the applicable matching requirement for 1890 land-grant institutions and 1862 land-grant institutions in insular areas is demonstration of one or more of the following:

(1) Impacts from natural disaster, flood, fire, tornado, hurricane, or drought;

(2) State and/or institution facing a financial crisis; or

(3) Lack of matching funds after demonstration of good faith efforts to obtain funds.

(d) Approval or disapproval of the request for a waiver will be based on the application submitted, as defined under § 3419.4.

■ 5. Add new § 3419.4 to read as follows:

§ 3419.4 Applications for waivers for both 1890 land-grant institutions and 1862 land-grant institutions in insular areas.

Application for waivers for both 1890 land-grant institutions and 1862 land-grant institutions in insular areas. The president of the eligible institution must submit any request for a waiver for matching requirements. A waiver application must include the name of the eligible institution, the type of Federal capacity funds (*i.e.* research, extension, Hatch, etc.), appropriate fiscal year, the basis for the request (*e.g.* one or more of the criteria identified in § 3419.3); current supporting documentation, where current is defined as within the past two years from the date of the letter requesting the waiver; and the amount of the request.

§ 3419.5 [Amended]

■ 6. Amend § 3419.5 by removing the word ''formula'' and adding, in its place, the word ''capacity''.

■ 7. Revise § 3419.6 to read as follows:

§ 3419.6 Use of matching funds.

The required matching funds for the capacity programs must be used by an eligible institution for the same purpose as Federal award dollars: Agricultural research and extension activities that have been approved in the plan of work required under sections 1445(c) and 1444(d) of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, section 7 of the Hatch Act of 1887, and section 4 of the Smith-Lever Act. For all programs, tuition dollars and student fees may not be used as matching funds.

§ 3419.7 [Redesignated as § 3419.8]

■ 8. Redesignate § 3419.7 as § 3419.8, and add a new § 3419.7 to read as follows:

§ 3419.7 Reporting of matching funds.

Institutions will report all capacity matching funds expended annually using Standard Form (SF) 425, in accordance with 7 CFR 3430.56(a).

■ 9. Revise newly redesignated § 3419.8 to read as follows:

§ 3419.8 Redistribution of Funds.

Unmatched research and extension funds will be reapportioned in accordance with the research and extension statutory distribution formulas applicable to the 1890 and 1862 land-grant institutions in insular areas, respectively. Any redistribution of funds must be subject to the same matching requirement under § 3419.2.

Done at Washington, DC, on November 2, 2017.

Sonny Ramaswamy,

NIFA Director, National Institute of Food and Agriculture.

[FR Doc. 2017–24327 Filed 11–9–17; 8:45 am]

BILLING CODE 3410–22–P

NATIONAL INDIAN GAMING COMMISSION

25 CFR Part 514

Fees

AGENCY: National Indian Gaming Commission.

ACTION: Proposed rule.

SUMMARY: The National Indian Gaming Commission proposes to amend its fee regulations. The proposed rule would require the Commission to adopt annual fee rates no later than November 1 of each year. In addition, the proposed rule defines the fiscal year of the gaming operation that will be used for calculating the fee payments. Finally, the proposed rule includes additional revisions intended to clarify the fee calculation and submission process for gaming operations.

DATES: The agency must receive comments on or before December 28, 2017.

ADDRESSES: You may send comments by any of the following methods:

- *Email: 514_Comments@nigc.gov.*
- *Fax:* 202–632–7066.
- *Mail:* National Indian Gaming Commission, 1849 C Street NW., MS 1621, Washington, DC 20240.
- *Hand Delivery:* National Indian Gaming Commission, 90 K Street NE., Suite 200, Washington, DC 20002,

between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Austin Badger, National Indian Gaming Commission; Telephone: 202–632–7003.

SUPPLEMENTARY INFORMATION:

I. Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal.

II. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law on October 17, 1988. The Act establishes the National Indian Gaming Commission (NIGC or Commission) and sets out a comprehensive framework for the regulation of gaming on Indian lands. The IGRA established an agency funding framework whereby gaming operations licensed by tribes pay a fee to the Commission for each gaming operation that conducts Class II or Class III gaming activity that is regulated by IGRA. 25 U.S.C. 2717(a)(1). These fees are used to fund the Commission in carrying out its regulatory authority. Fees are based on the gaming operation's gross revenues. The rate of fees is established annually by the Commission and shall be payable on a quarterly basis. 25 U.S.C. 2717(a)(3). IGRA limits the total amount of fees imposed during any fiscal year to 0.08 percent of the gross gaming revenues of all gaming operations subject to regulation under IGRA. Failure of a gaming operation to pay the fees imposed by the Commission's fee schedule can be grounds for a civil enforcement action. 25 U.S.C. 2713(a)(1).

The purpose of Part 514 is to establish how the NIGC sets and collects those fees, to establish a basic formula for tribes to utilize in calculating the amount of fees to pay, and to advise of the consequences for failure to pay the fees. Part 514 further establishes how the NIGC determines and assesses fingerprint processing fees.

Under the current fee regulations, the Commission adopts a preliminary fee rate by March 1 and a final fee rate by June 1 of every year. In addition, the NIGC annually reviews the costs involved in processing fingerprint cards and adopts a preliminary rate by March 1 and a final rate by June 1. The Commission believes that the current process would be improved by moving to an annual final fee rate announced on or before November 1 of each year. This change would improve the Commission's analysis and budgeting process and simplify the fee calculation and payment process for gaming operations, thereby reducing the frequency of error in fee calculation. Proposed changes to the fee regulations were therefore included as a topic in a November 22, 2016, letter to tribal leaders introducing the Commission's 2017 consultation series.

III. Development of the Proposed Rule

On March 24, 2017, in Tulsa, OK, April 5, 2017, in Scottsdale, AZ, April 13, 2017, in San Diego, CA, April 20, 2017, in Billings, MT, May 4, 2017, in Biloxi, MS, and on May 25, 2017, in Portland, OR, the NIGC consulted with tribes on the proposed change to the fee regulations. In addition, the Commission issued a discussion draft on January 30, 2017, and solicited written comments through July 1, 2017. Comments received were generally supportive of the proposed change to the fee regulations. The Commission developed the proposed rule after carefully considering the comments received.

A. Assessed Fiscal Year

The current regulation provides that the annual fee shall be computed using ''the most recent rates of fees adopted by the Commission'' and ''the assessable gross revenues for the previous fiscal year.'' As a result, the fee rate applied to a gaming operation's fiscal year changes depending on when the gaming operation's fiscal year ends. For example, if the Commission adopts a fee rate on November 1, 2014 (Rate A), a different fee rate on November 1, 2015 (Rate B), and the gaming operation's fiscal year ends on December 31, the gaming operations quarterly payments would be calculated as follows: (1) First quarter, payable March 31, 2015, would apply Rate A to the fiscal year ending December 31, 2014, (2) Second quarter, payable June 30, 2015, would apply Rate A to the fiscal year ending December 31, 2014, (3) Third quarter, payable September 30, 2015, would apply Rate A to the fiscal year ending December 31, 2014, and (4) Fourth quarter, payable December 31, 2015, would apply *Rate B* to the fiscal year ending December 31, 2014.

The Commission intends for the annual rate to be applied consistently to a gaming operation's assessable gross revenue for one fiscal year. The proposed rule therefore includes amendments intended to better describe the intended fee calculation. These amendments include defining ''assessed fiscal year.'' Under the proposed rule, the annual fee shall be computed using the ''most recent rates of fees adopted by the Commission'' and ''the assessable gross revenues for the gaming operation's assessed fiscal year.''

Assessed fiscal year means the most recent fiscal year ending prior to January 1 of the year the Commission adopted fee rates. For example, if the Commission adopted fee rates on November 1, 2018, the assessed fiscal year would be a gaming operation's fiscal year ending prior to January 1, 2018. For gaming operations with fiscal years ending December 31, the assessed fiscal year would be the fiscal year ending December 31, 2017. For gaming operations with fiscal years ending September 30, the assessed fiscal year would be the fiscal year ending September 30, 2017. For gaming operations with fiscal years ending June 30, the assessed fiscal year would be the fiscal year ending June 30, 2017.

As a result, under the proposed rule, if the Commission adopts a fee rate on November 1, 2014 (Rate A), a different fee rate on November 1, 2015 (Rate B), and the gaming operation's fiscal year ends on December 31, the gaming operation's quarterly payments would be calculated as follows: (1) First quarter (of the gaming operation's fiscal year), payable March 31, 2015, would apply Rate A to the fiscal year ending December 31, 2013, (2) Second quarter, payable June 30, 2015, would apply Rate A to the fiscal year ending December 31, 2013, (3) Third quarter, payable September 30, 2015, would apply Rate A to the fiscal year ending December 31, 2013, and (4) Fourth quarter, payable December 31, 2015, would apply Rate B to the fiscal year ending December 31, 2014. To continue the example, the subsequent quarterly payment, payable March 31, 2016, would apply Rate B to the fiscal year ending December 31, 2014.

As an additional example, under the proposed rule, if the Commission adopts a fee rate on November 1, 2014 (Rate A), a different fee rate on November 1, 2015 (Rate B), and the gaming operation's fiscal year ends on September 30, the gaming operation's quarterly payments would be calculated as follows: (1) First quarter (of the gaming operation's fiscal year), payable December 31, 2015, would apply Rate A to the fiscal year ending September 30, 2013, (2) Second quarter payable March 31, 2016, would apply Rate A to the fiscal year ending September 30, 2013, (3) Third quarter payable June 30, 2016, would apply

Rate A to the fiscal year ending September 30, 2013, (4) Fourth quarter, payable September 30, 2016, would apply Rate A to the fiscal year ending September 30, 2013. To continue the example, the subsequent first quarter, payable December 31, 2016, would apply Rate B to the fiscal year ending September 30, 2014.

B. Fees and Statements Required if a Gaming Operation Ceases Operations

In the course of developing the proposed rule, the Commission became aware that the current regulations do not describe the fees and statements required of gaming operations that cease operations. Section 514.7(b) of the proposed rule now provides that the gaming operation prepares and submits to the Commission the fees and statements required for the period from the end of the most recent quarter for which fees have been paid through the date the gaming operation ceased operations. For example, if a gaming operation with a September 30 fiscal year end ceases operations on July 31, 2017, the gaming operation will have submitted fees and statements through June 30, 2017. The gaming operation would therefore still owe a payment for the period from July 1, 2017, through July 31, 2017.

C. Transition Period

Comment: Some commenters recommended that the Commission take into account the transition period between the current regulation and the final rule, if adopted.

Response: The Commission agrees and will issue guidance to describe how gaming operations should calculate fee payments during the transition period. The Commission intends for the most recently announced fee rate to carry over until a new fee rate is announced once a final rule is promulgated.

D. Payment Adjustments

Comment: Some commenters recommended that the proposed rule make clear the gaming operation's obligations regarding underpayment or overpayment of the annual fee.

Response: The Commission agrees that payment adjustments are warranted when the gaming operation becomes aware that prior submissions over or underpaid the required fee amount. Section 514.6(d)(5) of the proposed rule provides that the amount to be remitted be adjusted for prior amounts paid and credits received, if applicable. The Commission notes, however, that pursuant to section 571.13 copies of financial statements and audits are required to have been provided to the Commission within 120 days after the end of the gaming operation's fiscal year. Therefore, under the proposed rule, audited financial statements for the assessed fiscal year are required to be complete before a fee payment calculated using the assessed fiscal year is due. The current regulation and the proposed rule continue, however, to require that the quarterly statements must be reconciled with a tribe's audited or reviewed financial statements for each gaming location.

E. Advanced Payment

Comment: A commenter sought clarification as to whether the Commission would accept pre-payments under the proposed rule.

Response: The Commission accepts pre-payments under the current regulations and will continue to do so under the proposed rule. Section 514.5(a) of the proposed rule provides that the annual fee payable to the Commission optionally may be paid in full in the first quarterly payment.

F. Other Comments

Comment: A commenter asked whether the NIGC would issue late payment fees instead of issuing a notice of violation when payments are submitted late.

Response: The Commission notes that the current regulation provides for late fees for payments submitted between one and ninety calendar days late. Statements and/or fee payments over ninety calendar days late constitute a failure to pay and may result in enforcement action. The proposed rule does not substantively amend the late fee or failure to pay provisions of the current regulation.

Comment: A commenter asked whether the Commission would amend the definition of assessable gross revenue to be consistent with standards set by professional accounting organizations.

Response: The Commission acknowledges that professional accounting definitions of gross revenue differ from the Commission's definition of assessable gross revenue. While the Commission's definition of assessable gross revenue must remain consistent with the definition for gross revenues contained in IGRA at 25 U.S.C. 2717(a)(6), the proposed rule includes one change intended to conform the Commission's definition of assessable gross revenue with appropriate accounting terminology. The proposed rule removes the word ''amortization'' from within the phrase ''allowance for amortization of capital expenditures for structures'' found in section 514.4(c) and 25 U.S.C. 2717(a)(6). The Commission understands that the term depreciation rather than amortization is appropriate for an allowance for capital expenditures for structures. The methods for determining the amount of the allowance provided for in section 514.4(e) remains unchanged.

Comment: A commenter asked whether the proposed rule would reduce fees for processing fingerprint cards.

Response: The proposed rule does not affect how the fees for processing fingerprint cards are determined. As provided by the current regulation and proposed rule, the fingerprint processing fee is based on the fees charged by the Federal Bureau of Investigation and the costs incurred by the Commission.

Regulatory Matters

Tribal Consultation

The National Indian Gaming Commission is committed to fulfilling its tribal consultation obligations—whether directed by statute or administrative action such as Executive Order (E.O.) 13175 (Consultation and Coordination with Indian Tribal Governments)—by adhering to the consultation framework described in its Consultation Policy published July 15, 2013. The NIGC's consultation policy specifies that it will consult with tribes on Commission Action with Tribal Implications, which is defined as: Any Commission regulation, rulemaking, policy, guidance, legislative proposal, or operational activity that may have a substantial direct effect on an Indian tribe on matters including, but not limited to the ability of an Indian tribe to regulate its Indian gaming; an Indian Tribe's formal relationship with the Commission; or the consideration of the Commission's trust responsibilities to Indian tribes. As discussed above, the NIGC engaged in extensive consultation on this topic and received and considered comments in developing this proposed rule.

Regulatory Flexibility Act

The proposed rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Moreover, Indian Tribes are not considered to be small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The proposed rule is not a major rule under 5 U.S.C. 804(2), the Small

Business Regulatory Enforcement Fairness Act. The rule does not have an effect on the economy of $100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies or geographic regions. Nor will the proposed rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the proposed rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the proposed rule does not unduly burden the judicial system and meets the requirements of section 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act

The Commission has determined that the proposed rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget (OMB) as required by 44 U.S.C. 3501 *et seq.* and assigned OMB Control Number 3141–0007, which expired in August of 2011. The NIGC is in the process of reinstating that Control Number.

List of Subjects in 25 CFR Part 514

Gambling, Indian—lands, Indian—tribal government, Reporting and recordkeeping requirements.

Therefore, for reasons stated in the preamble, the National Indian Gaming Commission proposes to revise 25 CFR part 514 to read as follows:

PART 514—FEES

Sec.

Authority: 25 U.S.C. 2706, 2710, 2717, 2717a.

§ 514.1 What is the purpose of this part?

Each gaming operation under the jurisdiction of the Commission, including a gaming operation operated by a tribe with a certificate of self-regulation, shall pay to the Commission annual fees as established by the Commission. The Commission, by a vote of not less than two of its members, shall adopt the rates of fees to be paid.

§ 514.2 When will the annual rates of fees be published?

(a) The Commission shall adopt the rates of fees no later than November 1st of each year.

(b) The Commission shall publish the rates of fees in a notice in the **Federal Register**.

§ 514.3 What is the maximum fee rate?

(a) The rates of fees imposed shall be—

(1) No more than 2.5% of the first $1,500,000 of the assessable gross revenues from each gaming operation, and

(2) No more than 5% of amounts in excess of the first $1,500,000 of the assessable gross revenues from each gaming operation.

(b) If a tribe has a certificate of self-regulation, the rate of fees imposed on assessable gross revenues from the class II gaming activity shall be no more than 0.25%.

(c) The total amount of all fees imposed on assessable gross revenues during any fiscal year shall not exceed 0.08% of the assessable gross gaming revenues of all gaming operations.

§ 514.4 How does a gaming operation calculate the amount of the annual fee it owes?

(a) The amount of annual fees owed shall be computed using:

(1) The most recent rates of fees adopted by the Commission, and

(2) The assessable gross revenues for the gaming operation's assessed fiscal year.

(b) Assessed fiscal year means the gaming operation's fiscal year ending prior to January 1 of the year the Commission adopted fee rates.

(c) For purposes of computing fees, assessable gross revenues for each gaming operation are the total amount of money wagered on class II and III games, plus entry fees (including table or card fees), less any amounts paid out as prizes or paid for prizes awarded, and less an allowance for capital expenditures for structures as reflected in the gaming operation's audited financial statements.

(d) Assessable gross revenue tiers. Tier 1 assessable gross revenues are the first $1,500,000 of the assessable gross revenues from each gaming operation. Tier 2 assessable gross revenues are the amounts in excess of the first $1,500,000 of the assessable gross revenues from each gaming operation.

(e) The allowance for capital expenditures for structures shall be either:

(1) An amount not to exceed 5% of the cost of structures in use throughout the assessed fiscal year and 2.5% of the cost of structures in use during only a part of the assessed fiscal year; or

(2) An amount not to exceed 10% of the total amount of depreciation expenses for the assessed fiscal year.

(f) Unless otherwise provided by regulation, generally accepted accounting principles shall be used.

§ 514.5 When must a gaming operation pay its annual fees?

(a) Annual fees are payable to the Commission on a quarterly basis. The annual fee payable to the Commission optionally may be paid in full in the first quarterly payment.

(b) Each gaming operation shall calculate the amount of fees to be paid, if any, and remit them with the quarterly statement required in § 514.6 within three (3) months, six (6) months, nine (9) months, and twelve (12) months of the end of the gaming operation's fiscal year.

§ 514.6 What are the quarterly statements that must be submitted with the fee payments?

(a) Each gaming operation shall file with the Commission quarterly statements showing its assessable gross revenues for the assessed fiscal year.

(b) These statements shall show the amounts derived from each type of game, the amounts deducted for prizes, and the amounts deducted for the allowance for capital expenditures for structures.

(c) The quarterly statements shall identify an individual or individuals to be contacted should the Commission need to communicate further with the gaming operation. A telephone number and email address for each individual identified shall be included.

(d) Each quarterly statement shall include the computation of the fees payable, showing all amounts used in the calculations. The required calculations are as follows:

(1) Multiply the Tier 1 assessable gross revenues by the rate for those revenues adopted by the Commission.

(2) Multiply the Tier 2 assessable gross revenues by the rate for those revenues adopted by the Commission.

(3) Add (total) the results (products) obtained in paragraphs (d)(1) and (2) of this section.

(4) Multiply the total obtained in paragraph (d)(3) of this section by ¼.

(5) Adjust for prior amounts paid and credits received, if applicable. The gaming operation shall provide a detailed justification for the adjustment.

(6) The amount computed in paragraph (d)(5) of this section is the amount to be remitted.

(e) As required by part 571 of this chapter, quarterly statements must be reconciled with a tribe's audited or reviewed financial statements for each gaming location. These reconciliations must be made available upon the request of any authorized representative of the NIGC.

§ 514.7 What should a gaming operation do if it changes its fiscal year or ceases operations?

(a) If a gaming operation changes its fiscal year, it shall notify the Commission of the change within thirty (30) days. The Commission may request that the gaming operation prepare and submit to the Commission the fees and statements required by this subsection for the stub period from the end of the previous fiscal year to the beginning of the new fiscal year. The submission must be sent to the Commission within ninety (90) days of its request.

(b) If a gaming operation ceases operations, it shall notify the Commission within (30) days. The Commission may request that the gaming operation, using the most recent rates of fees adopted by the Commission, prepare and submit to the Commission fees and statements for the period from the end of the most recent quarter for which fees have been paid to the date operations ceased. The submission must be sent to the Commission within (90) days of its request.

§ 514.8 Where should fees, quarterly statements, and other communications about fees be sent?

Remittances, quarterly statements, and other communications about fees shall be sent to the Commission by the methods provided for in the rates of fees notice published in the **Federal Register**.

§ 514.9 What happens if a gaming operation submits its fee payment or quarterly statement late?

(a) In the event that a gaming operation fails to submit a fee payment or quarterly statement in a timely manner, the Chair of the Commission may issue a notice specifying:

(1) The date the statement and/or payment was due;

(2) The number of calendar days late the statement and/or payment was submitted;

(3) A citation to the federal or tribal requirement that has been or is being violated;

(4) The action being considered by the Chair; and

(5) Notice of rights of appeal pursuant to subchapter H of this chapter.

(b) Within fifteen (15) days of service of the notice, the recipient may submit written information about the notice to the Chair. The Chair shall consider any information submitted by the recipient as well as the recipient's history of untimely submissions or failure to file statements and/or fee payments over the preceding five (5) years in determining the amount of the late fee, if any.

(c) When practicable, within thirty (30) days of issuing the notice described in paragraph (a) of this section to a recipient, the Chair of the Commission may assess a proposed late fee against a recipient for each failure to file a timely quarterly statement and/or fee payment:

(1) For statements and/or fee payments one (1) to thirty (30) calendar days late, the Chair may propose a late fee of up to, but not more than 10% of the fee amount for that quarter;

(2) For statements and/or fee payments thirty-one (31) to sixty (60) calendar days late, the Chair may propose a late fee of up to, but not more than 15% of the fee amount for that quarter;

(3) For statements and/or fee payments sixty-one (61) to ninety (90) calendar days late, the Chair may propose a late fee of up to, but not more than 20% of the fee amount for that quarter.

§ 514.10 When does a late payment or quarterly statement submission become a failure to pay?

Statements and/or fee payments over ninety (90) calendar days late constitute a failure to pay the annual fee, as set forth in IGRA, 25 U.S.C. 2717(a)(4), and NIGC regulations, 25 CFR 573.4(a)(2). In accordance with 25 U.S.C. 2717(a)(4), failure to pay fees shall be grounds for revocation of the approval of the Chair of any license, ordinance or resolution required under IGRA for the operation of gaming. In accordance with § 573.4(a)(2) of this chapter, if a tribe, management contractor, or individually owned gaming operation fails to pay the annual fee, the Chair may issue a notice of violation and, simultaneously with or subsequently to the notice of violation, a temporary closure order.

§ 514.11 Can a proposed late fee be appealed?

(a) Proposed late fees assessed by the Chair may be appealed under subchapter H of this chapter.

(b) At any time prior to the filing of a notice of appeal under subchapter H of this chapter, the Chair and the recipient may agree to settle the notice of late submission, including the amount of the proposed late fee. In the event a settlement is reached, a settlement agreement shall be prepared and executed by the Chair and the recipient. If a settlement agreement is executed, the recipient shall be deemed to have waived all rights to further review of the notice or late fee in question, except as otherwise provided expressly in the settlement agreement. In the absence of a settlement of the issues under this paragraph, the recipient may contest the proposed late fee before the Commission in accordance with subchapter H of this chapter.

§ 514.12 When does a notice of late submission and/or a proposed late fee become a final order of the Commission and final agency action?

If the recipient fails to appeal under subchapter H of this chapter, the notice and the proposed late fee shall become a final order of the Commission and final agency action.

§ 514.13 How are late submission fees paid, and can interest be assessed?

(a) Late fees assessed under this part shall be paid by the person or entity assessed and shall not be treated as an operating expense of the operation.

(b) The Commission shall transfer the late fee paid under this subchapter to the U.S. Treasury.

(c) Interest shall be assessed at rates established from time to time by the Secretary of the Treasury on amounts remaining unpaid after their due date.

§ 514.14 What happens if the fees imposed exceed the statutory maximum or if the Commission does not expend the full amount of fees collected in a fiscal year?

(a) The total amount of all fees imposed during any fiscal year shall not exceed the statutory maximum imposed by Congress. The Commission shall credit pro-rata any fees collected in excess of this amount against amounts otherwise due.

(b) To the extent that revenue derived from fees imposed under the schedule established under this paragraph are not expended or committed at the close of any fiscal year, such funds shall remain available until expended to defray the costs of operations of the Commission.

§ 514.15 May tribes submit fingerprint cards to the NIGC for processing?

Tribes may submit fingerprint cards to the Commission for processing by the Federal Bureau of Investigation and the Commission may charge a fee to process fingerprint cards on behalf of the tribes.

§ 514.16 How does the Commission adopt the fingerprint processing fee?

(a) The Commission shall review annually the costs involved in processing fingerprint cards and, by a vote of not less than two of its members, shall adopt the fingerprint processing fee no later than November 1st of each year.

(b) The Commission shall publish the fingerprint processing fee in a notice in the **Federal Register**.

(c) The fingerprint processing fee shall be based on fees charged by the Federal Bureau of Investigation and costs incurred by the Commission. Commission costs include Commission personnel, supplies, equipment costs, and postage to submit the results to the requesting tribe.

§ 514.17 How are fingerprint processing fees collected by the Commission?

(a) Fees for processing fingerprint cards will be billed monthly to each Tribe for cards processed during the prior month. Tribes shall pay the amount billed within forty-five (45) days of the date of the bill.

(b) The Chair may suspend fingerprint card processing for a tribe that has a bill remaining unpaid for more than forty-five (45) days.

(c) Remittances and other communications about fingerprint processing fees shall be sent to the Commission by the methods provided for in the rates of fees notice published in the **Federal Register**.

Dated: November 2, 2017.

Jonodev O. Chaudhuri,

Chairman.

Kathryn Isom-Clause,

Vice Chair.

E. Sequoyah Simermeyer,

Associate Commissioner.

[FR Doc. 2017–24363 Filed 11–9–17; 8:45 am]

BILLING CODE 7565–01–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 201 and 202

[Docket No. 2017–15]

Group Registration of Unpublished Works: Extension of Comment Period

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: The U.S. Copyright Office is extending the deadlines for the submission of written comments in response to its October 12, 2017 notice of proposed rulemaking, regarding the creation of a new group registration option for unpublished works to replace the existing ''unpublished collections'' registration option. In this document, the Office also clarifies that the new group registration option is not intended for group registration of unpublished photographs; that is the subject of a separate proposed rulemaking, which would permit submission of up to 750 photographs on one application.

DATES: The comment period for the notice of proposed rulemaking published on October 12, 2017 (82 FR 47415), is extended. Comments must be made in writing and must be received in the U.S. Copyright Office no later than November 17, 2017.

ADDRESSES: For reasons of government efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments are available on the Copyright Office Web site at *https://www.copyright.gov/rulemaking/groupunpublished/.* If electronic submission of comments is not feasible due to lack of access to a computer and/or the Internet, please contact the Office for special instructions using the contact information below.

FOR FURTHER INFORMATION CONTACT: Robert J. Kasunic, Associate Register of Copyrights and Director of Registration Policy and Practice; Erik Bertin, Deputy Director of Registration Policy and Practice; or Regan A. Smith, Deputy General Counsel, by telephone at 202–707–8040 or by email at *rkas@loc.gov, ebertin@loc.gov,* and *resm@loc.gov.*

SUPPLEMENTARY INFORMATION: As detailed in an October 12, 2017 notice of proposed rulemaking (''NPRM''),[1] the U.S. Copyright Office is proposing to create a new group registration option for a limited number of unpublished works (''GRUW''). Under that proposal, applicants will be allowed to include up to five works in each submission. This new group registration option will replace the current ''unpublished collections'' option.

After publication of the NPRM, there was some understandable confusion about the scope of the NPRM among the photographer community, who feared that the GRUW option would limit them to submitting five unpublished photographs per application. To clarify, the Office does not intend to impose such a limit on photographers. On December 1, 2016, the Office issued a separate notice of proposed rulemaking amending the existing option for group registration of photographs that would create an electronic application for group registration for published photographs, and also create an analogous application for group registration for unpublished photographs.[2] Under that separate proposed rule, photographers would be permitted to include up to 750 photographs on each such application, rather than the five works proposed under the new GRUW option. *See generally* 81 FR at 86649. The Office is working on the group registration of photographs final rule in conjunction

[1] 82 FR 47415 (Oct. 12, 2017).

[2] 81 FR 86643 (Dec. 1, 2016).

with the public comments received in that rulemaking. The Office fully intends to finalize that rule before finalizing the GRUW final rule.

Dated: November 7, 2017.

Sarang V. Damle,

General Counsel and Associate Register of Copyrights.

[FR Doc. 2017–24511 Filed 11–9–17; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2016–0309; FRL–9968–49–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Reasonably Available Control Technology for Cement Kilns, Revisions to Portland Cement Manufacturing Plant and Natural Gas Compression Station Regulations, and Removal of Nitrogen Oxides Reduction and Trading Program Replaced by Other Programs and Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of Maryland. This revision pertains to reasonably available control technology (RACT) for cement kilns, revisions to and recodification of certain provisions for Portland cement manufacturing plants (cement plants) and internal combustion (IC) engines at natural gas compression stations, and removal of the obsolete Nitrogen Oxides (NO_X) Reduction and Trading Program that has been replaced by other trading programs or addressed in other regulations. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before December 13, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2016–0309 at *http://www.regulations.gov,* or via email to *stahl.cynthia@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Marilyn Powers, (215) 814–2308, or by email at *powers.marilyn@epa.gov.*

SUPPLEMENTARY INFORMATION: On November 24, 2015, the State of Maryland, through the Maryland Department of the Environment (MDE), submitted a SIP revision for approval into the Maryland SIP. The submission is comprised of three State actions pertaining to amendments to COMAR 26.11.01.10, COMAR 26.11.09.08, COMAR 26.11.29, and COMAR 26.11.30. The amendments address the requirement for NO_X RACT for cement kilns for the 2008 ozone national ambient air quality standard (NAAQS), the removal of COMAR provisions related to the obsolete NO_X Budget Trading Program under the NO_X SIP Call [1] (that has been replaced by other trading programs), the consolidation of all existing and new requirements for cement kilns into one COMAR regulation, the consolidation of all existing and new requirements for IC engines into one COMAR regulation, the addition of new particulate matter (PM) monitoring requirements, and the addition of an alternate monitoring option for visible emissions at cement kilns. On February 17, 2017, MDE provided a letter to EPA clarifying the NO_X RACT limits and withdrawing from EPA's consideration a provision of its regulation for natural gas compression stations.

[1] *See* Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone, 63 FR 57371 (October 27, 1998).

I. Background

A. NO_X RACT for Cement Kilns

On March 12, 2008, EPA strengthened the NAAQS for ground level ozone, setting both the primary and secondary standards to a level of 0.075 parts per million (ppm), or 75 parts per billion (ppb), averaged over an 8-hour period (hereafter referred to as the 2008 ozone NAAQS). On May 21, 2012 (77 FR 30088), EPA designated 45 areas as nonattainment under the 2008 ozone NAAQS, including three areas or portions of areas in Maryland. Under section 182 of the CAA, states must review and revise the RACT requirements in their SIP to ensure that these requirements would still be considered RACT under the new, more stringent NAAQS. Major stationary sources of ozone precursor emissions located in ozone nonattainment areas classified as moderate and above (and sources located in the Ozone Transport Region (OTR), of which the entire state of Maryland is a part) are subject to RACT requirements. *See* sections 182(b)(2) and 184(b)(2) of the CAA. Section 182(f) of the CAA specifically requires RACT for major stationary sources of NO_X.[2] The cement kilns in Maryland are major stationary sources of NO_X and are therefore required to be evaluated for NO_X RACT under the 2008 ozone NAAQS.

B. Repeal of NO_X Budget Trading Program Requirements Under the NO_X SIP Call

In October 1998, EPA finalized the ''Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone''—commonly called the NOx SIP Call. The NOx SIP Call was designed to mitigate significant transport of NO_X, one of the precursors of ozone. The NO_X Budget Trading Program was established under the NO_X SIP Call to allow electric generating units (EGUs) greater than 25 megawatts and industrial non-electric generating units (or non-EGUs) with a rated heat input greater than 250 million British thermal units per hour (MMBtu/hr) (referred to as large non-EGUs) to participate in a regional NO_X cap and trade program.[3] The NO_X SIP call also

[2] A major stationary source of NO_X in a marginal or moderate ozone nonattainment area, or in an ozone transport region, is a source that emits or has the potential to emit 100 tons of NO_X.

[3] In the cap and trade program established under the NO_X SIP Call, a regional ozone season NO_X cap, or budget, was established, which was allocated as NO_X allowances to subject sources in the affected

Continued

established NO_X reduction requirements for other non-EGUs that were not a part of the NO_X Budget Trading Program, including cement kilns and stationary IC engines.

EPA discontinued administration of the NO_X Budget Trading Program in 2009 upon the start of the Clean Air Interstate Rule (CAIR) trading programs.[4] The NO_X SIP Call requirements continued to apply, and EGUs that were previously trading under the NO_X Budget Trading Program continued to meet NO_X SIP Call requirements under the more stringent requirements of the CAIR ozone season trading program. Certain large non-EGUs were not addressed in CAIR. Therefore, states needed to assess their state requirements and take regulatory action as necessary to ensure that all their non-EGU obligations continued to be met.

Maryland regulations, COMAR 26.11.29—*NO_X Reduction Requirements and Trading Program* and COMAR 26.11.30—*Policies and Procedures Relating to Maryland's NO_X Reduction and Trading Program,* were previously approved into the Maryland SIP to implement the NO_X Budget Trading Program and allowed EGUs and large non-EGUs in the state to participate in the regional NO_X cap and trade program established under EPA's NO_X SIP Call. COMAR 26.11.29 also included NO_X reductions, monitoring, and recordkeeping requirements for cement kilns and IC engines. After EPA discontinued the NO_X Budget Trading Program under the NO_X SIP Call, Maryland's EGU obligations under the NO_X SIP Call continued to be addressed in Maryland regulation COMAR 26.11.28—*Clean Air Interstate Rule.* However, in order to fill the gap for large non-EGUs created by the discontinuance of the NO_X Budget Trading Program upon implementation of CAIR and then CSAPR, Maryland needed to take regulatory action to address NO_X reduction requirements for its large non-EGUs. Maryland originally addressed these requirements for large non-EGUs as part of its regulation for kraft pulp mills, and submitted revisions to that regulation as a separate SIP revision, for which EPA took separate rulemaking action.[5] However, Maryland has identified additional large non-EGUs that are subject to the NO_X SIP Call at two sources, and is now required to take regulatory action to re-allocate the budget to cover both existing and new units. MDE is in the process of developing a new regulation to re-allocate the budget to include all units that are subject to the NO_X SIP Call.

The action in this notice pertains only to the cement kiln and IC engine provisions, which were previously approved in COMAR 26.11.29 to address NO_X SIP Call requirements.

II. Summary of SIP Revision and EPA Analysis

Maryland's submittal explained that NO_X RACT for cement kilns, which are major stationary sources of NO_X subject to RACT requirements, was established consistent with the Ozone Transport Commission (OTC) recommended RACT requirements for the 2008 ozone NAAQS. The 2007 *OTC Technical Support Document on Identification and Evaluation of Candidate Control Measures*[6] (OTC TSD) recommended NO_X emission rates for cement kilns based on applying a 60 percent reduction to uncontrolled emissions.

There are two cement kilns in Maryland—a long, dry kiln in Washington County (Lehigh Cement Company) and a pre-calciner kiln in Carroll County (Holcim Cement Plant). Revised COMAR 26.11.30 establishes a limit of 3.4 pounds (lbs) of NO_X per ton of clinker (lbs NO_X/ton of clinker) for long, dry kilns, and 2.4 lbs NO_X/ton of clinker for pre-calciner kilns. It defines a pre-calciner kiln as a ''cement kiln that contains a pre-calciner at the bottom of the pre-heater tower before the materials enter the kiln,'' and is commonly referred to as a pre-heater/pre-calciner kiln.

In its November 24, 2015 submittal, MDE stated that the NO_X emission rates for cement kilns are consistent with the OTC recommendations for cement kilns, and on February 17, 2017, MDE provided additional clarification on the justification for the NO_X RACT limits for the cement kilns. As part of its submittal, MDE also provided an estimate of costs to comply with the revised NO_X rates for cement kilns, including the costs to install selective non-catalytic reduction (SNCR) controls to meet the more stringent NO_X rate limits required by its May 21, 2010 regulatory action and the additional costs to increase the amount of reagent used in the SNCR to meet the requirements in its July 10, 2015 action further lowering the NO_X emission rate.

EPA agrees with Maryland's determination of NO_X RACT for cement kilns for the 2008 ozone NAAQS, based on our analysis of the cost effectiveness associated with installation of SNCR, the cost effectiveness for additional operating costs for the increase in ammonia use, as well as the technological considerations involved with further increasing the amount of ammonia used. A more detailed discussion of the NO_X RACT limits for the cement kilns and EPA's analysis is provided in the technical support document (TSD) for this action, available in the docket for this rulemaking at *www.regulations.gov.*

The November 24, 2015 SIP revision submittal also included several state regulatory actions for inclusion into the Maryland SIP. On May 21, 2010, Maryland repealed COMAR 26.11.29 and COMAR 26.11.30, with a State effective date of May 31, 2010. The requirements for large non-EGUs, cement kilns, and IC engines pursuant to the NO_X SIP Call continue to apply, as noted previously. Therefore, Maryland recodified certain portions of the Portland cement plant and natural gas compression station provisions (formerly found at COMAR 26.11.29.15) into new COMAR 26.11.29 (with a State effective date of July 20, 2015), retitled NO_X *Reduction Requirements for Non-Electric Generating Units.* The cement kiln provisions necessary to address the NO_X SIP Call requirements were revised to add a compliance date of April 1, 2017 for the existing NO_X emission rate limits in the regulation and to remove an alternative control method.

COMAR 26.11.30 formerly included large non-EGUs as participants in the NO_X Reduction and Trading Program and established an ozone season allocation of 947 tons of NO_X for the large non-EGUs at the only kraft pulp mill located in Maryland.[7] With repeal

states. Each allowance equaled one ton of NO_x and allowances could be traded among sources. To comply, sources were required to hold enough allowances to cover their NO_X emissions during the ozone season.

[4] CAIR was subsequently vacated and remanded. *See North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008), modified by 550 F.3d 1176 (remanding CAIR). CAIR was replaced with the Cross-State Air Pollution Rule (CSAPR) (76 FR 48208, August 8, 2011), which, after legal challenges, was implemented starting in January 2015.

[5] The NO_X SIP Call requirements applicable to large non-EGUs that were previously in COMAR 26.11.29 are now addressed in Maryland regulation COMAR 26.11.14—*Control of Emissions from Kraft Pulp Mills,* which MDE submitted to EPA as a separate SIP revision submittal. *See* rulemaking docket EPA–R03–OAR–2016–0054 for Maryland submittal #14–04 dated October 8, 2014. EPA approved the submittal on July 17, 2017 (82 FR 32641).

[6] The NO_X limits adopted in Maryland's July 10, 2015 rulemaking were based on the 2007 ''Ozone Transport Commission (OTC) Technical Support Document on Identification and Evaluation of Candidate Control Measures,'' which was included in the State's submission and is available in the docket for this proposed rulemaking action and online at *www.regulations.gov.*

[7] 40 CFR 97 Appendix C established Maryland's large non-EGU budget as 1013 tons. The kraft pulp mill was allocated 947 tons, with the remainder of

of the NO_X Reduction and Trading Program, Maryland modified its kraft pulp mill regulation in COMAR 26.11.14.07 to limit NO_X emissions from fuel burning equipment at kraft pulp mills to 947 tons per year (matching the ozone season allocation formerly in COMAR 26.11.30).[8] While this addresses the State's current reduction requirements for large non-EGUs, if a new large non-EGU locates in the State at an existing or new kraft pulp mill, Maryland would be required to demonstrate that it is still meeting its federal NO_X SIP Call requirements. If a new large non-EGU locates in the state at a source other than a pulp mill, MDE must take regulatory action to re-allocate the non-EGU budget to cover all large non-EGUs in the State, and require 40 CFR part 75 monitoring for the new non-EGU.

On July 10, 2015, Maryland made some additional regulatory modifications to both COMAR 26.11.29 and 26.11.30. COMAR 26.11.29 was revised to include only the provisions pertaining to IC engines and retitled *Control of NO_X Emissions from Natural Gas Pipeline Compression Stations.* The provisions for Portland cement manufacturing plants were removed from COMAR 26.11.29 and recodified and consolidated with the requirements for cement kilns, which were previously scattered among other COMAR regulations, into new COMAR 26.11.30—*Control of Portland Cement Manufacturing Plants* (with a State effective date of July 20, 2015). New COMAR 26.11.30 consolidates previous SIP approved requirements for PM, NO_X, sulfur dioxide (SO_2), and visible emissions that apply to Portland cement manufacturing plants.

COMAR 26.11.30 also now contains revised provisions pertaining to PM monitoring requirements. The SIP currently requires compliance with the PM emission limits by stack tests using Method 5 or 5I of 40 CFR part 60. The revision to COMAR 26.11.30 aligned the PM emissions monitoring requirements with the monitoring requirements applicable under the National Emission Standards for Hazardous Air Pollutants from the Portland Cement Manufacturing Industry, 40 CFR part 63, subpart LLL (Portland cement NESHAP) (78 FR 10006, February 12, 2013). The revision requires performance testing using Method 5 or 5I to establish the parameter to be monitored by the PM continuous parametric monitoring system (CPMS). The PM CPMS will demonstrate continuing compliance with the PM emission limits established in COMAR 26.11.30.04. As explained in more detail in EPA's TSD, the revision strengthens the SIP by the addition of PM CPMS, and is at least as stringent as the monitoring requirements for PM previously approved in the Maryland SIP for cement kilns.

COMAR 26.11.30 also allows cement kilns the option of using PM CPMS for monitoring visible emissions in lieu of a continuous opacity monitor (COM) when a PM CPMS is installed and operated as specified in the rule. In the Portland cement NESHAP, in disagreeing with industry commenters who stated a preference for COMs, EPA explained that ''PM CPMS has a clear advantage in low PM concentration measurement over continuous opacity monitoring systems'' and that ''the CPMS is considerably more sensitive than an opacity monitor or bag leak detector at detecting fluctuations in PM level.'' The revision in COMAR 26.11.30 allowing the use of PM CPMS in lieu of COMs is approvable under section 110 of the CAA for the reasons noted above and as discussed in EPA's TSD. EPA does not expect it to interfere with attainment of any of the NAAQS, with reasonable further progress, or with any other CAA requirement.

Finally, the November 24, 2015 submittal proposed to remove from the Maryland SIP former COMAR provisions which implemented EPA's NO_X Budget Trading Program under the NO_X SIP Call as discussed in detail in EPA's TSD for this rulemaking. EPA's NO_X Budget Trading Program under the NO_X SIP Call is obsolete as it was replaced by CAIR, which was subsequently replaced by CSAPR in 2015 and the CSAPR Update in 2017. Therefore, the removal of the NOx Budget Trading Program requirements from the Maryland SIP that were formerly in COMAR 26.11.29 and .30 does not impact any of the NAAQS, reasonable further progress or any other CAA requirements as those NO_X reductions now are achieved through the CSAPR Update, and the removal is thus approvable under section 110(l) of the CAA.

EPA's TSD prepared for this proposed rulemaking action provides further detail on Maryland's submittal and EPA's analysis of Maryland's SIP revision submittal. EPA's TSD is available in the docket for this rulemaking action and online at *www.regulations.gov.*

III. Proposed Action

EPA is proposing to approve Maryland's November 24, 2015 SIP revision submittal, as clarified by its February 17, 2017 letter, pursuant to sections 110, 182 and 184 of the CAA. EPA's review of this material indicates that Maryland's November 24, 2015 submittal, as clarified by its February 17, 2017 letter, is approvable as it meets requirements for NO_X RACT for cement kilns for the 2008 ozone NAAQS under sections 110, 182 and 184 of the CAA. EPA is also proposing to approve the Maryland SIP submittal which includes removal of regulations related to the NO_X Reduction and Trading Program under the NO_X SIP Call as that trading program is no longer operating as it has been replaced by the CSAPR Update as noted previously. Thus, the Maryland regulations in the SIP which addressed the NO_X Reduction and Trading Program no longer provide emission reductions. Additionally, EPA is proposing to approve as part of the SIP Maryland's revised COMAR regulations that recodified certain requirements applicable to Portland cement manufacturing plants and natural gas compression stations and added new requirements for Portland cement plants and natural gas compression stations which are SIP strengthening under section 110 of the CAA. Finally, EPA is proposing to approve a new regulatory provision for inclusion in the Maryland SIP which creates new emission and monitoring requirements for cement kiln emissions as the new provision will strengthen the Maryland SIP and is approvable under section 110 of the CAA. EPA is taking comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. Incorporation by Reference

In this proposed rulemaking action, EPA is proposing to include in a final EPA rule, regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the revisions to COMAR 26.01.10, COMAR 26.11.09.08, COMAR 26.11.29 and COMAR 26.11.30 as described in this proposed rulemaking action. These documents are available electronically through *www.regulations.gov* and/or may be viewed at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

the budget reserved in a set-aside account for allocation to new sources.

[8] The NO_X SIP Call requirements applicable to large non-EGUs that were previously in COMAR 26.11.30 are now addressed in Maryland regulation COMAR 26.11.14—*Control of Emissions from Kraft Pulp Mills,* which was submitted to EPA as a separate SIP revision submittal, and for which EPA is taking separate action. *See* rulemaking docket EPA–R03–OAR–2016–0054 for Maryland submittal #14–04 dated October 8, 2014.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

This rulemaking action proposing to approve NO_X RACT for cement kilns for the 2008 ozone NAAQS; to remove Maryland's NO_X Reduction and Trading Program regulations under the NO_X SIP Call; and to include revised and recodified provisions for natural gas compression stations and Portland cement manufacturing plants in Maryland regulations COMAR 26.11.29 and COMAR 26.11.30 respectively, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This is due to the fact that this SIP does not apply to Indian country, and therefore will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: October 25, 2017.

Cosmo Servidio,

Regional Administrator, Region III.

[FR Doc. 2017–24536 Filed 11–9–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2016–0078; 4500030113]

RIN 1018–BB64

Endangered and Threatened Wildlife and Plants; Threatened Species Status for Chorizanthe parryi var. fernandina (San Fernando Valley Spineflower)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce that a Candidate Conservation Agreement (CCA) has been prepared for *Chorizanthe parryi* var. *fernandina* (San Fernando Valley spineflower). The CCA was developed as a collaborative effort between the Newhall Land and Farming Company (Newhall Land), a California limited partnership, and the Service to implement conservation measures for the species. With the release of the CCA, we are reopening for an additional 30 days the comment period on the proposed rule to list *C. parryi* var. *fernandina* as a threatened species. We will submit a final listing determination to the **Federal Register** on or before March 15, 2018.

DATES: The comment period for the proposed rule that published September 15, 2016, at 81 FR 63454 is reopened. We will accept comments received or postmarked on or before December 13, 2017. If you comment using the Federal eRulemaking Portal (see **ADDRESSES**), you must submit your comments by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.* In the Search box, enter the docket number for this proposed rule, which is FWS–R8–ES–2016–0078. Then click on the Search button. You may submit a comment by clicking on ''Comment Now!'' Please ensure that you have found the correct rulemaking before submitting your comment.

(2) *U.S. mail or hand delivery:* Public Comments Processing, Attn: Docket No. FWS–R8–ES–2016–0078; U.S. Fish and Wildlife Service, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Stephen P. Henry, Field Supervisor, U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, 2493 Portola Road, Ventura, CA 93003; telephone 805–644–5763; facsimile 805–644–3958. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

On September 15, 2016, we published a proposed rule (81 FR 63454) to add *Chorizanthe parryi* var. *fernandina* as a threatened species to the List of Endangered and Threatened Plants under the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). That proposal had a 60-day comment period, ending November 16, 2016. For a description of previous Federal actions concerning *C. parryi* var. *fernandina,* please refer to the September 15, 2016, proposed listing rule (81 FR 63454). On July 19, 2017, the Service announced a 6-month extension of the final determination of whether to list the species as a result of scientific disagreement and uncertainty (82 FR 33036), and reopened an additional 30-day comment period.

Newhall Land and the Service have developed a CCA to provide additional conservation measures for *Chorizanthe parryi* var. *fernandina.* The CCA provides for Newhall Land to voluntarily implement additional conservation measures described in the San Fernando Valley Spineflower Enhancement and Introduction Plan (Introduction Plan) with the goal of enhancing the status of the species. The Introduction Plan provides for Newhall

Land to voluntarily establish new, protected *C. parryi* var. *fernandina* occurrences within the species' historical range that will increase the resiliency of the existing populations and expand the redundancy and representation of the species. Newhall Land will voluntarily conserve an additional 1,498 acres of its property for the benefit of the *C. parryi* var. *fernandina* and carry out additional conservation activities within portions of these 1,498 acres and within a portion of the Petersen Ranch Mitigation Bank. Spineflower introduction will occur on a total of at least 10 acres within the Additional Conservation Areas. These actions, collectively known as the Additional Conservation Measures, would contribute to reducing and eliminating current and potential future threats to the persistence of the species by expanding the area of protected conservation land for the plant, increasing the number and extent of protected *C. parryi* var. *fernandina* occurrence locations with outplanting, and providing protection for the introduction sites from development-related stressors with conservation easements and management actions. The Additional Conservation Measures would result in at least two new, self-sustaining, and persistent *C. parryi* var. *fernandina* occurrences and would increase the number of ecoregions in which the species is represented. All documents are posted to *http://www.regulations.gov* in Docket No. FWS–R8–ES–2016–0078.

Information Requested

We will accept written comments and information during this reopened comment period on our proposed listing for *Chorizanthe parryi* var. *fernandina* that was published in the **Federal Register** on September 15, 2016 (81 FR 63454) and the CCA. We will consider information and recommendations from all interested parties. We intend that any final action resulting from the proposal will be as accurate as possible and based on the best available scientific and commercial data.

In consideration of the CCA, we are particularly interested in new information and comments regarding:

(1) The efficacy of seed introduction for long-term establishment into suitable, unoccupied habitat of *Chorizanthe* or related taxa.

(2) Whether the new areas proposed for seeding under the CCA will be appropriate to support populations of *Chorizanthe parryi* var. *fernandina.*

(3) Whether the Additional Conservation Areas and Measures established under the Introduction Plan will afford sufficient resiliency, redundancy, and representation for the conservation of the species.

If you previously submitted comments or information on the September 15, 2016, proposed rule (81 FR 63454) and/or the July 19, 2017, reopening of the comment period on the proposed rule (82 FR 33036), please do not resubmit them. We have incorporated previously submitted comments into the public record, and we will fully consider them in the preparation of our final determination. Our final determination concerning the proposed listing will take into consideration all written comments and any additional information we receive.

You may submit your comments and materials concerning the proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**). You may obtain copies of the proposed rule at *http://www.regulations.gov* at Docket No. FWS–R8–ES–2016–0078. Copies of the proposed rule are also available at *http://www.fws.gov/cno/es//.*

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: October 4, 2017.

Gregory Sheehan,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2017–24474 Filed 11–9–17; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 82, No. 217
Monday, November 13, 2017

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.

DEPARTMENT OF AGRICULTURE

Office of Procurement and Property Management

Notice of Request for an Extension of a Currently Approved Information Collection

AGENCY: Office of Procurement and Property Management (OPPM), U.S. Department of Agriculture (USDA).

ACTION: Notice and request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Office of Procurement and Property Management's intention to request an extension of a currently approved information collection for Guidelines for the Transfer of Excess Computers or Other Technical Equipment Pursuant to Section 14220 of the 2008 Farm Bill.

DATES: Comments on this notice must be received by January 12, 2018 to be assured of consideration.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for sending comments.
- *Email: Sect14220.2008FarmBill@dm.usda.gov.* Include OMB Control No. 0505–0023 in the subject line of the message.
- *Fax:* (202) 720–8972.
- *Mail:* Office of Procurement and Property Management, Property Management Division, Attn: Michael R. Johnson, 1400 Independence Ave. SW., Suite 1575, Mailstop 9304, Washington, DC 20250.
- *Hand Delivery/Courier:* 1400 Independence Ave. SW., Suite 1575, Mailstop 9304, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Mr. Michael R. Johnson, OPPM at (202) 720–9779 or by mail at USDA, OPPM, 1400 Independence Ave. SW., Suite 1575, Mailstop 9304, Washington, DC 20250. Please cite OMB Control No. 0505–0023.

SUPPLEMENTARY INFORMATION:

Title: Guidelines for the Transfer of Excess Computers or Other Technical Equipment Pursuant to Section 14220 of the 2008 Farm Bill.

OMB Number: 0505–0023.

Expiration Date of Approval: 03/31/2018.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: USDA requires information in order to verify eligibility of requestors, determine availability of excess property, and have contact information for the requestor available to ensure an organization is designated to receive property on behalf of an eligible recipient. Information will be used to coordinate the transfer of excess property to eligible recipients. Respondents will be authorized representatives of a city, town, or local government entity located in a rural area as defined in 7 U.S.C. 1991(a)(13)(A).

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .167 hours per response.

Respondents: City, town, or local government entities located in a rural area.

Estimated Number of Respondents: 10.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 2 hours.

Comments are invited on: (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 including the validity of the methodology and assumptions used; (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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

George M. Cabaniss Jr.,

Director.

[FR Doc. 2017–24479 Filed 11–9–17; 8:45 am]

BILLING CODE 3410–TX–P

BROADCASTING BOARD OF GOVERNORS

Government In The Sunshine Act Meeting Notice

DATE AND TIME: Wednesday, November 15, 2017, 1:00 p.m. ET.

PLACE: Cohen Building, Room 3321, 330 Independence Ave. SW., Washington, DC 20237.

SUBJECT: Notice of Meeting of the Broadcasting Board of Governors.

SUMMARY: The Broadcasting Board of Governors (Board) will be meeting at the time and location listed above. The Board will vote on a consent agenda consisting of the minutes of its August 30, 2017 meeting, a resolution honoring 35th Anniversary of Voice of America Broadcasts in Amharic-Language, and a resolution proposing 2018 BBG Board schedule. The Board will receive a report from the Chief Executive Officer and Director of BBG.

This meeting will be available for public observation via streamed webcast, both live and on-demand, on the agency's public Web site at *www.bbg.gov.* Information regarding this meeting, including any updates or adjustments to its starting time, can also be found on the agency's public Web site.

The public may also attend this meeting in person at the address listed above as seating capacity permits. Members of the public seeking to attend the meeting in person must register at *https://bbgboardmeetingnovember2017.eventbrite.com* by 12:00 p.m. (ET) on November 14. For more information, please contact BBG Public Affairs at (202) 203–4400 or by email at *pubaff@bbg.gov.*

CONTACT PERSON FOR MORE INFORMATION: Persons interested in obtaining more information should contact Oanh Tran at (202) 203–4545.

Oanh Tran,

Managing Director.

[FR Doc. 2017–24643 Filed 11–8–17; 4:15 pm]

BILLING CODE 8610–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Arizona Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Arizona Advisory Committee (Committee) to the Commission will be held at 2:00 p.m. (Pacific Time) Friday, November 17, 2017. The purpose of the meeting is for the Committee to deliberate on voting rights project proposal and begin initial brainstorm.

DATES: The meeting will be held on Friday, November 17, 2017, at 2:00 p.m. PT

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 877–723–9521, conference ID number: 7584074. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov*. Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://facadatabase.gov/committee/meetings.aspx?cid=235*. Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Approval of minutes from November 1, 2017 meeting
III. Review Project Proposal
IV. Review Briefing Timeline
V. Brainstorm Venue location and Potential Dates
VI. Next Steps
VII. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstance of the committee needing to plan a briefing on voting rights to satisfy the U.S. Commission on Civil Rights' 2018 Statutory Enforcement report timeline.

Dated: November 7, 2017.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017–24482 Filed 11–9–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–66–2015]

Proposed Foreign-Trade Zone—Hitchcock, Texas; Amendment of Application

A request has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the Port of Houston Authority (PHA), grantee of FTZ 84, at the request of the City of Hitchcock, to amend the City's pending application requesting authority to establish a new foreign-trade zone in Hitchcock, Texas. The pending application was docketed on October 6, 2015 (FTZ Board Docket B–66–2015, 80 FR 61358, October 13, 2015).

PHA is requesting authority to include the site originally proposed for FTZ designation as part of a new zone in Hitchcock, Texas as an additional magnet site of FTZ 84, adjacent to the Houston Customs and Border Protection port of entry. The proposed site is as follows: Proposed Site 1 (280.54 acres)—Blimp Base, 7529 Blimp Base Road, Hitchcock. If approved, the proposed site would be assigned a new site number under FTZ 84. The amended application is limited to FTZ designation for the proposed Blimp Base site (*i.e.,* it does not request authority for the ASF service area originally proposed in the application).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at: Foreign-Trade Zones Board, U.S. Department of Commerce, Room 21013, 1401 Constitution Ave. NW., Washington, DC 20230.

The closing period for their receipt is December 13, 2017. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to December 28, 2017).

For further information, contact Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: November 6, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–24518 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–967]

Aluminum Extrusions From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2015–2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on aluminum extrusions from the People's Republic of China (PRC). The period of review (POR) is May 1, 2015, through April 30, 2016. These final results cover 10 companies and the PRC-wide entity for which an administrative review was initiated.

DATES: *Applicable:* November 13, 2017.

FOR FURTHER INFORMATION CONTACT: Deborah Scott or Mark Flessner, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2657 or (202) 482–6312, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department initiated this review on July 7, 2016.[1] On June 6, 2017, the Department published the *Preliminary Results* of this administrative review.[2] At that time, we invited interested parties to comment on the *Preliminary Results.* On July 6, 2017, we received a case brief from the Aluminum Extrusions Fair Trade Committee (the petitioner).[3] No other parties submitted case or rebuttal briefs. These final results cover 10 companies and the PRC-wide entity for which an administrative review was initiated and not rescinded.[4]

Scope of the Order

The merchandise covered by the *Order*[5] is aluminum extrusions which are shapes and forms, produced by an extrusion process, made from aluminum alloys having metallic elements corresponding to the alloy series designations published by The Aluminum Association commencing with the numbers 1, 3, and 6 (or proprietary equivalents or other certifying body equivalents).[6]

Imports of the subject merchandise are provided for under the following categories of the Harmonized Tariff Schedule of the United States (HTSUS): 6603.90.8100, 7616.99.51, 8479.89.94, 8481.90.9060, 8481.90.9085, 9031.90.9195, 8424.90.9080, 9405.99.4020, 9031.90.90.95, 7616.10.90.90, 7609.00.00, 7610.10.00, 7610.90.00, 7615.10.30, 7615.10.71, 7615.10.91, 7615.19.10, 7615.19.30, 7615.19.50, 7615.19.70, 7615.19.90, 7615.20.00, 7616.99.10, 7616.99.50, 8479.89.98, 8479.90.94, 8513.90.20, 9403.10.00, 9403.20.00, 7604.21.00.00, 7604.29.10.00, 7604.29.30.10, 7604.29.30.50, 7604.29.50.30, 7604.29.50.60, 7608.20.00.30, 7608.20.00.90, 8302.10.30.00, 8302.10.60.30, 8302.10.60.60, 8302.10.60.90, 8302.20.00.00, 8302.30.30.10, 8302.30.30.60, 8302.41.30.00, 8302.41.60.15, 8302.41.60.45, 8302.41.60.50, 8302.41.60.80, 8302.42.30.10, 8302.42.30.15, 8302.42.30.65, 8302.49.60.35, 8302.49.60.45, 8302.49.60.55, 8302.49.60.85, 8302.50.00.00, 8302.60.90.00, 8305.10.00.50, 8306.30.00.00, 8414.59.60.90, 8415.90.80.45, 8418.99.80.05, 8418.99.80.50, 8418.99.80.60, 8419.90.10.00, 8422.90.06.40, 8473.30.20.00, 8473.30.51.00, 8479.90.85.00, 8486.90.00.00, 8487.90.00.80, 8503.00.95.20, 8508.70.00.00, 8515.90.20.00, 8516.90.50.00, 8516.90.80.50, 8517.70.00.00, 8529.90.73.00, 8529.90.97.60, 8536.90.80.85, 8538.10.00.00, 8543.90.88.80, 8708.29.50.60, 8708.80.65.90, 8803.30.00.60, 9013.90.50.00, 9013.90.90.00, 9401.90.50.81, 9403.90.10.40, 9403.90.10.50, 9403.90.10.85, 9403.90.25.40, 9403.90.25.80, 9403.90.40.05, 9403.90.40.10, 9403.90.40.60, 9403.90.50.05, 9403.90.50.10, 9403.90.50.80, 9403.90.60.05, 9403.90.60.10, 9403.90.60.80, 9403.90.70.05, 9403.90.70.10, 9403.90.70.80, 9403.90.80.10, 9403.90.80.15, 9403.90.80.20, 9403.90.80.41, 9403.90.80.51, 9403.90.80.61, 9506.11.40.80, 9506.51.40.00, 9506.51.60.00, 9506.59.40.40, 9506.70.20.90, 9506.91.00.10, 9506.91.00.20, 9506.91.00.30, 9506.99.05.10, 9506.99.05.20, 9506.99.05.30, 9506.99.15.00, 9506.99.20.00, 9506.99.25.80, 9506.99.28.00, 9506.99.55.00, 9506.99.60.80, 9507.30.20.00, 9507.30.40.00, 9507.30.60.00, 9507.90.60.00, and 9603.90.80.50.

The subject merchandise entered as parts of other aluminum products may be classifiable under the following additional Chapter 76 subheadings: 7610.10, 7610.90, 7615.19, 7615.20, and 7616.99, as well as under other HTSUS chapters. In addition, fin evaporator coils may be classifiable under HTSUS numbers: 8418.99.80.50 and 8418.99.80.60. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this *Order* is dispositive.

Analysis of Comments Received

All issues raised in the case briefs filed by parties in this review are addressed in the Issues and Decision Memorandum, which is incorporated herein by reference. A list of the issues which any party raised, and to which we respond in the Issues and Decision Memorandum, follows in the 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 (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

For the purposes of these final results, the Department made no changes to the *Preliminary Results.*

PRC-Wide Entity

For the purposes of the final results of this administrative review, the Department finds that the following entities are part of the PRC-wide entity because they failed to submit both a Q&V response and information to establish eligibility for a separate rate: (1) Kam Kiu; (2) Atlas Integrated Manufacturing Ltd.; (3) Classic & Contemporary Inc.; (4) Dongguan Golden Tiger Hardware Industrial Co., Ltd.; (5) Jiaxing Jackson Travel Products Co., Ltd.; (6) Taishan City Kam Kiu Aluminium Extrusion Co., Ltd.; (7) Shenyang Yuanda Aluminium Industry Engineering Co. Ltd.; (8) Sincere Profit Limited; and (9) Suzhou New Hongji Precision Part Co.

The Department's change in policy regarding conditional review of the PRC-wide entity applies to this administrative review.[7] Under this policy, the PRC-wide entity will not be under review unless a party specifically

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[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 44260 (July 7, 2016) (*Initiation Notice*).

[2] *See Aluminum Extrusions from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Rescission of Review in Part; 2015–2016,* 82 FR 26055 (June 6, 2017) (*Preliminary Results*), and accompanying preliminary decision memorandum (Preliminary Decision Memorandum).

[3] *See* Petitioner Letter re: Aluminum Extrusions from the People's Republic of China: Case Brief, dated July 6, 2017.

[4] This administrative review initially covered 191 companies and the PRC-wide entity. *See Initiation Notice,* 81 FR at 44262. However, the Department rescinded this review with respect to 181 companies for which all administrative review requests were timely withdrawn. *See Preliminary Results,* 82 FR at 26056.

[5] *See Aluminum Extrusions from the People's Republic of China: Antidumping Duty Order,* 76 FR 30650 (May 26, 2011) (*Order*).

[6] For a complete description of the scope of the *Order, see* Memorandum, ''Issues and Decisions Memorandum for the Final Results of the Antidumping Duty Administrative Review: Aluminum Extrusions from the People's Republic of China; 2015–2016,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[7] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65970 (November 4, 2013).

requests, or the Department self-initiates, a review of the entity. The petitioner [8] requested a review of the PRC-wide entity in the instant review; therefore, the PRC-wide entity is currently under review and the rate for the PRC-wide entity is subject to change.

Adjustments for Countervailable Subsidies

Because no mandatory respondent established eligibility for an adjustment under section 777A(f) of the Act for countervailable domestic subsidies, the Department, for these final results, did not make an adjustment pursuant to section 777A(f) of the Act for countervailable domestic subsidies for the separate-rate recipients.[9]

Pursuant to section 772(c)(1)(C) of the Act, we made an adjustment for countervailable export subsidies for tenKsolar. We calculated this adjustment as the simple average of the countervailable export subsidies determined for the mandatory respondents in the 2014 (*i.e.,* most recently completed) CVD administrative review [10] and deducted this amount from the weighted-average dumping margin assigned to tenKsolar.[11] The adjusted rate for tenKsolar is 85.96 percent.

Pursuant to section 772(c)(1)(C) of the Act, we also made an adjustment for countervailable export subsidies for the PRC-wide entity. We adjusted the PRC-wide entity cash deposit rate by the lowest countervailable export subsidy determined for the mandatory respondents in the 2014 (*i.e.,* most recently completed) CVD administrative review.[12]

Final Results of Review

The Department determines that the following weighted-average dumping margins exist for the 2015–2016 POR:

Exporter	Weighted-average dumping margin (percent)	Margin adjusted for liquidation and cash deposit purposes (percent)
tenKsolar (Shanghai) Co., Ltd	86.01	85.96
PRC-wide Entity	86.01	85.96

Additionally, as explained above, the Department determines that the following companies are part of the PRC-wide entity: (1) Kam Kiu; (2) Atlas Integrated Manufacturing Ltd.; (3) Classic & Contemporary Inc.; (4) Dongguan Golden Tiger Hardware Industrial Co., Ltd.; (5) Jiaxing Jackson Travel Products Co., Ltd.; (6) Taishan City Kam Kiu Aluminium Extrusion Co., Ltd.; (7) Shenyang Yuanda Aluminium Industry Engineering Co. Ltd.; (8) Sincere Profit Limited; and (9) Suzhou New Hongji Precision Part Co.

Assessment

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b), the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review in the **Federal Register**. Consistent with the Department's assessment practice in NME cases, if the Department determines that an exporter under review had no shipments of subject merchandise, any suspended entries that entered under the exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the PRC-wide rate.[13] For the companies eligible for a separate rate, the Department will instruct CBP to assess antidumping duties on the company's entries of subject merchandise at the rates listed above in the section ''Final Results of Review.''

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the companies eligible for a separate rate, the cash deposit rate will that listed above in the section ''Final Results of Review;'' (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the exporter-specific rate published for the most-recently completed segment of this proceeding in which the exporter was reviewed; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be that established for the PRC-wide entity, which is 85.96 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter with the subject merchandise. These 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 and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance

[8] The petitioner is the Aluminum Extrusions Fair Trade Committee.

[9] *See* Preliminary Decision Memorandum, at 17–18.

[10] *Aluminum Extrusions from the People's Republic of China: Final Results and Partial Rescission of Countervailing Duty Administrative Review; 2014,* 81 FR 92778 (December 20, 2016).

[11] *See* Preliminary Decision Memorandum, at 12 and 17–18.

[12] *Id.,* at 17–18.

[13] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

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.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h).

Dated: November 3, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Discussion of the Issues
   Comment: The Margin Assigned to the PRC-Wide Entity
5. Recommendation

[FR Doc. 2017–24407 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with September anniversary dates. In accordance with the Department's regulations, we are initiating those administrative reviews.

DATES: Applicable November 13, 2017.

FOR FURTHER INFORMATION CONTACT: Brenda E. Waters, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

The Department has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various antidumping and countervailing duty orders and findings with September anniversary dates.

All deadlines for the submission of various types of information, certifications, or comments or actions by the Department discussed below refer to the number of calendar days from the applicable starting time.

Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (POR), it must notify the Department within 30 days of publication of this notice in the **Federal Register.** All submissions must be filed electronically at *http://access.trade.gov* in accordance with 19 CFR 351.303.[1] Such submissions are subject to verification in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy must be served on every party on the Department's service list.

Respondent Selection

In the event the Department limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, the Department intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review. We intend to place the CBP data on the record within five days of publication of the initiation notice and to make our decision regarding respondent selection within 30 days of publication of the initiation **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted seven days after the placement of the CBP data on the record of this review. Parties wishing to submit rebuttal comments should submit those comments five days after the deadline for the initial comments.

In the event the Department decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, the Department has found that determinations concerning whether particular companies should be ''collapsed'' (*i.ee.g.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, the Department will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*e.g.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if the Department determined, or continued to treat, that company as collapsed with others, the Department will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, the Department will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value (Q&V) Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where the Department considered collapsing that entity, complete Q&V data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that the Department may extend this time if it is reasonable to do so. In order to provide parties additional certainty with respect to when the Department will exercise its discretion to extend this 90-day deadline, interested parties are advised that the Department does not intend to extend the 90-day deadline unless the requestor demonstrates that an extraordinary circumstance has prevented it from submitting a timely withdrawal request. Determinations by the Department to extend the 90-day deadline will be made on a case-by-case basis.

[1] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

Separate Rates

In proceedings involving non-market economy (NME) countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is the Department's policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, the Department analyzes each entity exporting the subject merchandise. In accordance with the separate rates criteria, the Department assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate rate eligibility, the Department requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on the Department's Web site at *http://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the ''Instructions for Filing the Certification'' in the Separate Rate Certification. Separate Rate Certifications are due to the Department no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding [2] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,[3] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Status Application will be available on the Department's Web site at *http://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Status Application, refer to the instructions contained in the application. Separate Rate Status Applications are due to the Department no later than 30 calendar days of publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Status Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

For exporters and producers who submit a separate-rate status application or certification and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than September 30, 2018.

	Period to be reviewed
Antidumping Duty Proceedings	
India: Certain Lined Paper Products, A–533–843	9/1/16–8/31/17
Goldenpalm Manufacturers PVT Limited.	
Kokuyo Riddhi Paper Products Pvt. Ltd.	
Lodha Offset Limited.	
Lotus Global Private Limited.	
Magic International Pvt. Ltd.	
Marisa International.	
Navneet Education Ltd.	
Pioneer Stationery Pvt. Ltd.	
PP Bafna Ventures Private Limited.	
SAB International.	
SGM Paper Products.	
Super Impex.	
India: Cold-Rolled Steel Flat Products, A–533–865	3/7/16–8/31/17
Anil Special Steel Industries Ltd.	
Bhandari Foils & Tubes Ltd.	
Bhiwadi Metal Rollwell Pvt Ltd.	
Bhushan Power & Steel Ltd.	
Bhushan Steel Ltd.	
Bhusan Steel and Strips Limited.	
Bhuvee Profiles & Stainless Steel Pvt Ltd.	
BRG & Steel Pvt.	

[2] Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceeding (*e.g.,* an ongoing administrative review, new shipper review, etc.) and entities that lost their separate rate in the most recently completed segment of the proceeding in which they participated.

[3] Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

	Period to be reviewed
Disha Auto Components Pvt Ltd.	
Essar Steel Ltd.	
Fit-Wel Industries.	
Good Luck Steel Tubes Ltd.	
Hi-Tech Pipes Ltd.	
Indian Steel Corp. Ltd.	
IUP Jindal Metals & Alloys Ltd.	
Jai Corp Ltd.	
Jainex Ltd.	
Jindal Stainless Ltd.	
JSW Steel Limited.	
JSW Steel Coated Products Limited.	
JSW Ispat Steel Ltd.	
KR Steelunion Ltd.	
Lloyds Group.	
Mehta Alloys Ltd.	
Metalman Industries Ltd.	
National Steel & Agro Industries Ltd.	
Niko Steel Centre.	
POSCO India.	
Quality Foils (India) Pvt Ltd.	
Rabirun Vinimay Pvt Ltd.	
Rapsri Engineering Products Co Ltd.	
Real Strips Ltd.	
Rimjhim Ispat Ltd.	
RSAL—Ruchi Strips & Alloys Ltd.	
Sahu Refrigeration Industries Ltd.	
SAIL–Steel Authority of India Ltd.	
Sandvik Asia Ltd.	
Shah Alloys Ltd.	
Shresty India.	
Soni Ispat Ltd.	
Steel Corp.	
Steelco Gujarat Ltd.	
Stelco Ltd.	
Sunflag Iron & Steel Co Ltd.	
Surya Global Ltd.	
Swastik Pipes Ltd.	
Tarun International Ltd.	
Tata Steel Ltd.	
The Tinplate Co of India Ltd.	
Tube Products of India Ltd.	
Unichem Steel & Alloys Pvt Ltd.	
Uttam Galva Steels Ltd.	
Uttam Value Steels Ltd.	
Mexico: Certain Magnesia Carbon Bricks, A–201–837	9/1/16–8/31/17
RHI-Refmex SA de C.V.	
Vesuvius Mexico S.A. de C.V.	
Mexico: Heavy Walled Rectangular Welded Carbon Pipes and Tubes, A–201–847	3/1/16–8/31/17
Arco Metal S.A. de C.V.	
Forza Steel S.A. de C.V.	
Industrias Monterrey, S.A. de C.V.	
Maquilacero S.A. de C.V.	
Perfiles y Herrajes LM S.A. de C.V.	
Productos Laminados de Monterrey S.A. de C.V.	
PYTCO S.A. de C.V.	
Regiomontana de Perfiles y Tubos S.A. de C.V.	
Ternium S.A. de C.V.	
Tuberia Nacional S.A. de C.V.	
Tuberia Procarsa S.A. de C.V.	
Republic of Korea: Cold-Rolled Steel Flat Products, A–580–881	3/7/16–8/31/17
Ameri-Source Korea.	
Dongkuk Industries Co., Ltd.	
Dongbu Steel Co., Ltd.	
Dongkuk Steel Mill Co., Ltd.	
GS Gobal Corp.	
Hanawell Co., Ltd.	
Hankum Co., Ltd.	
Hyuk San Profile Co., Ltd.	
Hyundai Glovis Co., Ltd.	
Hyundai Steel Company.	
Kindus Inc.	
POSCO.	

	Period to be reviewed
Daewoo International Corporation.	
Samsung C&T Corp.	
Steel N Future.	
Taihan Electric Wire Co., Ltd.	
Uin Global Co.	
Republic of Korea: Heavy Walled Rectangular Welded Carbon Pipes and Tubes, A–580–880	3/1/16–8/31/17
Ahshin Pipe & Tube Company.	
Bookook Steel Co., Ltd.	
Dongbu Steel Co., Ltd.	
Dong-A Steel Company.	
Histeel Co., Ltd.	
Husteel Co., Ltd.	
Hyundai Steel Pipe Company.	
Hyundai Steel Co.	
Miju Steel Manufacturing Co., Ltd.	
NEXTEEL Co., Ltd.	
Sam Kang Industries Co., Ltd.	
SeAH Steel Corporation.	
Kukje Steel Co., Ltd.	
Yujin Steel Industry Co. Ltd.	
Republic of Korea: Oil Country Tubular Goods, A–580–870	9/1/16–8/31/17
AJU Besteel Co., Ltd.	
BDP International.	
Daewoo International Corporation.	
Daewoo America.	
Dong-A Steel Co. Ltd.	
Dong Yang Steel Pipe.	
Dongbu Incheon Steel.	
DSEC.	
Erndtebruecker Eisenwerk and Company.	
Hansol Metal.	
Husteel Co., Ltd.	
HYSCO.	
Hyundai RB.	
Hyundai Steel Co., Ltd.	
Hyundai Steel Company.	
ILJIN Steel Corporation.	
Jim And Freight Co., Ltd.	
Kia Steel Co. Ltd.	
KSP Steel Company.	
Kukje Steel.	
Kurvers.	
NEXTEEL Co., Ltd.	
POSCO Daewoo Corporation.	
POSCO Daewoo America.	
Samsung.	
Samsung C and T Corporation.	
SeAH Besteel Corporation.	
SeAH Steel Corporation.	
Steel Canada.	
Sumitomo Corporation.	
TGS Pipe.	
Yonghyun Base Materials.	
ZEECO Asia.	
Taiwan: Narrow Woven Ribbons with Woven Selvedge, A–583–844	9/1/16–8/31/17
Banduoo Ltd.	
Fujian Rongshu Industry Co., Ltd.	
Ming Wei Co., Ltd.	
Roung Shu Industry Corporation.	
Xiamen Yi-He Textile Co., Ltd.	
The People's Republic of China: Certain Steel Nails,[4] A–570–909	8/1/16–7/31/17
The People's Republic of China: Magnesia Carbon Bricks, A–570–954	9/1/16–8/31/16
Fedmet Resources Corporation.	
Fengchi Imp. and Exp. Co., Ltd. of Haicheng City.	
Fengchi Mining Co., Ltd. of Haicheng City.	
Fengchi Refractories Co., of Haicheng City.	
RHI Refractories Liaoning Co., Ltd.	
The People's Republic of China: Freshwater Crawfish Tailmeat, A–570–848	9/1/16–8/31/17
China Kingdom (Beijing) Import & Export Co., Ltd.	
Deyan Aquatic Products and Food Co., Ltd.	
Hubei Nature Agriculture Industry Co., Ltd.	
Hubei Qianjiang Huashan Aquatic Food and Product Co., Ltd.	
Hubei Yuesheng Aquatic Products Co., Ltd.	

	Period to be reviewed
Jingzhou Tianhe Aquatic Products Co., Ltd.	
Nanjing Gemsen International Co., Ltd.	
Shanghai Ocean Flavor International Trading Co., Ltd.	
Weishan Hongda Aquatic Food Co., Ltd.	
Xiping Opeck Food Co., Ltd.	
Xuzhou Jinjiang Foodstuffs Co., Ltd.	
Yancheng Hi-King Agriculture Developing Co., Ltd.	
The People's Republic of China: New Pneumatic Off-the-Road Tires, A–570–912	9/1/16–8/31/17
Maxon Int'l Co., Limited.	
Tianjin Leviathan International Trade Co., Ltd.	
Weihai Zhongwei Rubber Co., Ltd.	
The People's Republic of China: Raw Flexible Magnets, A–570–922	9/1/16–8/31/17
SOM International Limited.	
Wenzhou Haibao Printing Co., LTD.	
Turkey: Oil Country Tubular Goods, A–489–816	9/1/16–8/31/17
Cayirova Boru San A.S.	
Çayirova Boru Sanayi ve Ticaret A.Ş. and Yücel Boru Ithalat-Ihracat ve Pazarlama A.Ş. (collectively Yücel).	
HG Tubulars Canada Ltd.	
Toscelik Profil ve Sac Endustrisi A.S.	
Tosyali Dis Ticaret A.S.	
Yucelboru Ihracat, Ithalat.	
United Kingdom: Cold-Rolled Steel Flat Products, A–412–824	3/7/16–8/31/17
Caparo Precision Strip, Ltd./Liberty Performance Steels Ltd.[5].	
Countervailing Duty Proceedings	
India: Certain Lined Paper Products, C–533–844	1/1/16–12/31/16
Goldenpalm Manufacturers Pvt Limited.	
India: Cold-Rolled Steel Flat Products, C–533–866	9/16/16–12/31/16
Anil Special Steel Industries Ltd.	
Bhandari Foils & Tubes Ltd.	
Bhiwadi Metal Rollwell Pvt Ltd.	
Bhushan Power & Steel Ltd.	
Bhushan Steel Ltd.	
Bhusan Steel and Strips Limited.	
Bhuvee Profiles & Stainless Steel Pvt Ltd.	
BRG & Steel Pvt.	
Disha Auto Components Pvt Ltd.	
Essar Steel Ltd.	
Fit-Wel Industries.	
Good Luck Steel Tubes Ltd.	
Hi-Tech Pipes Ltd.	
Indian Steel Corp. Ltd.	
IUP Jindal Metals & Alloys Ltd.	
Jai Corp Ltd.	
Jainex Ltd.	
Jindal Stainless Ltd.	
JSW Steel Limited.	
JSW Steel Coated Products Limited.	
JSW Ispat Steel Ltd.	
KR Steelunion Ltd.	
Lloyds Group.	
Mehta Alloys Ltd.	
Metalman Industries Ltd.	
National Steel & Agro Industries Ltd.	
Niko Steel Centre.	
POSCO India.	
Quality Foils (India) Pvt Ltd.	
Rabirun Vinimay Pvt Ltd.	
Rapsri Engineering Products Co Ltd.	
Real Strips Ltd.	
Rimjhim Ispat Ltd.	
RSAL—Ruchi Strips & Alloys Ltd.	
Sahu Refrigeration Industries Ltd.	
SAIL- Steel Authority of India Ltd.	
Sandvik Asia Ltd.	
Shah Alloys Ltd.	
Shresty India.	
Soni Ispat Ltd.	
Steel Corp.	
Steelco Gujarat Ltd.	
Stelco Ltd.	
Sunflag Iron & Steel Co Ltd.	
Surya Global Ltd.	

	Period to be reviewed
Swastik Pipes Ltd.	
Tarun International Ltd.	
Tata Steel Ltd.	
The Tinplate Co of India Ltd.	
Tube Products of India Ltd.	
Unichem Steel & Alloys Pvt Ltd.	
Uttam Galva Steels Ltd.	
Republic of Korea: Cold-Rolled Steel Flat Products, C–580–882	7/29/16–12/31/16
Dongbu Incheon Steel Co., Ltd.	
Dongkuk Industries Co., Ltd.	
Dongkuk Steel Mill Co., Ltd.	
Dongbu Steel Co., Ltd.	
Hyuk San Profile Co., Ltd.	
Hyundai Steel Co., Ltd.	
Hyundai Steel Company.	
POSCO.	
Taihan Electric Wire Co., Ltd.	
Union Steel Co., Ltd.	
The People's Republic of China: Magnesia Carbon Bricks, C–570–955	1/1/16–12/31/16
Fedmet Resources Corporation.	
Fengchi Imp. and Exp. Co., Ltd. of Haicheng City.	
Fengchi Mining Co., Ltd. of Haicheng City.	
Fengchi Refractories Co., of Haicheng City.	
RHI Refractories Liaoning Co., Ltd.	
The People's Republic of China: Narrow Woven Ribbons with Woven Selvedge, C–570–953	1/1/16–12/31/16
Yama Ribbons and Bows Co., Ltd.	
The People's Republic of China: New Pneumatic Off-the-Road Tires, C–570–913	1/1/16–12/31/16
Techking Tires Limited.	
Tianjin Leviathan International Trade Co., Ltd.	
Shandong Huitong Tyre Co., Ltd.	
The People's Republic of China: Raw Flexible Magnets, C–570–923	1/1/16–12/31/16
SOM International Limited.	
Wenzhou Haibao Printing Co., LTD.	
Turkey: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes, C–489–825	12/28/15–4/25/16 9/12/16–12/31/16
Ozdemir Boru Profil San. Ve Tic. Ltd. Sti.	
Turkey: Oil Country Tubular Goods,[6] C–489–817	1/1/16–12/31/16
Borusan Mannesmann Boru Sanayi ve Ticaret A.S.	
Borusan Istikbal Ticaret.	
Cayirova Boru San A.S.	
Cayirova Boru Sanayi ve Ticaret A.S.	
HG Tubulars Canada Ltd.	
Yucel Boru Ihracat ve Pazarlama A.S.	
Yucelboru Ihracat, Ithalat.	
Turkey: Oil Country Tubular Goods, C–489–817	1/1/16–12/31/16
Borusan Mannesmann Boru Sanayi ve Ticaret A.S.	
Borusan Istikbal Ticaret.	
Cayirova Boru San A.S.	
Cayirova Boru Sanayi ve Ticaret A.S.	
HG Tubulars Canada Ltd.	
Tosyali Dis Ticaret A.S.	
Yucel Boru Ihracat ve Pazarlama A.S.	
Yucelboru Ihracat, Ithalat.	

Suspension Agreements

None.

[4] In the initiation that published on October 16, 2017 (82 FR 48051), the Department incorrectly identified that an administrative review was initiated on the antidumping duty order of Certain Steel Nails from the PRC for Shanxi Hairut Trade Co. Ltd. The Department is now correcting that notice: The Department is initiating administrative reviews on the antidumping duty order of Certain Steel Nails from the PRC for the following companies: (1) Shanxi Hairui Trade Co., Ltd.; and (2) Qingdao D&L Group Ltd.

[5] We have previously determined that Liberty Performance Steels Ltd. is the successor-in-interest to Caparo Precision Strip, Ltd.

Duty Absorption Reviews

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

[6] The Department also received a request for review of Tosyali Dis Ticaret A.S.. However, this company was excluded from the CVD order as a result of litigation. *See Oil Country Tubular Goods from the Republic of Turkey: Amendment of Countervailing Duty Order,* 82 FR 46483 (October 26, 2017).

Gap Period Liquidation

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period, of the order, if such a gap period is applicable to the POR.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in accordance with the procedures outlined in the Department's regulations at 19 CFR 351.305. Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Factual Information Requirements

The Department's regulations identify five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). These regulations require any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The regulations, at 19 CFR 351.301, also provide specific time limits for such factual submissions based on the type of factual information being submitted. Please review the final rule, available at *http://enforcement.trade.gov/frn/2013/1304frn/2013–08227.txt,* prior to submitting factual information in this segment.

Any party submitting factual information in an antidumping duty or countervailing duty proceeding must certify to the accuracy and completeness of that information.[7] Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives. All segments of any antidumping duty or countervailing duty proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule*.[8] The Department intends to reject factual submissions in any proceeding segments if the submitting party does not comply with applicable revised certification requirements.

Extension of Time Limits Regulation

Parties may request an extension of time limits before a time limit established under Part 351 expires, or as otherwise specified by the Secretary. *See* 19 CFR 351.302. In general, an extension request will be considered untimely if it is filed after the time limit established under Part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are not limited to: (1) Case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning U.S. Customs and Border Protection data; and (5) quantity and value questionnaires. Under certain circumstances, the Department may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, the Department will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This modification also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which the Department will grant untimely-filed requests for the extension of time limits. These modifications are effective for all segments initiated on or after October 21, 2013. Please review the final rule, available at *http://www.gpo.gov/fdsys/pkg/FR–2013–09–20/html/2013–22853.htm,* prior to submitting factual information in these segments.

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: November 3, 2017.

James Maeder,

Senior Director perfoming the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2017–24517 Filed 11–9–17; 8:45 am]

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[7] *See* section 782(b) of the Act.

[8] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* the frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–910]

Circular Welded Carbon Quality Steel Pipe From the People's Republic of China: Rescission of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is rescinding the administrative review of the antidumping duty order on circular welded carbon quality steel pipe from the People's Republic of China (PRC) covering the period July 1, 2016, through June 30, 2017.

DATES: Applicable November 13, 2017.

FOR FURTHER INFORMATION CONTACT: Eli Lovely, AD/CVD Operations, Office IV, Enforcement & Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1593.

SUPPLEMENTARY INFORMATION:

Background

On September 13, 2017, based on a timely request by Zekelman Industries (Zekelman), the Department published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on circular welded carbon quality steel pipe from the PRC with respect to 20 companies.[1] On September 29, 2017, pursuant to 19

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 82 FR 42974 (September 13, 2017).

CFR 351.213(d)(1), Zekelman timely withdrew its request for an administrative review of all 20 companies.[2]

Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if the party that requested the review withdraws the requests within 90 days of the date of publication of the notice of initiation of the requested review. Zekelman withdrew its review request by the 90-day deadline, and no other parties requested an administrative review of this order. Therefore, we are rescinding the administrative review of the antidumping duty order on circular welded carbon quality steel pipe from the PRC covering the period July 1, 2016 to June 30, 2017, in its entirety.

Assessment

The Department will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. Because the Department is rescinding this administrative review in its entirety, the entries to which this administrative review pertains shall be assessed antidumping duties that are equal to the cash deposits of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions to CBP within 15 days after the publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as the only 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 review period. Failure to comply with this requirement could result in the presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Orders

This notice also serves as the only reminder to parties subject to 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, 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 terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: November 6, 2017.

James Maeder,

Senior Director performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2017–24514 Filed 11–9–17; 8:45 a.m.]

BILLING CODE 3510–DS–P

[2] *See* Letter from Zekelman Industries, regarding ''Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Withdrawal of Request for Administrative Review,'' dated September 29, 2017.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–850, A–588–851, A–485–805]

Certain Large Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe From Japan; Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe From Japan and Romania: Continuation of Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable November 13, 2017.

SUMMARY: As a result of the determinations by the Department of Commerce (the Department) and the U.S. International Trade Commission (USITC) that revocation of the antidumping duty orders on certain large diameter carbon and alloy seamless standard, line and pressure pipe (large diameter pipe) from Japan and certain small diameter carbon and alloy seamless standard, line and pressure pipe (small diameter pipe) from Japan and Romania would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States, the Department is publishing a notice of continuation of the antidumping duty orders.

FOR FURTHER INFORMATION CONTACT: Thomas Schauer, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–0410.

SUPPLEMENTARY INFORMATION:

Background

On June 26, 2000, and August 10, 2000, the Department published the AD orders on large diameter pipe from Japan and small diameter pipe from Japan and Romania, respectively.[1] On September 1, 2016, the Department published the notice of initiation of the third sunset review of the antidumping duty orders on large diameter pipe from Japan and small diameter pipe from Japan and Romania pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On December 16, 2016, the USITC instituted its review of the orders.[3]

As a result of its review, the Department determined that revocation of the antidumping duty orders on large diameter pipe from Japan and small diameter pipe from Japan and Romania would likely lead to continuation or recurrence of dumping and, therefore, notified the USITC of the magnitude of the margins of dumping likely to prevail should the orders be revoked.[4]

On October 16, 2017, the USITC published its determination, pursuant to section 751(c)(1) of the Act, that revocation of the antidumping duty orders on large diameter pipe from Japan and small diameter pipe from Japan and Romania would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

[1] *See Notice of Antidumping Duty Orders: Certain Large Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe from Japan; and Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe from Japan and the Republic of South Africa,* 65 FR 39360 (June 26, 2000), and *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe from Romania,* 65 FR 48963 (August 10, 2000).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 81 FR 60343 (September 1, 2016).

[3] *See Carbon and Alloy Seamless Standard, Line, and Pressure Pipe from Japan and Romania Institution of Five-Year Reviews; Notice of Commission Determination to Conduct Full Five Year Reviews,* 81 FR 91199 (December 16, 2016).

[4] *See Certain Large Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe from Japan; Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe from Japan and Romania: Final Results of the Expedited Third Five-Year Sunset Reviews of the Antidumping Duty Orders,* 81 FR 93648 (December 21, 2016).

[5] *See Carbon and Alloy Seamless Standard, Line, and Pressure Pipe from Japan and Romania; Determinations,* 82 FR 48113 (October 16, 2017) and *USITC Publication 4731* (October 2017), titled *Carbon and Alloy Seamless Standard, Line, and*

Continued

Scope of the Orders

Large Diameter Pipe From Japan

The products covered by this order are large diameter seamless carbon and alloy (other than stainless) steel standard, line, and pressure pipes. The seamless pipes subject to this order are currently classifiable under the subheadings 7304.10.10.30, 7304.10.10.45, 7304.10.10.60, 7304.10.50.50, 7304.19.10.30, 7304.19.10.45, 7304.19.10.60, 7304.19.50.50, 7304.31.60.10, 7304.31.60.50, 7304.39.00.04, 7304.39.00.06, 7304.39.00.08, 7304.39.00.36, 7304.39.00.40, 7304.39.00.44, 7304.39.00.48, 7304.39.00.52, 7304.39.00.56, 7304.39.00.62, 7304.39.00.68, 7304.39.00.72, 7304.51.50.15, 7304.51.50.45, 7304.51.50.60, 7304.59.20.30, 7304.59.20.55, 7304.59.20.60, 7304.59.20.70, 7304.59.60.00, 7304.59.80.30, 7304.59.80.35, 7304.59.80.40, 7304.59.80.45, 7304.59.80.50, 7304.59.80.55, 7304.59.80.60, 7304.59.80.65, and 7304.59.80.70 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheading is provided for convenience and customs purposes. The written product description remains dispositive.[6]

Small Diameter Pipe From Japan and Romania

The products covered by these orders include small diameter seamless carbon and alloy (other than stainless) steel standard, line, and pressure pipes and redraw hollows. The seamless pipes subject to these orders are currently classifiable under the subheadings 7304.10.10.20, 7304.10.50.20, 7304.19.10.20, 7304.19.50.20, 7304.31.30.00, 7304.31.60.50, 7304.39.00.16, 7304.39.00.20, 7304.39.00.24, 7304.39.00.28, 7304.39.00.32, 7304.51.50.05, 7304.51.50.60, 7304.59.60.00, 7304.59.80.10, 7304.59.80.15, 7304.59.80.20, and 7304.59.80.25 of the HTSUS. The HTSUS subheading is provided for convenience and customs purposes. The written product description remains dispositive.[7]

Continuation of the Orders

As a result of these determinations by the Department and the USITC that revocation of the antidumping duty orders would be likely to lead to continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, the Department hereby orders the continuation of the antidumping orders on large diameter pipe from Japan and small diameter pipe from Japan and Romania. U.S. Customs and Border Protection will continue to collect antidumping duty cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of these orders will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, the Department intends to initiate the next five-year review of the orders not later than 30 days prior to the fifth anniversary of the effective date of continuation.

These five-year (sunset) reviews and this notice are in accordance with section 751(c) of the Act and published pursuant to section 777(i)(1) of the Act.

Dated: November 6, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, Performing the Non-exclusive Functions and Duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2017–24515 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–011]

Certain Crystalline Silicon Photovoltaic Products From the People's Republic of China: Notice of Court Decision Not in Harmony With Amended Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On September 8, 2017, the United States Court of International Trade (CIT) entered final judgment sustaining the Department of Commerce's (the Department's) final results of remand redetermination pertaining to the countervailing duty (CVD) investigation of certain crystalline silicon photovoltaic products (solar products) from the People's Republic of China (PRC). The Department is notifying the public that the CIT's final judgment in this case is not in harmony with the Department's final determination, as amended, in the CVD investigation of solar products from the PRC.

DATES: Applicable September 18, 2017.

FOR FURTHER INFORMATION CONTACT: Gene H. Calvert, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–3586.

SUPPLEMENTARY INFORMATION:

Background

On December 23, 2014, the Department published its final determination in the CVD investigation of solar products from the PRC.[1] On February 18, 2015, the Department published an amended final determination and CVD order.[2] In the *Final Determination,* the Department found that certain unreported assistance discovered during the investigation was countervailable using adverse facts available (AFA) pursuant to section 776 of the Tariff Act of 1930, as amended (the Act).[3] Additionally, the Department determined not to initiate investigations into the mandatory respondents' creditworthinesss in certain years, finding that SolarWorld Americas, Inc.'s (SolarWorld) creditworthiness allegation failed to satisfy the threshold initiation requirements of 19 CFR 351.505(a)(6)(i).[4] In the *Amended Final Determination,* the Department found that it made a ministerial error in countervailing one of the unreported programs, and removed that program from the net countervailable subsidy rate calculated for Changzhou Trina Solar Energy Co., Ltd. (Trina Solar).[5]

Trina Solar and SolarWorld appealed the *Amended Final Determination* to the CIT, and on December 30, 2016, the CIT

Pressure Pipe from Japan and Romania, Investigation Nos. 731–TA–847 and 849 (Third Review).

[6] A full description of the scope of the order is contained in the Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Third Sunset Reviews of the Antidumping Duty Orders on Certain Large Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe from Japan (A–588–850), Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe from Japan (A–588–851) and Romania (A–485–805),'' dated December 15, 2016.

[7] *Id.*

[1] *See Countervailing Duty Investigation of Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China: Final Affirmative Countervailing Duty Determination,* 79 FR 76962 (December 23, 2014) (*Final Determination*).

[2] *See Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China: Antidumping Duty Order; and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 FR 8592 (February 18, 2015) (*Amended Final Determination*).

[3] *See Final Determination,* and accompanying Issues and Decision Memorandum at Comment 15.

[4] *Id.* at Comment 17.

[5] *See Amended Final Determination,* 80 FR at 8593.

sustained, in part, and remanded, in part, the *Amended Final Determination*.[6] First, the CIT remanded the *Amended Final Determination* for the Department to make the necessary factual findings to support its determinations, based upon AFA, to countervail the unreported government subsidies discovered during the investigation.[7] The CIT further held that should the Department continue to find those government subsidies countervailable on remand, the Department must then explain how it selected the AFA rates for those subsidies.[8] Second, the CIT granted the Department's request for a voluntary remand to reconsider its determination not to initiate creditworthiness investigations for Trina Solar and the other mandatory company respondent, Wuxi Suntech Power Co., Ltd. (Suntech).

In accordance with the CIT's remand order, the Department reconsidered these issues and submitted its Final Remand Results with the CIT on April 28, 2017.[9] In the Final Remand Results, the Department continued to countervail all but one of the unreported programs using AFA. The Department also revised its determination regarding whether to initiate creditworthiness investigations for Trina Solar and Suntech, in part, and ultimately found Trina Solar and Suntech to be uncreditworthy in certain years. As a result of these changes, on remand, the Department determined revised countervailable subsidy rates of 39.50 percent for Trina Solar, 27.65 percent for Suntech, and 33.58 percent for all other producers/exporters of solar products from the PRC.[10] On September 8, 2017, the CIT sustained the Department's Final Remand Results in full.[11]

Timken Notice

In its decision in *Timken,*[12] as clarified in *Diamond Sawblades,*[13] the Court of Appeals for the Federal Circuit held that, pursuant to section 516A(e) of the Act, the Department must publish a notice of a court decision that is not ''in harmony'' with a Department determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's September 8, 2017, judgment sustaining the Final Remand Results constitutes a final decision of the CIT that is not in harmony with the Department's *Amended Final Determination.* This notice is published in fulfillment of the publication requirement of *Timken.*

Amended Final Determination

As there is now a final court decision with respect to the *Amended Final Determination,* the Department amends its *Amended Final Determination.* The Department finds that the revised net countervailable subsidy rates exist:

Company	Subsidy rate (*ad valorem*) (%)
Changzhou Trina Solar Energy Co., Ltd	33.50
Wuxi Suntech Power Co., Ltd	27.65
All Others	33.58

Cash Deposit Requirements

Because there has been a subsequent administrative review for Trina Solar, the cash deposit rate for Trina Solar will remain the rate established in the final results of the administrative review of solar products from the PRC covering the period June 10, 2014, through December 31, 2015, which is 13.93 percent.[14] As there have been no subsequent administrative reviews for Suntech, the Department will instruct U.S. Customs and Border Protection (CBP) to set the cash deposit rate for Suntech as listed above.

Finally, the Department will instruct CBP that the all-others cash deposit rate is to be amended to reflect the simple average of the revised subsidy rates calculated for Trina Solar and for Suntech, as listed above.

This notice is issued and published in accordance with sections 516(e), 705(c)(1)(B), and 777(i)(1) of the Act.

Dated: November 6, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, Performing the Non-exclusive Functions and Duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2017–24516 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See Changzhou Trina Solar Energy Co., Ltd. et al.* v. *United States,* Consol. Court No. 15–00068; Slip Op. 16–121 (CIT December 30, 2016) (*Remand Opinion and Order*).

[7] *Id.* at 24–25.

[8] *Id.* at 26–28.

[9] *See* Final Results of Redetermination Pursuant to Court Remand, *Changzhou Trina Solar Energy Co., Ltd. et al.* v. *United States,* Consol. Court No. 15–00068; Slip Op. 161–121 (April 28, 2017) (Final Remand Results).

[10] *See* Final Remand Results at 48.

[11] *See Changzhou Trina Solar Energy Co., Ltd. et al.,* v. *United States,* Consol. Court No. 15–00068; Slip Op. 17–122 (CIT September 8, 2017).

[12] *See Timken Co.* v. *United States,* 893 F.2d 337, 341 (Fed. Cir. 1990) (*Timken*).

[13] *See Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d. 1374 (Fed. Cir. 2010) *Diamond Sawblades.*

[14] *See Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China: Final Results of Countervailing Duty Administrative Review, and Partial Rescission of Countervailing Duty Administrative Review; 2014–2015,* 82 FR 42792 (September 12, 2017).

DEPARTMENT OF COMMERCE

International Trade Administration

United States Travel and Tourism Advisory Board: Meeting of the United States Travel and Tourism Advisory Board

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The United States Travel and Tourism Advisory Board (Board or TTAB) will hold an open meeting via teleconference on Wednesday, November 29, 2017. The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry. The purpose of the meeting is for Board members to consider recommendations being developed by the Hurricane Recovery subcommittee on how to accelerate recovery in destinations affected by the recent hurricanes. The final agenda will be posted on the Department of Commerce Web site for the Board at *http://trade.gov/ttab* at least one week in advance of the meeting.

DATES: Wednesday, November 29, 2017, 4:00 p.m.–5:00 p.m. EST. The deadline for members of the public to register, including requests to make comments during the meeting and for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EST on Wednesday, November 22, 2017.

ADDRESSES: The meeting will be held via conference call. The call-in number and passcode will be provided by email to registrants. Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted to: National Travel and Tourism Office, U.S. Department of Commerce, 1401 Constitution Ave. NW., Room 10003, Washington, DC 20230 or by email to *TTAB@trade.gov.* Members of the public are encouraged to submit registration requests and written comments via email to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Brian Beall, the United States Travel

and Tourism Advisory Board, National Travel and Tourism Office, U.S. Department of Commerce, 1401 Constitution Ave. NW., Room 10003, Washington, DC 20230; telephone: 202–482–5634; email: *TTAB@trade.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry.

Public Participation: The meeting will be open to the public and will be accessible to people with disabilities. Any member of the public requesting to join the meeting is asked to register in advance by the deadline identified under the **DATES** caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted, but may not be possible to grant. There will be fifteen (15) minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for public speaking time may be limited to three (3) minutes per person. Members of the public wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name and address of the proposed speaker. If the number of registrants requesting speaking time is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EST on Wednesday, November 22, 2017, for inclusion in the meeting records and for circulation to the members of the Board.

In addition, any member of the public may submit pertinent written comments concerning the Board's affairs at any time before or after the meeting. Comments may be submitted to Brian Beall at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EDT on Wednesday, November 22, 2017, to ensure transmission to the Board prior to the meeting. Comments received after that date and time will be distributed to the members but may not be considered during the meeting. Copies of Board meeting minutes will be available within 90 days of the meeting.

Dated: October 31, 2017.

Brian Beall,

Designated Federal Officer, United States Travel and Tourism Advisory Board.

[FR Doc. 2017–24488 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF822

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting via webinar.

SUMMARY: The New England Fishery Management Council's Scientific and Statistical Committee will hold a webinar to reconsider its recommendations for setting an overfishing limit and acceptable biological catch for Southern New England/Mid-Atlantic yellowtail flounder and possibly for each of several other flounder stocks using an empirical stock assessment approach. Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Monday, November 27, 2017 beginning at 9:30 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/7349973934358582785;* Call in information: +1 (415) 930–5321, Attendee Access Code: 179–198–666.

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Scientific and Statistical Committee will consider an alternative to the method it used at its October 23–24, 2017 meeting for calculating acceptable biological catch for Southern New England/Mid-Atlantic yellowtail flounder for fishing years 2018–20. Other business will be discussed as needed.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: November 7, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017–24505 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF828

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Announcement of rescheduled meeting and an additional meeting of the South Atlantic Fishery Management Council's Citizen Science Advisory Panel Finance and Infrastructure Action Team.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of its Citizen Science Advisory Panel Finance and Infrastructure Action Team via webinar. The meeting via webinar was originally scheduled for November 9, 2017 but has been rescheduled as a result of schedule changes (See **SUPPLEMENTARY INFORMATION**). In December 2017, the Council will also hold another meeting of the Citizen Science Advisory Panel Finance and Infrastructure Action Team via webinar.

DATES: The meeting via webinar has been rescheduled for November 29, 2017 at 1 p.m. The additional Action Team webinar for December 2017 is scheduled for December 13, 2017 at 1 p.m. Both meetings are scheduled to last approximately 90 minutes each.

Additional Action Team meetings and plenary webinar dates and times will publish in a subsequent issue in the **Federal Register**.

ADDRESSES:

Meeting address: The meetings will be held via webinar and are open to members of the public. Webinar registration is required and registration links will be posted to the Citizen Science program page of the Council's Web site at *www.safmc.net.*

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Amber Von Harten, Citizen Science Program Manager, SAFMC; phone (843) 302–8433 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: *amber.vonharten@safmc.net.*

SUPPLEMENTARY INFORMATION: Due to schedule changes, the scheduled meeting of the Council's Citizen Science Finance and Infrastructure Action Team originally scheduled for Thursday, November 9, 2017 at 2 p.m. is rescheduled for Wednesday, November 29, 2017 at 1 p.m. The original notice for that meeting published in the **Federal Register** on October 16, 2017 (82 FR 48063). The Council will also hold another meeting of the Council's Citizen Science Finance and Infrastructure Action Team on Wednesday, December 13, 2017 at 1 p.m.

The Council created a Citizen Science Advisory Panel Pool in June 2017. The Council appointed members of the Citizen Science Advisory Panel Pool to five Action Teams in the areas of *Volunteers, Data Management, Projects/Topics Management, Finance and Infrastructure,* and *Communication/Outreach/Education* to develop program policies and operations for the Council's Citizen Science Program.

The Finance and Infrastructure Action Team will meet to continue work on developing recommendations on program policies and operations to be reviewed by the Council's Citizen Science Committee. Public comment will be accepted at the beginning of the meeting.

Items to be addressed during these meetings:

1. Discuss work on tasks in the Terms of Reference
2. Other Business

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: November 7, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017–24507 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; NOAA Customer Surveys

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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.

DATES: Written comments must be submitted on or before January 12, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *pracomments@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Sarah Brabson, NOAA Office of the Chief Information Officer, (301) 628–5751 or *sarah.brabson@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved generic information collection.

This collection follows the guidelines contained in the OMB Resource Manual for Customer Surveys. In accordance with Executive Order 12862, the National Performance Review, and good management practices, NOAA offices seek approval to continue to gather customer feedback on services and/or products, which can be used in planning for service/product modification and prioritization. Under this generic clearance, individual offices would use approved questionnaires and develop new questionnaires, as needed, by selecting subsets of the approved set of collection questions and tailoring those specific questions to be meaningful for their particular programs. These proposed questionnaires would then be submitted to OMB using a fast-track request for approval process, for which separate **Federal Register** notices are not required. Surveys currently being conducted include Web site satisfaction surveys, Weather Service product surveys and National Marine Sanctuary participation surveys.

The generic clearance will not be used to survey any bodies NOAA regulates unless precautions are taken to ensure that the respondents believe that they are not under any risk for not responding or for the contents of their responses; *e.g.,* in no survey to such a population will the names and addresses of respondents be required.

II. Method of Collection

Information will be collected via mail, email or online.

III. Data

OMB Control Number: 0648–0342.

Form Number(s): None.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: Individuals or households; not-for-profit institutions; state, local or tribal government; business or other for-profit organizations.

Estimated Number of Respondents: 24,000.

Estimated Time per Response: Response times averages 5–10 minutes.

Estimated Total Annual Burden Hours: 22,500.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed 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 (including hours and cost) of the proposed collection of information; (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 approval of this information collection; they also will become a matter of public record.

Dated: November 7, 2017.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2017–24470 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Alaska Chinook Salmon Economic Data Report (EDR)

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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.

DATES: Written comments must be submitted on or before January 12, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *pracomments@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Scott Miller, (907) 586–7228.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection.

National Marine Fisheries Service (NMFS) manages the Bering Sea pollock fishery under the American Fisheries Act (AFA) (16 U.S.C. 1851). AFA fishing vessels harvest pollock in the Bering Sea pollock fishery using pelagic (mid-water) trawl gear, which consists of large nets towed through the water by the vessel. At times, Chinook salmon and pollock occur in the same locations in the Bering Sea; consequently, Chinook salmon are incidentally caught in the nets as pollock is harvested. This incidental catch is called bycatch and is also called prohibited species catch (PSC).

The Chinook Salmon Economic Data Report (Chinook Salmon EDR) Program provides NMFS and the North Pacific Fishery Management Council (Council) with data to evaluate the effectiveness of Chinook salmon bycatch management measures for the Bering Sea pollock fishery that were implemented under Amendment 91 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (75 FR 53026, August 30, 2010). The EDR consists of three data collections that are submitted annually by owners and operators of catcher vessels, catcher/processors, motherships, and the Western Alaska Community Development Quota Program groups qualified to participate in the Bering Sea pollock fishery (50 CFR 679.65). The Chinook Salmon EDR Program also includes a means for NMFS to verify the data submitted in these three collections.

NMFS and the Council use the information to determine the effectiveness of the Incentive Plan Agreement (IPA), the IPA incentives, the PSC limits, and the performance standard in terms of minimizing salmon bycatch in times of high and low levels of salmon abundance. NMFS and the Council also use the data to evaluate how Amendment 91 affects where, when, and how pollock fishing and salmon bycatch occur and to study and verify conclusions drawn by industry in the IPA annual reports.

II. Method of Collection

The Compensated Transfer Report, Vessel Fuel Survey, and Vessel Master Survey are completed and submitted annually using a data reporting web application on the Pacific States Marine Fisheries Commission Web site at *https://www.psmfc.org//chinookedr/.* Data for the Chinook EDR Verification/Audit are submitted by email, electronically, fax, or mail.

III. Data

OMB Control Number: 0648–0633.

Form Number(s): None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 133.

Estimated Time per Response: 40 hours for Compensated Transfer Report; 4 hours each for Vessel Fuel Survey, Vessel Master Survey; and Chinook EDR Verification/Audit.

Estimated Total Annual Burden Hours: 1,168.

Estimated Total Annual Cost to Public: $4,631 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed 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 (including hours and cost) of the proposed collection of information; (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 approval of this information collection; they also will become a matter of public record.

Dated: November 7, 2017.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2017–24467 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF826

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Groundfish Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, November 29, 2017 at 9 a.m.

ADDRESSES: The meeting will be held at the Courtyard Marriott Boston Logan Airport, 225 McClellan Highway, Boston, MA; phone: (617) 569–5250.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will review Framework Adjustment 57/ Specifications and Management Measures, review the draft alternatives under consideration, the Groundfish Plan Development Team's (PDT) impact analysis, and make recommendations on preferred alternatives to the Council. They will also discuss Amendment 23/ Groundfish Monitoring and review an updated draft outline prepared by the PDT of the likely range of alternatives and make recommendations to the Council. The committee will also hold a discussion of possible groundfish priorities for 2018 and make recommendations to the Council. They also plan to discuss several recent Executive Orders that have been issued about streamlining current regulations, and NOAA is seeking public input on the efficiency and effectiveness of current regulations and whether they can be improved. Discuss whether there are any regulations in the Northeast Multispecies fishery management plan that could be eliminated, improved, or streamlined. The committee will also review Groundfish Advisory Panel and Recreational Advisory Panel recommendations and make recommendations to the council. Other business will be discussed as necessary.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date. This meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

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

Dated: November 7, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017–24506 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF818

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Scallop Advisory Panel to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, November 29, 2017 at 9 a.m.

ADDRESSES: The meeting will be held at the Hilton Garden Inn Logan Airport, 100 Boardman Street, Boston, MA 02128; phone: (617) 567–6789.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Scallop Advisory Panel will review Framework 29 (FW 29) alternatives and analyses, and make final recommendations. FW 29 will set specifications including acceptable biological catch/annual catch limit (ABC/ACLs), Days at Sea (DAS), access area allocations for Limited Access (LA) and Limited Access General Category (LAGC), Total Allowable Catch (TAC) for Northern Gulf of Maine (NGOM) management area, target-TAC for LAGC incidental catch and set-asides for the observer and research programs for fishing year 2018 and default specifications for fishing year 2019. Make final recommendations for potential FW 29 specifications that includes areas that may open through Omnibus Habitat Amendment 2 (OHA2). The Advisory Panel will also review FW 29 management measures and make final recommendations. These measures may include, but are not limited to: (1) NGOM management measures; (2) Flatfish accountability measures for Northern windowpane flounder, Georges Bank yellowtail flounder, and Southern New England yellowtail flounder; (3) Measures to modify and/or create access area and open area boundaries, consistent with potential changes to habitat and groundfish closed areas; (4) measures to allocate unused CAI carryover pounds under certain scenarios of OHA2 approval. Other business may be discussed as necessary.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

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

Dated: November 7, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017–24504 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Alaska Prohibited Species Donation Program.

OMB Control Number: 0648–0316.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 1.

Average Hours per Response: 50 hours for a three-year permit, annualized to 17.

Burden Hours: 17.

Needs and Uses: The prohibited species donation (PSD) program for salmon and halibut has effectively reduced regulatory discard of salmon and halibut by allowing fish that would otherwise be discarded to be donated to needy individuals through tax-exempt organizations. Vessels and processing plants participating in the PSD program voluntarily retain and process salmon and halibut bycatch. An authorized, tax-exempt distributor, chosen by the National Marine Fisheries Service (NMFS), is responsible for monitoring retention and processing of fish donated by vessels and processors. The authorized distributor also coordinates processing, storage, transportation, and distribution of salmon and halibut. The PSD program requires an information collection so that NMFS can monitor the authorized distributors' ability to effectively supervise program participants and ensure that donated fish are properly processed, stored, and distributed.

Affected Public: Not-for-profit institution.

Frequency: Every three years.

Respondent's Obligation: Mandatory.

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

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: November 7, 2017.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2017–24471 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF829

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

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

ACTION: Notice; request for comments.

SUMMARY: The Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit application contains all of the required information and warrants further consideration. This Exempted Fishing Permit would exempt a commercial fishing vessel from Atlantic sea scallop regulations in support of research conducted by the Coonamessett Farm Foundation. Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed Exempted Fishing Permits.

DATES: Comments must be received on or before November 28, 2017.

ADDRESSES: You may submit written comments by any of the following methods:

- *Email: nmfs.gar.efp@noaa.gov*. Include in the subject line ''DA17–100 CFF BREP LA Flounder Sweep Study EFP.''
- *Mail:* John K. Bullard, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on DA17–100 CFF BREP LA Flounder Sweep Study EFP.''

FOR FURTHER INFORMATION CONTACT: Shannah Jaburek, Fisheries Management Specialist, 978–282–8456.

SUPPLEMENTARY INFORMATION: Coonamessett Farm Foundation (CFF) submitted an application for an EFP on September 18, 2017, for a 2017 Bycatch Reduction Engineering Program project titled ''A Modified Flounder Sweep for Flatfish Bycatch Reduction in the Limited Access (LA) Scallop Fishery.'' The project would test a modified flounder cookie sweep on the outer bale bars of the scallop dredge and film fish-dredge interactions to monitor the effectiveness of the gear modification in reducing flatfish bycatch.

To conduct this experiment, vessels would require exemptions from the following regulations: Atlantic sea scallop crew size restrictions at 50 CFR 648.51(c); dredge gear obstruction restrictions at § 648.51(b)(4)(ii); Atlantic sea scallop observer program requirements at § 648.11(g); and closed area exemptions for Closed Area I at § 648.60(c), Closed Area II at § 648.60(d), Closed Area II Extension at § 648.60(e), and Nantucket Lightship at § 648.60(f). It would also exempt participating vessels from possession limits and minimum fish size requirements specified in 50 CFR part 648, subsections B and D through O, for biological sampling purposes only.

Vessels would conduct scallop dredging between November 2017-June 2018, on 2 trips each lasting approximately 7 days-at-sea (DAS) each for a project total of 14 DAS. An average of 10 tows per day would be conducted for a maximum duration of 50 minutes at a tow speed range of 4.8–5.1 knots (2.5–2.6 m/s). Trips would take place in scallop open areas of Southern New England and Georges Bank along with scallop access areas Nantucket Lightship and Closed Areas I and II.

The vessel would conduct all tows with two 15-foot (4.57-m) New Bedford Style dredges, one acting as a control dredge and one acting as an experimental dredge. The vessel would tow both dredges simultaneously to reduce spatial and temporal variability. Researchers would attach the two 9-foot (2.74-m) cookie sweeps to each of the outer bale bars using chain and shackles on the experimental dredge. The cookie sweeps would alternate between the two dredges each tow to reduce ''side'' effects. The cookie sweeps would be constructed of round rubber disks with lead cookies approximately 3–4 inches (7.6–10.2 cm) in diameter evenly spaced to encourage bottom contact. The attachment chains would be evenly spaced and varied in length to account for dredge position while being towed to ensure contact with the ocean bottom. Exemption from the dredge gear obstruction regulation would allow researchers to use the cookie sweep for the experimental tows.

Researchers would weigh all scallop catch in industry bushel baskets caught in both dredges and measure a one-basket sub-sample from each side in 5-

millimeter increments. The researchers would also obtain total weight of bycatch species and individual measurements to the nearest centimeter. If the volume of the catch is large, subsampling protocols would be necessary. All bycatch would be returned to the sea as soon as practicable following data collection. Exemption from possession limit and minimum sizes would support catch sampling activities, and ensure the vessel is not in conflict with possession regulations while collecting catch data. Researchers would discard all catch above a possession limit or below a minimum size as soon as practicable following data collection. The table below lists the anticipated catch for the project. No catch would be landed for sale.

Species	Weight (lb)	Weight (kg)
Scallop	20,000	9,072
Northeast Skate Complex (Barndoor Skate not included)	50,000	22,680
Barndoor Skate	250	113
Summer Flounder	90	41
Winter Flounder	250	113
Yellowtail Flounder	750	340
Windowpane Flounder	750	340
Monkfish	1,750	794

Researchers need additional exemptions to deploy dredge gear in closed areas in order to help locate large enough aggregations of flatfish to test the experimental gear. Participating vessels need crew size waivers to accommodate science personnel and possession waivers would enable them to conduct data collection activities. We would waive the observer program notification requirements because the research activity is not representative of standard fishing activity.

If approved, the applicant may request minor modifications and extensions to the EFP throughout the year. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

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

Dated: November 7, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–24520 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF816

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 55 Assessment Scoping webinar II.

SUMMARY: The SEDAR 55 assessment of the South Atlantic stock of Vermilion Snapper will consist of a series of webinars. See **SUPPLEMENTARY INFORMATION.**

DATES: A SEDAR 55 Assessment Scoping webinar II will be held on Tuesday, November 28, 2017, from 9 a.m. until 1 p.m.

ADDRESSES:

Meeting address: The meetings will be held via webinar. The webinars are open to members of the public. Those interested in participating should contact Julia Byrd at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Julia Byrd, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4366; email: *julia.byrd@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. The product of the SEDAR webinar series will be a report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses, and describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Assessment Scoping webinar II are as follows:

Participants will review data and discuss data issues, as necessary, and initial model issues.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SAFMC

office (see **ADDRESSES**) at least 5 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: November 7, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017–24503 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Monitoring Programs for Vessels in the Pacific Coast Groundfish Fishery

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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.

DATES: Written comments must be submitted on or before January 12, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *pracomments@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to the West Coast Regional Office—7600 Sand Point Way NE., Seattle, WA 98115, Keeley Kent, telephone number ((206) 526–4655), or *keeley.kent@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

In 2011, NMFS mandated observer requirements for the West Coast groundfish trawl catch shares program. For all fishery sectors, observers must be obtained through third-party observer provider companies operating under permits issued by NMFS. The regulations at §§ 660.140 (h), 660.150 (j), 660.160 (g), specify observer coverage requirements for trawl vessels and define the responsibilities for observer providers, including reporting requirements. Regulations at § 660.140 (i) specify requirements for catch monitor coverage for first receivers. Data collected by observers are used by NMFS to estimate total landed catch and discards, monitor the attainment of annual groundfish allocations, estimate catch rates of prohibited species, and as a component in stock assessments. These data are necessary to comply with the Magnuson-Stevens Act requirements to prevent overfishing. In addition, observer data is used to assess fishing related mortality of protected and endangered species.

II. Method of Collection

This collection utilizes both electronic and paper forms, depending on the specific item. Methods of submittal include email of electronic forms, and mail and facsimile transmission of paper forms. Additionally, this collection utilizes interviews for some information collection and phone calls for transmission of other information.

III. Data

OMB Control Number: 0648–0500.

Form Number(s): None.

Type of Review: Regular (extension of a current information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 268 (5 providers (supplying a total of 75 observers or catch monitors) and 263 fishing vessels).

Estimated Time per Response: For providers: 15 minutes for observer training/briefing/debriefing registration, notification of observer physical examination, observer status reports, other reports on observer harassment, safety concerns, or performance problems, catch monitor status reports, and other catch monitor reports on harassment, prohibited actions, illness or injury, or performance problems; 5 minutes for observer safety checklist submission to NMFS, observer provider contracts, observer information materials, catch monitor provider contracts, and catch monitor informational materials; 10 minutes for certificate of insurance; 7 minutes for catch monitor training/briefing registration, notification of catch monitor physical examination, and catch monitor debriefing registration. For vessels: 10 minutes for fishing departure reports and cease-fishing reports.

Estimated Total Annual Burden Hours: 525 (305 for providers and 220 for fishing vessels).

Estimated Total Annual Cost to Public: $0 in capital costs as it is assumed that each of the 5 observer/catch monitor providers will maintain a computer system with email capacity for general business purposes and that each vessel owner/operator has access to a telephone for toll-free calls.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed 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 (including hours and cost) of the proposed collection of information; (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 approval of this information collection; they also will become a matter of public record.

Dated: November 7, 2017.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2017–24469 Filed 11–9–17; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2017–0037]

Request for Information Regarding Consumers' Experience With Free Access to Credit Scores

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for information.

SUMMARY: The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank) established the Office of Financial Education within the Bureau of Consumer Financial Protection (CFPB or Bureau) to develop and launch initiatives that will educate consumers and help them make better informed financial decisions.

The CFPB's Office of Financial Education seeks to learn more about the experience consumers are having with access to free credit scores and the experience of companies, and nonprofits, offering their customers and

the general public free access to their credit scores. The Bureau encourages comments from all interested members of the public, including consumers, consumer advocacy groups, credit card companies and other lenders, nonprofit credit and financial counseling providers, credit reporting companies, researchers and any other interested party.

DATES: Comments must be received on or before February 12, 2018 to be assured of consideration.

ADDRESSES: You may submit comments regarding the ''Request for Information Regarding Consumers' Experience with Free Access to Credit Scores,'' identified by title and by Docket No. CFPB–2017–0037, by any of the following methods:

- *Electronic: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Consumer Financial Protection Bureau (Attention: Office of Financial Education), 1700 G Street NW., Washington, DC 20552.
- *Hand Delivery/Courier:* Consumer Financial Protection Bureau (Attention: Office of Financial Education), 1700 G Street NW., Washington, DC 20552.

Instructions: The Bureau encourages the early submission of comments. All submissions must include the document title and docket number. Because paper mail in the Washington, DC area and at the Bureau is subject to delay, commenters are encouraged to submit comments electronically. In general, all comments received will be posted without change to *http://www.regulations.gov*. In addition, comments will be available for public inspection and copying at 1700 G Street NW., Washington, DC 20552, on official business days between the hours of 10 a.m. and 5 p.m. eastern standard time. You can make an appointment to inspect the documents by telephoning 202–435–7275.

All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Do not include sensitive personal information such as account numbers or Social Security numbers. Comments will not be edited to remove any identifying or contact information, such as name and address information, email addresses, or telephone numbers.

FOR FURTHER INFORMATION CONTACT: For general inquiries, submission process questions or any additional information, please contact Monica Jackson, Office of the Executive Secretary, at 202–435–7275. For information about the ''Request for Information Regarding Consumers' Experience with Free Access to Credit Scores,'' please contact Irene Skricki, Office of Financial Education, at 202–435–7181.

SUPPLEMENTARY INFORMATION:

I. Background

Over the last few years, many financial institutions, credit card issuers, and other companies have offered consumers free access to a credit score, giving consumers an important tool to manage their financial lives.

To raise consumer awareness of this service, the CFPB's Office of Financial Education published in March 2017 a list of companies that told the Bureau they offer existing credit card customers free access to a credit score. The list was compiled based on comments received in response to a public notice published in the **Federal Register** in October 2016.

As a next step, through this request for information, the Bureau seeks to learn more about the experience consumers are having with access to free credit scores. The Bureau also seeks to learn about the experience of companies and of nonprofit credit and financial counseling providers offering their customers and the general public free access to credit scores.

A core part of the mission of the Bureau is educating and empowering consumers to take more control over their financial lives. The information gathered through this request for information will be used to identify educational content that is providing the most value to consumers, and additional educational content that the Bureau or others could develop to increase consumers' understanding of credit scores and credit reports. This request for information will also be used to gain a broader understanding of the industry practices that best support educating and empowering consumers.

The Bureau encourages comments from all interested members of the public, including consumers, consumer advocacy groups, credit card companies and other lenders, nonprofit credit and financial counseling providers, credit reporting companies, researchers and any other interested party. The Bureau is interested in all input from commenters, including consumer experiences, knowledge of the industry practices that best support educating and empowering consumers, educational content that is providing the most value to consumers, and views on the questions included in this notice.

Please feel free to comment generally and/or respond to any or all of the questions below.

1. How are companies, and nonprofit credit and financial counseling providers, offering existing customers and the general public free access to credit scores?

2. What sources are consumers using to access free credit scores?

3. How have consumers benefitted from having increased free regular access to one of their credit scores? Are there ways in which consumers have been hurt from having this access? What are examples of the ways in which consumers have benefitted or been hurt from having increased free regular access to one of their credit scores?

4. What have been the benefits and costs to companies for providing consumers with increased free regular access to one of their credit scores? What are examples of these benefits and costs?

5. What has been the rate of uptake, frequency, and duration of use of the service that provides consumers with free regular access to one of their credit scores?

6. How is access to free credit scores and/or frequency and duration of use of this service related to observed changes in consumers' credit standing or credit behavior? For example, these changes might include positive or negative trends in credit scores, or changes in loan payment behavior, the speed of payment of outstanding loan balances, the rate of applications for new loans, or any other factor.

7. What are examples of the questions consumers ask companies, as well as credit and financial counseling providers, after they have seen their free credit scores?

8. Do consumers face challenges in accessing free credit scores? If so, what are examples of those challenges?

9. What are examples of implementation challenges companies have faced, continue to face, or are likely to emerge in the future, in providing consumers with free regular access to one of their credit scores?

10. What are examples of solutions companies have identified to address these implementation challenges?

11. What are examples of the educational content that is provided to consumers when they access their free credit scores? With regards to this educational content, what information appears to be most effective in helping consumers understand their credit scores and the factors that impact their scores?

12. Can consumers have free regular access to one of their credit scores without receiving marketing for other products and services? If marketing is provided with the access to a free score, what are examples of the types of products and services being marketed? How have consumers benefitted or

otherwise been impacted by being offered products and services at the time when they access and see their credit scores?

13. What features related to how regular free access to a credit score is offered to consumers appear to be most effective in helping consumers make use of this service?

14. The CFPB also offers a number of educational supports to help consumers understand and act on their credit reports and scores, including a *Credit Reports & Scores* information portal available at *consumerfinance.gov/consumer-tools/credit-reports-and-scores/*; many frequently asked questions in *Ask CFPB* on the Bureau's Web site; and online brochures that include *Check your credit report, Understand your credit score, You have many credit scores, Credit report review check list,* and a list of consumer reporting companies. Is there additional educational content or topics that could be developed by the CFPB or others to support increased consumer understanding of credit scores and credit reports—for example, educational content that focuses on increasing awareness of credit scores to young consumers; how student debt can impact a consumer's credit score; or a person's credit standing over time, which might be of interest to older adults/seniors?

15. Has increased access to free credit scores encouraged consumers that use this service to also check their credit reports or take other steps to learn more about their credit standing? What are examples of the steps these consumers have taken?

Thank you for your contribution to improve consumer financial awareness.

Dated: November 4, 2017.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2017–24555 Filed 11–9–17; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2017–0034]

Notice of an Update to the Public List of Companies That Offer Customers Free Access to a Credit Score

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice.

SUMMARY: The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank) established the Office of Financial Education within the Bureau of Consumer Financial Protection (CFPB or Bureau) to develop and launch initiatives that will educate consumers and help them make better informed financial decisions.

The CFPB's Office of Financial Education published in March 2017 a list of companies that told us they offer existing credit card customers free access to a credit score. The Bureau is updating this list and will use the responses received to this notice to publish an updated list. The Bureau will leverage this updated list to bring consumer attention to the topic of consumers' credit standing, of which their credit score is a valuable indicator. The Bureau will follow up the publication of this updated list with content to educate consumers about the availability of credit scores and credit reports and how this information can be used effectively.

DATES: Comments must be received on or before January 12, 2018 to be assured of consideration.

ADDRESSES: You may submit comments regarding the ''Notice of an Update to the Public List of Companies That Offer Customers Free Access to a Credit Score,'' identified by title and by Docket No. CFPB–2017–0034, by any of the following methods:

- *Electronic: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Consumer Financial Protection Bureau (Attention: Office of Financial Education), 1700 G Street NW., Washington, DC 20552.
- *Hand Delivery/Courier:* Consumer Financial Protection Bureau (Attention: Office of Financial Education), 1700 G Street NW., Washington, DC 20552.

Instructions: The Bureau encourages the early submission of comments. All submissions must include the document title and docket number. Because paper mail in the Washington, DC area and at the Bureau is subject to delay, commenters are encouraged to submit comments electronically. In general, all comments received will be posted without change to *http://www.regulations.gov*. In addition, comments will be available for public inspection and copying at 1700 G Street NW., Washington, DC 20552, on official business days between the hours of 10 a.m. and 5 p.m. eastern standard time. You can make an appointment to inspect the documents by telephoning 202–435–7275.

All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Do not include sensitive personal information such as account numbers or Social Security numbers. Comments will not be edited to remove any identifying or contact information, such as name and address information, email addresses, or telephone numbers.

FOR FURTHER INFORMATION CONTACT: For general inquiries, submission process questions or any additional information, please contact Monica Jackson, Office of the Executive Secretary, at 202–435–7275. For information about the ''Notice of an Update to the Public List of Companies That Offer Customers Free Access to a Credit Score,'' please contact Irene Skricki, Office of Financial Education, at 202–435–7181.

SUPPLEMENTARY INFORMATION:

I. Background

Over the last few years, many financial institutions, credit card issuers, and other companies have offered consumers free access to a credit score, giving consumers an important tool to manage their financial lives. The Consumer Financial Protection Bureau (''the Bureau'') would like to highlight and build consumer awareness of this practice. A core part of the mission of the Bureau is educating and empowering consumers to take more control over their financial lives. The Bureau believes that enabling consumers to see their credit scores can be a first step towards consumers learning about their credit history, becoming aware of and encouraged to request a free copy of their credit reports, ensuring the accuracy and completeness of their credit reports, and ultimately making informed decisions about credit that serve their own financial and life goals.

The Bureau published in March 2017 a list of companies that told us they offer existing credit card customers free access to a credit score. The Bureau is updating this list and will use the responses received to this Notice to publish an updated list.

The Bureau will leverage this updated list to bring consumer attention to the topic of consumers' credit standing, of which their credit score is a valuable indicator. The Bureau will follow up the publication of this updated list with content to educate consumers about the availability of credit scores and credit reports and how this information can be used effectively.

If your company was included on the list published in March 2017 and would like to be included in the updated list, your company must submit a new entry. Please indicate in your comment if your company would like the entry

submitted last year to be included in the new list without any changes. Or, alternatively, please submit a new entry providing an update on how your company offers this service to consumers.

II. Criteria To Be Included in the Update to This Public List

If your company is a credit card issuer, fits the criteria outlined below, and would like to be included in the updated list the Bureau plans to publish, contact us by following the instructions included in this Notice for submitting an entry.[1]

If your company is not a credit card issuer, but offers existing consumer customers free access to a credit score, fits the criteria outlined below, and would like to be included in a possible list for companies in other markets, you may contact us as well. Depending on the feedback received, the Bureau may decide to expand the scope of the initial list of companies offering free credit scores beyond credit card issuers to companies in some other markets, include such companies in a future separate list, or decide not to publish a list of companies in other markets offering this service.

To be included in this list of credit card issuers, or in a possible list of companies in other markets, you must meet the following criteria:

- Offer or provide a consumer financial product or service;
- Offer existing customers [2] (at least some, but not necessarily all) the ability to obtain free of charge a credit score [3] that either your company or other lenders use for account origination, portfolio management, or for other business purposes;
- Offer this access to a credit score on a continuous basis, as opposed to on a time-limited or promotional basis, and periodically update the score.

You may include other information you think is relevant for consumers reading the public list to understand whether the service applies to them. The updated list will include a link to the comment your company submits—or a link to your company's entry from last year, if you indicate that you would like last year's submission to be included again. Consumers reading the list will be encouraged to check this information, or to contact each company, to find out which specific credit card or financial products are eligible for the service, and on what conditions, if any.

By responding to this **Federal Register** Notice (FRN) you are stating that you meet the criteria and are consenting to include the name of your company in a public list of credit card issuers, or in a possible list of companies in other markets as applicable, offering free access to credit scores to their existing customers. The Bureau reserves the right to conduct due diligence on a company's assertions about meeting the criteria stated in this notice. Your response to this FRN and inclusion in this public list are completely voluntary, and your choice to do so, or refrain from doing so, is not connected to supervisory activity by the Bureau.

We emphasize that these lists will be created to further inform the public about where to find a credit score, and will not be an endorsement of the financial institutions, credit card issuers, or any other company mentioned in any document the Bureau publishes.

Thank you for your contribution to improve consumer financial awareness.

Dated: November 4, 2017.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2017–24552 Filed 11–9–17; 8:45 am]

BILLING CODE 4810–AM–P

[1] ''Credit card issuer'' refers to any entity to which a consumer is legally obligated, or would be legally obligated, under the terms of a credit card agreement. Alternatively, you can also be included in this list if you are a bank or a credit union and you contract with a third party to issue credit cards on your behalf and under your brand name.

[2] ''Customers'' refers to individuals, not corporations or small businesses.

[3] By ''credit score'' we refer to a score that is empirically derived, demonstrably and statistically sound, and based on current data from a consumer reporting agency to predict the likelihood of certain credit behavior for the applicant.

DEPARTMENT OF EDUCATION

[Docket No.: ED–2017–ICCD–0136]

Agency Information Collection Activities; Comment Request; Teacher Education Assistance for College and Higher Education Grant Eligibility Regulations

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before January 12, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2017–ICCD–0136. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 216–34, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Teacher Education Assistance for College and Higher Education Grant Eligibility Regulations.

OMB Control Number: 1845–0084.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments;

Individuals or Households; Private Sector.

Total Estimated Number of Annual Responses: 232,324.

Total Estimated Number of Annual Burden Hours: 36,673.

Abstract: The Teacher Education Assistance for College and Higher Education (TEACH) Grant program is a non-need-based grant program that provides up to $4,000 per year to students who are enrolled in an eligible program and who agree to teach in a high-need field, at a low-income elementary or secondary school for at least four years within eight years of completing the program for which the TEACH Grant was awarded. The TEACH Grant program regulations are required to ensure accountability of the program participants, both institutions and student recipients, for proper program administration, to determine eligibility to receive program benefits and to prevent fraud and abuse of program funds. The regulations include both record-keeping and reporting requirements. The record-keeping by the school allows for review of compliance with the regulation during on-site institutional reviews. The Department uses the required reporting to allow for close-out of institutions that are no longer participating or who lose eligibility to participate in the program.

Dated: November 7, 2017.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–24533 Filed 11–9–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Notice of Public Meeting of the Supercritical CO_2 Oxy-combustion Technology Group

AGENCY: National Energy Technology Laboratory, Office of Fossil Energy, Department of Energy.

ACTION: Notice of public meeting.

SUMMARY: The National Energy Technology Laboratory (NETL) will host a public meeting via WebEx December 11, 2017, of the Supercritical CO_2 Oxy-combustion Technology Group, to address challenges associated with oxy-combustion systems in directly heated supercritical CO_2 (sCO_2) power cycles.

DATES: The public meeting will be held on December 11, 2017, from 1:00 p.m. to 3:00 p.m.

ADDRESSES: The public meeting will be held via WebEx and hosted by NETL.

FOR FURTHER INFORMATION CONTACT: For further information regarding the public meeting, please contact Seth Lawson or Walter Perry at NETL by telephone at (304) 285–4469, by email at *Seth.Lawson@netl.doe.gov, Walter.Perry@netl.doe.gov,* or by postal mail addressed to National Energy Technology Laboratory, 3610 Collins Ferry Road, P.O. Box 880, Morgantown, WV 26507–0880. Please direct all media inquiries to the NETL Public Affairs Officer at (304) 285–0228.

SUPPLEMENTARY INFORMATION:

Instructions and Information on the Public Meeting

The public meeting will be held via WebEx. The public meeting will begin at 1:00 p.m. and end at 3:00 p.m. Agenda details will be available prior to the meeting on the NETL Web site, *https://www.netl.doe.gov/events/sco2-tech-group.* Interested parties may RSVP, to confirm their participation and receive login instructions, by emailing *Seth.Lawson@netl.doe.gov.*

The objective of the Supercritical CO_2 Oxy-combustion Technology Group is to promote a technical understanding of oxy-combustion for direct-fired sCO_2 power cycles by sharing information or viewpoints from individual participants regarding risk reduction and challenges associated with developing the technology.

Oxy-combustion systems in directly heated supercritical CO_2 (SCO_2) power cycles utilize natural gas or syngas oxy-combustion systems to produce a high temperature SCO_2 working fluid and have the potential to be efficient, cost effective and well-suited for carbon dioxide (CO_2) capture. To realize the benefits of direct fired SCO_2 power cycles, the following challenges must be addressed: Chemical kinetic uncertainties, combustion instability, flowpath design, thermal management, pressure containment, definition/prediction of turbine inlet conditions, ignition, off-design operation, transient capabilities, in-situ flame monitoring, and modeling, among others.

The format of the meeting will facilitate equal opportunity for discussion among all participants; all participants will be welcome to speak. Following a detailed presentation by one volunteer participant regarding lessons learned from his or her area of research, other participants will be provided the opportunity to briefly share lessons learned from their own research. Meetings are expected to take place every other month with a different volunteer presenting at each meeting. Meeting minutes shall be published for those who are unable to attend.

This meeting is considered ''open-to-the-public;'' the purpose for this meeting has been examined during the planning stages, and NETL management has made specific determinations that affect attendance. All information presented at this meeting must meet criteria for public sharing or be published and available in the public domain. Participants should not communicate information that is considered official use only, proprietary, sensitive, restricted or protected in any way. Foreign nationals, who may be present, have not been approved for access to DOE information and technologies.

Dated: October 20, 2017.

Heather Quedenfeld,

Associate Director, Coal Technology Development & Integration Center National Energy Technology Laboratory.

[FR Doc. 2017–24497 Filed 11–9–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14795–002]

Shell Energy North America (US), LP; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Original major license.

b. *Project No.:* P–14795–002.

c. *Date filed:* November 1, 2017.

d. *Applicant:* Shell Energy North America (US), LP.

e. *Name of Project:* Hydro Battery Pearl Hill Pumped Storage Project.

f. *Location:* On the Columbia River and Rufus Woods Lake, near Bridgeport, Douglas County, Washington. The project would be located on state lands and the lower reservoir and power generation and pumping equipment would be located on Rufus Woods Lake, a reservoir operated by the Army Corps of Engineers.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Kent Watt, Shell US Hosting Company, Shell Woodcreek Office, 150 North Dairy Ashford, Houston, TX 77079, (832) 337–1160, *kent.watt@shell.com.*

i. *FERC Contact:* Ryan Hansen, 888 1st St. NE., Washington, DC 20426, (202) 502–8074, *ryan.hansen@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See*, 94 FERC 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* January 2, 2018.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14795–002.

m. The application is not ready for environmental analysis at this time.

n. The proposed project would utilize the existing U.S. Army Corps of Engineers' Rufus Woods Lake Reservoir, and would consist of the following new facilities: (1) A 300-foot-diameter, 20-foot-tall lined corrugated steel tank upper reservoir with a storage capacity of 26.5 acre-feet; (2) a 3-foot-diameter, 3,400-foot-long above-ground carbon steel penstock transitioning to a 3-foot-diameter, 2,700-foot-long buried carbon steel penstock; (3) a 77-foot-long, 77-foot-wide structural steel power platform housing five 2,400 horsepower vertical turbine pumps, one 5 megawatt twin-jet Pelton turbine and synchronous generator, and accompanying electrical equipment; (4) five vertical turbine pump intakes, each fitted with a 27-inch-diameter by 94-inch-long T-style fish screen; (5) a 2,500-foot-long, 24.9-kilovolt buried/affixed transmission line interconnecting to an existing non-project transmission line; (6) an approximately 3,847-foot long gravel access road; and (7) appurtenant facilities. The average annual generation is estimated to be 24 gigawatt-hours.

o. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *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. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. *Procedural schedule:* The application will be processed according to the following preliminary schedule. At this time we anticipate issuing a single EA. Revisions to the schedule will be made as appropriate.

Issue Notice of Acceptance—February 2018
Issue Scoping Document 1 for comments—March 2018
Comments on Scoping Document 1—May 2018
Issue Scoping Document 2—June 2018
Issue notice of ready for environmental analysis—May 2018
Commission issues EA—November 2018
Comments on EA—December 2018

Dated: November 6, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–24459 Filed 11–9–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC18–13–000.

Applicants: Plum Point Energy Associates, LLC, Plum Point Services Company, LLC, Excalibur Power, L.L.C.

Description: Application Under FPA Section 203 of Plum Point Energy Associates, LLC, et. al.

Filed Date: 11/3/17.

Accession Number: 20171103–5182.

Comments Due: 5 p.m. ET 11/24/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–245–000.

Applicants: Georgia Power Company.

Description: § 205(d) Rate Filing: GPCo 2017 PBOP Filing to be effective 1/1/2017.

Filed Date: 11/3/17.

Accession Number: 20171103–5116.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER18–246–000.

Applicants: Arizona Public Service Company.

Description: Compliance filing: Rate Schedule No. 289—SCE Expiration Agreement to be effective 12/22/2015.

Filed Date: 11/3/17.

Accession Number: 20171103–5118.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER18–247–000.

Applicants: Mississippi Power Company.

Description: § 205(d) Rate Filing: PBOP 2017 Filing to be effective 1/1/2017.

Filed Date: 11/3/17.

Accession Number: 20171103–5119.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER18–248–000.

Applicants: Southern Electric Generating Company.

Description: § 205(d) Rate Filing: SEGCo 2017 PBOP Filing to be effective 1/1/2017.

Filed Date: 11/3/17.

Accession Number: 20171103–5120.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER18–249–000.

Applicants: Public Service Company of New Mexico.

Description: Initial rate filing: Executed TCIA with Western Spirit Clean Line LLC to be effective 11/1/2017.

Filed Date: 11/3/17.

Accession Number: 20171103–5166.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER18–250–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: DEC-Brookfield-TVA Pseudo-Tie Agrmnts to be effective 11/14/2017.

Filed Date: 11/3/17.

Accession Number: 20171103–5173.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER18–251–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2017–11–03 Powerex Canadian EIM Entity Agreement to be effective 2/15/2018.

Filed Date: 11/3/17.

Accession Number: 20171103–5180.
Comments Due: 5 p.m. ET 11/24/17.
Docket Numbers: ER18–251–001.
Applicants: California Independent System Operator Corporation.
Description: Tariff Amendment: 2017–11–03 Powerex Canadian EIM Entity Scheduling Coordinator Agreement to be effective 2/15/2018.
Filed Date: 11/3/17.
Accession Number: 20171103–5185.
Comments Due: 5 p.m. ET 11/24/17.
Docket Numbers: ER18–251–002.
Applicants: California Independent System Operator Corporation.
Description: Tariff Amendment: 2017–11–03 Powerex EIM Participating Resource Agreement to be effective 2/15/2018.
Filed Date: 11/3/17.
Accession Number: 20171103–5196.
Comments Due: 5 p.m. ET 11/24/17.
Docket Numbers: ER18–251–003.
Applicants: California Independent System Operator Corporation.
Description: Tariff Amendment: 2017–11–03 Powerex EIM Participating Resource Scheduling Coordinator Agreement to be effective 2/15/2018.
Filed Date: 11/3/17.
Accession Number: 20171103–5203.
Comments Due: 5 p.m. ET 11/24/17.
Docket Numbers: ER18–251–004.
Applicants: California Independent System Operator Corporation.
Description: Tariff Amendment: 2017–11–03 CAISO and BC Hydro Data Sharing Agreement to be effective 2/15/2018.
Filed Date: 11/3/17.
Accession Number: 20171103–5206.
Comments Due: 5 p.m. ET 11/24/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) 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.

Dated: November 3, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–24454 Filed 11–9–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14799–001]

Lock 13 Hydro Partners, LLC; Notice of Intent To File License Application, Filing of Pre-Application Document, and 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.:* 14799–001.
c. *Date Filed:* September 7, 2017.
d. *Submitted By:* Lock 13 Hydro Partners, LLC.
e. *Name of Project:* Evelyn Hydroelectric Project.
f. *Location:* On the Kentucky River, in Lee and Estill Counties, Kentucky. No federal land occupied by the project works or located within the project boundary.
g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.
h. *Potential Applicant Contact:* David Brown Kinloch, Lock 13 Hydro Partners, LLC, 414 S. Wenzel Street, Louisville, KY 40204; (502) 589–0975; email—*kyhydropower@gmail.com.*
i. *FERC Contact:* Sarah Salazar at (202) 502–6863; or email at *sarah.salazar@ferc.gov.*
j. Lock 13 Hydro Partners, LLC filed its request to use the Traditional Licensing Process on September 7, 2017. Lock 13 Hydro Partners, LLC provided public notice of its request on September 14, 2017. In a letter dated November 6, 2017, the Director of the Division of Hydropower Licensing approved Lock 13 Hydro Partners, LLC'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 and/or NOAA Fisheries 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 Kentucky State Historic Preservation Officer, as required by section 106 of the 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 Lock 13 Hydro Partners, LLC 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. Lock 13 Hydro Partners, LLC 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 is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site (*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). A copy is also available for inspection and reproduction at the address in paragraph h.
o. Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: November 6, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–24460 Filed 11–9–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–236–000]

GSP Merrimack LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of GSP Merrimack LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket

authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 24, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 3, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–24450 Filed 11–9–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–234–000]

GSP Newington LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of GSP Newington LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 24, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 3, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–24456 Filed 11–9–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–241–000]

Luz Solar Partners Ltd., V; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Luz Solar Partners Ltd., V's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 24, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC

Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 3, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–24458 Filed 11–9–17; 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 electric rate filings:

Docket Numbers: ER17–718–001.

Applicants: PJM Interconnection, L.L.C.

Description: Compliance filing: Compliance Filing per 10/3/2017 Order re: TMEPs in Docket No. ER17–718 et al to be effective 6/28/2017.

Filed Date: 11/2/17.

Accession Number: 20171102–5254.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER17–721–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2017–11–02_Compliance filing re Targeted Market Efficiency Amendments to be effective 6/28/2017.

Filed Date: 11/2/17.

Accession Number: 20171102–5269.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER18–241–000.

Applicants: Luz Solar Partners Ltd., V.

Description: Baseline eTariff Filing: Luz Solar Partners Ltd., V Application for Market-Based Rates to be effective 1/1/2018.

Filed Date: 11/2/17.

Accession Number: 20171102–5255.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER18–242–000.

Applicants: Southern California Edison Company.

Description: Notice of Cancellation of the Amended and Restated Mutual Assistance Transmission Agreement (Rate Schedule No. 174) of Southern California Edison Company.

Filed Date: 11/2/17.

Accession Number: 20171102–5282.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER18–243–000.

Applicants: San Diego Gas & Electric Company.

Description: Notice of Cancellation of the Amended and Restated Mutual Assistance Transmission Agreement (Rate Schedule No. 62) of San Diego Gas & Electric Company.

Filed Date: 11/2/17.

Accession Number: 20171102–5284.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER18–244–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to WMPA SA No. 3234, Queue No. W4–060 to be effective 9/17/2014.

Filed Date: 11/3/17.

Accession Number: 20171103–5097.

Comments Due: 5 p.m. ET 11/24/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) 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.

Dated: November 3, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–24453 Filed 11–9–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–238–000]

GSP Schiller LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of GSP Schiller LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 24, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 3, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–24452 Filed 11–9–17; 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 electric rate filings:

Docket Numbers: ER14–2046–004.

Applicants: Plum Point Energy Associates, LLC.

Description: Compliance filing: Informational Filing Pursuant to

Schedule 2 of the MISO OATT to be effective N/A.

Filed Date: 11/6/17.

Accession Number: 20171106–5196.

Comments Due: 5 p.m. ET 11/27/17.

Docket Numbers: ER16–2217–005.

Applicants: Logan Generating Company, L.P.

Description: Compliance filing: Information Filing Pursuant to Schedule 2 of the PJM OATT to be effective N/A.

Filed Date: 11/6/17.

Accession Number: 20171106–5204.

Comments Due: 5 p.m. ET 11/27/17.

Docket Numbers: ER17–2515–001.

Applicants: Chambers Cogeneration, Limited Partnership.

Description: Compliance filing: Informational Filing Pursuant to Schedule 2 of the PJM OATT to be effective N/A.

Filed Date: 11/6/17.

Accession Number: 20171106–5200.

Comments Due: 5 p.m. ET 11/27/17.

Docket Numbers: ER18–252–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Rev to OA, Sched 1, sec 6.4.1 and OATT, Att K-Appx, sec 6.4.1 RE: Offer Capping to be effective 1/3/2018.

Filed Date: 11/3/17.

Accession Number: 20171103–5217.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER18–253–000.

Applicants: Duke Energy Progress, LLC.

Description: § 205(d) Rate Filing: DEP-French Broad EMC RS Nos. 195 & 210 to be effective 1/1/2016.

Filed Date: 11/3/17.

Accession Number: 20171103–5231.

Comments Due: 5 p.m. ET 11/24/17.

Docket Numbers: ER18–254–000.

Applicants: PJM Interconnection, L.L.C., Buckeye Power, Inc.

Description: § 205(d) Rate Filing: Revised SA No. 4753—NITSA among PJM and Buckeye Power, Inc. to be effective 1/1/2018.

Filed Date: 11/6/17.

Accession Number: 20171106–5302.

Comments Due: 5 p.m. ET 11/27/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) 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.

Dated: November 6, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–24455 Filed 11–9–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–237–000]

GSP White Lake LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of GSP White Lake LLC's application for, market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 24, 2017.

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Dated: November 3, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–24451 Filed 11–9–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–239–000]

GSP Lost Nation LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of GSP Lost Nation LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 24, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic

service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 3, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–24457 Filed 11–9–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Boulder Canyon Project-Rate Order No. WAPA–178

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of order concerning formula rates for electric service and calculation of the fiscal year 2018 base charge and rates for the Boulder Canyon Project.

SUMMARY: The Deputy Secretary of Energy confirmed and approved Rate Order No. WAPA–178 and Rate Schedule BCP–F10, placing formula rates for electric service from the Boulder Canyon Project (BCP) of the Western Area Power Administration (WAPA) into effect on an interim basis. The provisional formula rates will provide sufficient revenue to pay all annual costs, including interest expense, and repay required investment within the allowable periods. The Deputy Secretary has also confirmed and approved the fiscal year (FY) 2018 base charge and rates for BCP electric service.

DATES: Rate Schedule BCP–F10 is effective as of December 13, 2017, and will remain in effect through September 30, 2022, pending approval by the Federal Energy Regulatory Commission (FERC) on a final basis or until superseded. The FY 2018 base charge and rates for BCP are applicable December 13, 2017, and will remain in effect through September 30, 2018.

FOR FURTHER INFORMATION CONTACT: Mr. Ronald E. Moulton, Regional Manager, Desert Southwest Region, Western Area Power Administration, P.O. Box 6457, Phoenix, AZ 85005–6457, (602) 605–2453, email *moulton@wapa.gov* or Mr. Jack Murray, Vice President of Power Marketing, Desert Southwest Region, Western Area Power Administration, P.O. Box 6457, Phoenix, AZ 85005–6457, (602) 605–2555, email *jmurray@wapa.gov*.

SUPPLEMENTARY INFORMATION: Rate Schedule BCP–F9 under Rate Order No. WAPA–171 [1] was approved for a five-year period beginning on October 1, 2015, and ending September 30, 2020. On June 19, 2017, WAPA proposed to update the formula rates under Rate Schedule BCP–F10 and calculate the FY 2018 base charge and rates in a notice published in the **Federal Register** on June 19, 2017 (82 FR 27813). The notice detailed the proposed formula rates, initiated a public consultation and comment period, and set forth the date and location of public information and comment forums.

By Delegation Order No. 00–037.00B, effective November 19, 2016, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the Administrator of WAPA; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to FERC. Federal rules (10 CFR part 903) govern Department of Energy procedures for public participation in power and transmission rate adjustments.

Under Delegation Order Nos. 00–037.00B and 00–001.00F and in compliance with 10 CFR part 903, 10 CFR part 904 and 18 CFR part 300, I hereby confirm, approve and place Rate Order No. WAPA–178, which places formula rates for BCP electric service into effect on an interim basis, and calculates the base charge and rates for FY 2018. Rate Schedule BCP–F10 will be submitted promptly to FERC for confirmation and approval on a final basis.

Dated: November 3, 2017.

Dan Brouillette,

Deputy Secretary of Energy.

DEPARTMENT OF ENERGY

DEPUTY SECRETARY

In the matter of: Western Area Power Administration, Boulder Canyon Project Rate Adjustment for Electric Service

Rate Order No. WAPA–178

Order Confirming, Approving and Placing Formula Rates for Electric Service Into Effect on an Interim Basis and Calculation of Fiscal Year 2018 Base Charge and Rates

The formula rates set forth in this order are established pursuant to Section 302 of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152). This act transferred to and vested in the Secretary of Energy the power marketing functions of the Secretary of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)), and other acts that specifically apply to the project involved.

By Delegation Order No. 00–037.00B, effective November 19, 2016, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the Administrator of the Western Area Power Administration (WAPA); (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to the Federal Energy Regulatory Commission (FERC). Federal rules (10 CFR part 903) govern DOE procedures for public participation in power and transmission rate adjustments.

Acronyms and Definitions

As used in this Rate Order, the following acronyms and definitions apply:

Base Charge: The total charge paid by the contractors for their allocated contingent capacity and firm energy based on the annual revenue requirement. The base charge is composed of a capacity and an energy component.

Boulder Canyon Project (BCP): All works and the real property associated with such works authorized by the Boulder Canyon Project Act, as amended, the Hoover Power Plant Act of 1984, as amended, and any future additions authorized by Congress, to be constructed and owned by the United States, but exclusive of the main canal and its related appurtenances authorized by the Boulder Canyon Project Act, known as the All-American Canal.

[1] Rate Order No. WAPA–171 was approved by FERC on a final basis on December 11, 2015, in Docket No. EF15–7–000 (153 FERC ¶ 62,189).

Contractor: Any party that has a fully executed contract with WAPA for BCP electric service.

DOE: Department of Energy.

DSW: Desert Southwest Region.

FERC: Federal Energy Regulatory Commission.

Reclamation: Department of the Interior, Bureau of Reclamation.

WAPA: Western Area Power Administration.

Working Capital: Funds advanced by the contractors to meet BCP cash flow needs.

Effective Date

Rate Schedule BCP–F10 is effective as of December 13, 2017, and will remain in effect through September 30, 2022, pending approval by FERC on a final basis or until superseded. The FY 2018 base charge and rates are applicable December 13, 2017, and will remain in effect through September 30, 2018.

Public Notice and Comment

WAPA followed the Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions (10 CFR parts 903) and General Regulations for the Charges for the Sale of Power from the BCP (10 CFR 904), in developing these formula rates and schedule. WAPA took the following steps to involve the public in the rate adjustment process:

1. WAPA published a **Federal Register** notice on June 19, 2017 (82 FR 27813), announcing the proposed formula rates, initiating the 90-day public consultation and comment period, setting forth the date and location of public information and public comment forums, and outlining the procedures for public participation.

2. On July 19, 2017, WAPA held a public information forum in Phoenix, Arizona. WAPA's representatives explained the need for the formula rate adjustment and proposed changes to the formula rates, answered questions, and provided presentation handouts.

3. On August 18, 2017, WAPA held a public comment forum in Phoenix, Arizona, to provide contractors and interested parties an opportunity to comment for the record.

4. WAPA posts information about this public process at: *https://www.wapa.gov/regions/DSW/Rates/Pages/boulder-canyon-rates.aspx.*

Comments

WAPA received comments from the Irrigation & Electrical Districts Association of Arizona and the Colorado River Commission during the public consultation and comment period and responds to them in the paragraphs that follow. All comments received were considered in preparing this Rate Order. The comments have been paraphrased where appropriate without compromising their meaning.

Comment: A commenter requested further explanation of how Reclamation's $15 million for working capital was derived and whether the increase in working capital over the prior marketing period was necessary. The commenter requested steps be taken to further moderate the impact of collecting the working capital amount in the FY 2018 base charge.

Response: The greatest need for working capital is generally during the first quarter of a FY when receipts are not sufficient to cover obligations and expenditures. Because the working capital for the new marketing period will be incrementally funded over 12 billing cycles, the full amount will not be available until FY 2019. For FY 2018, the carryover balance from the marketing period ending September 30, 2017, will be available to cover funding shortfalls before the full $15 million of working capital is collected. Because the carryover balance for the marketing period ending September 30, 2017, must be refunded by September 30, 2018, Reclamation must have the $15 million in working capital to maintain a positive cash balance at the end of FY 2018.

Following the public comment forum, Reclamation reviewed their budgets and revenue projections for FY 2018. To moderate the base charge increase, Reclamation was able to further reduce its replacement budget by $800,000 and increased revenue projections for the Hoover Dam Visitor Center by $3 million. This resulted in a net decrease to the base charge of $3.8 million.

Comment: A commenter requested Reclamation's working capital analysis and footnotes be updated with the latest budget figures reflected in the revised base charge.

Response: The analysis was updated with the revised budget figures and posted to WAPA's Web site provided above. There was no change to Reclamation's working capital needs.

Comment: A commenter thanked all parties involved for the efforts made to moderate the impact of Reclamation's working capital needs on the in FY 2018 base charge. The commenter encouraged further efforts as well.

Response: Reclamation and WAPA were able to collectively moderate the impact of the working capital collection by reducing agency budgets by approximately $4.5 million. Reclamation and WAPA will continue to work collaboratively to ensure the stability of the base charge.

Comment: A commenter thanked Reclamation and WAPA for their collaborative efforts to moderate the impact of the working capital collection in FY 2018 by billing over a 12-month period rather than a one-time collection. The commenter also requested that pre-2017 and post-2017 marketing period balances be accounted for separately, included the post retirement benefit (PRB) amounts.

Response: Reclamation and WAPA are able to separately identify balances between pre-2017 and post-2017 marketing periods, including PRB balances.

Background and Provisional Base Charge and Rates

The Hoover Dam, authorized by the Boulder Canyon Project Act (45 Stat. 1057, December 21, 1928), sits on the Colorado River along the Arizona-Nevada border. The Hoover Dam's power plant has 19 generating units (two for plant use) and an installed capacity of 2,078.8 megawatts (4,800 kilowatts for plant use). High-voltage transmission lines and substations deliver this power to southern Nevada, Arizona, and southern California.

The rate-setting process for BCP is different from most WAPA power systems. The Boulder Canyon Project Amended and Restated Implementation Agreement (BCPIA), executed in 2016 between WAPA, Reclamation, and contractors, carried forward the rate methodology used for the marketing period ending September 30, 2017. This rate methodology requires contractors to pay a base charge rather than a unit rate for power. The base charge is designed to collect sufficient revenue to cover all annual costs and to repay investment obligations within allowable time periods. Each contractor is billed a base charge in proportion to their allocation of power from the Hoover Dam. A unit rate is calculated for comparative purposes but is not used to determine charges for electric service.

Since a new 50-year marketing period commences on October 1, 2017, WAPA is updating the formula rates for a five-year period and calculating the base charge and rates for FY 2018.

The revision to Rate Schedule BCP–F10 is:

Capacity: Shall be equal to the annual capacity dollars divided by 2,074 megawatt hours. This rate is applied to unauthorized overruns.

The existing formula used to calculate the forecast capacity rate was revised from 1,951 to 2,074 megawatts to reflect the current generating (nameplate) capacity for the BCP, as required by the Hoover Power Allocation Act of 2011.

No other changes to the formula rates in the rate schedule were proposed.

The update to the FY 2018 formula driven base charge and rates are:

	FY 2017 base charge	FY 2018 base charge	Percent change
Base Charge	$69,662,289	$76,910,193	10.4
Composite Rates (mills/kWh)	19.63	19.98	1.75

The FY 2018 base charge increased from $69.6 million in FY 2017 to $76.9 million in FY 2018, a 10.4 percent increase. The composite rate increased to 19.98 mills per kilowatt month, a 1.75 percent increase. Although the overall BCP budget decreased in FY 2018, the establishment of a working capital fund for the new 50-year marketing period caused the FY 2018 base charge to increase. As part of the BCPIA, Reclamation is establishing a $15 million working capital fund to cover short-term liabilities until sufficient revenues are received. This fund is particularly important at the beginning of a fiscal year when project-related expenses tend to be greater than the revenue collected. This working capital fund balance will be reviewed annually in accordance with the BCPIA.

Certification of Rates

WAPA's Administrator certified that the provisional formula rates for BCP electric service under Rate Schedule BCP–F10 result in the lowest possible rates consistent with sound business principles. The provisional formula rates were developed following administrative policies and applicable laws.

Availability of Information

All brochures, studies, comments, letters, memorandums and other documents used by WAPA to develop the provisional formula rates are available for inspection and copying at the Desert Southwest Regional Office, Western Area Power Administration, 615 South 43rd Avenue, Phoenix, Arizona. Many of these documents are also available on WAPA's Web site: *https://www.wapa.gov/regions/DSW/Rates/Pages/boulder-canyon-rates.aspx*.

RATEMAKING PROCEDURE REQUIREMENTS

Environmental Compliance

In compliance with the National Environmental Policy Act (NEPA) of 1969, 42 U.S.C. 4321–4347; the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500–1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021), WAPA has determined that this action is categorically excluded from preparing an environmental assessment or an environmental impact statement.

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Submission to FERC

The formula rates herein confirmed, approved, and placed into effect on an interim basis, together with supporting documents, will be submitted to FERC for confirmation and final approval.

Order

In view of the foregoing and under the authority delegated to me, I confirm and approve, on an interim basis, the formula rates under Rate Schedule BCP–F10. Rate Schedule BCP–F10 is applicable the first full billing period on or after November 13, 2017, and will remain in effect through September 30, 2022, pending FERC's confirmation and approval of the rate schedule or substitute formula rates on a final basis.

Dated: November 3, 2017.

Dan Brouillette,

Deputy Secretary of Energy.

Rate Schedule BCP–F10

(Supersedes Rate Schedule BCP–F9)

UNITED STATES DEPARTMENT OF ENERGY

WESTERN AREA POWER ADMINISTRATION

DESERT SOUTHWEST REGION

Boulder Canyon Project

SCHEDULE OF RATES FOR ELECTRIC SERVICE

Effective

The first day of the first full billing period beginning on or after December 13, 2017, and extending through September 30, 2022, or until superseded by another rate schedule, whichever occurs earlier.

Available

In the marketing area serviced by the Boulder Canyon Project.

Applicable

To power supplied by the Boulder Canyon Project through one meter, at one point of delivery, unless otherwise provided by contract.

Character and Conditions of Service

Alternating current at 60 hertz, three-phase, delivered and metered at the voltages and points established by contract.

Base Charge

The charge paid by each contractor for their allocated capacity and firm energy based on the annual revenue requirement. The base charge shall be composed of a capacity component and an energy component:

Capacity Charge: Each month WAPA shall bill each contractor for a capacity charge equal to one-twelfth (1/12) of the capacity dollars multiplied by each contractor's contingent capacity percentage as provided by contract.

Energy Charge: Each month WAPA shall bill each contractor for an energy charge equal to that period's monthly energy ratio, multiplied by the contractor's energy dollars as provided by contract.

Forecast Rates

Energy: Shall be equal to the annual energy dollars divided by the lesser of the total master schedule energy or 4,501 megawatt hours. This rate is applied to excess energy, unauthorized overruns, and water pump energy.

Capacity: Shall be equal to the annual capacity dollars divided by 2,074 megawatt hours. This rate is applied to unauthorized overruns.

Calculated Energy Rate

Within ninety (90) days after the end of the fiscal year, a calculated energy rate shall be calculated. For any rate year in which energy deemed delivered is greater than 4,501 megawatt hours, WAPA shall apply the calculated energy rate to each contractor's energy deemed delivered to determine the contractor's actual energy charge. A credit or debit shall be established for each contractor based on the difference between the contractor's energy dollars and the contractor's actual energy charge, to be applied in the month following the

calculation or as soon as possible thereafter.

Lower Colorado River Basin Development Fund (Contribution Charge)

The Contribution Charge is 4.5 mills for each kilowatt hour measured or scheduled to an Arizona purchaser and 2.5 mills for each kilowatt hour measured or scheduled to a California or Nevada purchaser, except for purchased power.

Billing for Unauthorized Overruns

For each billing period in which there is a contract violation involving an unauthorized overrun of contractual power obligations, such overrun shall be billed at ten (10) times the forecast energy rate and forecast capacity rate. The Contribution Charge shall also be applied to each kilowatt hour of overrun.

Adjustments

None.

[FR Doc. 2017–24496 Filed 11–9–17; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2016–0632; FRL–9959–51–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Willingness To Pay Survey To Evaluate Recreational Benefits of Nutrient Reductions in Coastal New England Waters (New)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''Willingness to Pay Survey to Evaluate Recreational Benefits of Nutrient Reductions in Coastal New England Waters (New)'' (EPA ICR No. 2558.01, OMB Control No. 2080–NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request for approval of a new collection. Public comments were previously requested via the **Federal Register** (81 FR 78809) on 11/09/2016 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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: Additional comments may be submitted on or before December 13, 2017.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–ORD–2016–0632, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *Docket_ORD@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

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: Marisa Mazzotta, U.S. Environmental Protection Agency, Office of Research and Development, Atlantic Ecology Division, 27 Tarzwell Drive, Narragansett, Rhode Island 02882; telephone number: 401–782–3026; fax number: 401–782–3139; email address: *mazzotta.marisa@epa.gov.*

SUPPLEMENTARY INFORMATION: 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.*

Abstract: Researchers at the EPA's Office of Research and Development (ORD), Atlantic Ecology Division (AED) are piloting an effort to better understand how reduced water quality due to nutrient enrichment affects the economic prosperity, social capacity, and ecological integrity of coastal New England communities. This project proposes a survey to collect data for a case study of changes in recreation demand and values due to changes in nutrients in northeastern coastal waters. This includes the development of methods and tools for estimating recreational values that can be applied in other locations, either by EPA researchers, EPA's regional offices or state partners. Cape Cod is in the midst of an extensive regional planning effort related to its coastal waters, and this research can provide helpful socio-economic information to decision makers about the use of those waters. Because the 100-mile radius from Cape Cod includes a large area of southern New England and the largest population centers in New England, the results will be more broadly applicable to residents of southern New England.

One of the key water quality concerns on Cape Cod, and throughout New England, is nonpoint sources of nitrogen, which lead to ecological impairments in estuaries, with resultant socio-economic impacts. The decisions needed to meet water quality standards are highly complex and involve significant cross-disciplinary challenges in identifying, implementing, and monitoring social and ecological management needs. We will focus on understanding recreational uses as valued economic goods in coastal New England (including beachgoing, swimming, fishing, shellfishing, and boating).

Form Numbers: 6000–02 and 6000–03.

Respondents/affected entities: Individuals and Households.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 2,455 (total).

Frequency of response: Once.

Total estimated burden: 205 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $7,129 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: This is a new collection.

Courtney Kerwin,

Director, Collection Strategies Division.

[FR Doc. 2017–24446 Filed 11–9–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Issuance of Technical Bulletin 2017–2, Assigning Assets to Component Reporting Entities

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and the FASAB

Rules of Procedure, as amended in October 2010, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has issued Technical Bulletin 2017–2, *Assigning Assets to Component Reporting Entities.*

The Technical Bulletin is available on the FASAB Web site at *http://www.fasab.gov/accounting-standards/*. Copies can be obtained by contacting FASAB at (202) 512–7350.

FOR FURTHER INFORMATION CONTACT: Ms. Wendy M. Payne, Executive Director, 441 G Street NW., Mailstop 6H19, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act, Pub. L. 92–463.

Dated: November 1, 2017.

Wendy M. Payne,

Executive Director.

[FR Doc. 2017–24510 Filed 11–9–17; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Issuance of Technical Bulletin 2017–1, Intragovernmental Exchange Transactions

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and the FASAB Rules Of Procedure, as amended in October 2010, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has issued Technical Bulletin 2017–1, *Intragovernmental Exchange Transactions.*

The Technical Bulletin is available on the FASAB Web site at *http://www.fasab.gov/accounting-standards/*. Copies can be obtained by contacting FASAB at (202) 512–7350.

FOR FURTHER INFORMATION CONTACT: Ms. Wendy M. Payne, Executive Director, 441 G Street NW., Mailstop 6H19, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act, Pub. L. 92–463.

Dated: November 1, 2017.

Wendy M. Payne,

Executive Director.

[FR Doc. 2017–24509 Filed 11–9–17; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 7, 2017.

A. Federal Reserve Bank of St. Louis (David L. Hubbard, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *Southern Missouri Bancorp, Inc., Poplar Bluff, Missouri;* to merge with Southern Missouri Bancshares, Inc., Marshfield, Missouri, and thereby indirectly acquire Southern Missouri Bank of Marshfield, Marshfield, Missouri.

Board of Governors of the Federal Reserve System, November 6, 2017.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2017–24432 Filed 11–9–17; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 29, 2017.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Henderson State Company, Henderson, Nebraska;* to engage in lending activities, pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, November 6, 2017.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2017–24431 Filed 11–9–17; 8:45 am]

BILLING CODE 6210–01–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 (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 notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than November 27, 2017.

A. Federal Reserve Bank of San Francisco (Gerald C. Tsai, Director, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *Matthew Moskowitz, Plainview, New York; Yaakov Markowitz, Brooklyn, New York; Jarret Prussin, Westport, Connecticut; Paul Brown, Monte Carlo, Monaco; and Menachem Wilenkin, Brooklyn, New York;* to acquire voting shares of All West Bancorp, and thereby indirectly acquire shares of FinWise Bank, both of Sandy, Utah.

Board of Governors of the Federal Reserve System, November 7, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017–24522 Filed 11–9–17; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[Notice–PBS–2017–03; Docket 2017–0002; Sequence 22]

Notice of Intent To Prepare a Supplemental Environmental Impact Statement for the Modernization of the San Luis I Land Port of Entry (LPOE) Modernization

AGENCY: Public Building Service, (PBS), General Services Administration (GSA).

ACTION: Notice of intent; announcement of meeting.

SUMMARY: Pursuant to the requirements of the National Environmental Policy Act of 1969 (NEPA), the Council on Environmental Quality Regulations, and the GSA Public Buildings Service NEPA Desk Guide, GSA is issuing this notice to advise the public that an Environmental Impact Statement (EIS) will be prepared for the San Luis I LPOE. The action to be evaluated by this EIS is the modernization of the existing San Luis I LPOE, located in San Luis, Arizona, to improve its functionality, capacity, and security.

DATES: *Meeting Date:* A public scoping meeting will be held on Wednesday, November 29, 2017, from 4:00 p.m., Mountain Standard Time (MST), to 6:00 p.m., MST.

ADDRESSES: The public scoping meeting will be held in the City Council Chambers at 1090 E. Union Street, San Luis, AZ, where GSA will meet with governmental and public stakeholders to explain the project, and obtain input on the scoping of the project. The meeting will be an informal open house, where visitors may come, receive information, and provide written comments.

FOR FURTHER INFORMATION CONTACT: Osmahn Kadri, Regional Environmental Quality Advisor/NEPA PM, by phone at 415–522–3617 or via email at *osmahn.kadri@gsa.gov.* Please also call this number if special assistance is needed to attend and participate in the public scoping meeting.

SUPPLEMENTARY INFORMATION: GSA intends to prepare an EIS to analyze the potential impacts resulting from proposed modifications and design changes to the San Luis I LPOE modernization project. The San Luis I LPOE consists of several facilities that are in need of modernization.

The primary users of the LPOE are officers belonging to Customs and Border Protection and Immigrations and Customs Enforcement, as well as the general public seeking to enter or exit the country. The LPOE needs modernization due to unacceptable building conditions and increasing traffic demand.

Currently, the LPOE is physically constrained on both the north and south, by Urtuzuastegui Street and the Mexico-U.S. border, respectively. Traffic from the LPOE must be routed into downtown San Luis, which often creates traffic jams. All vehicular traffic coming into town has been rerouted recently to exit via First Street, while outgoing traffic enters the port via Main Street.

The possible phasing for the demolition and modernization of the LPOE includes:

- Phase 1: Acquire a portion of Friendship Park, a Public-Facing Building, Parking Garage, Vault, Impound, and Utility Yard.
- Phase 2: Construct new privately owned vehicle processing facilities and kennel.
- Phase 3: Construct new main building and outbound east exits.
- Phase 4: Demolish main building, construct pedestrian processing, and construct outbound west exits.

Alternatives Under Consideration: Two modernization alternatives for the proposed project are currently under consideration and will be analyzed in the EIS for the potential environmental impacts. In addition, the ''No Action'' alternative will be analyzed.

Alternative 1—GSA will demolish then reconstruct a modernized LPOE. The existing San Luis LPOE will be demolished and reconstructed in four (4) phases. Some adjacent land on the west side of the LPOE will be acquired which will allow modernization of the facility to accommodate modern operational requirements, and alleviate traffic strain in downtown San Luis.

Alternative 2—Renovate, expand, and modernize the existing LPOE. GSA will renovate and modernize the existing San Luis LPOE and expand the existing footprint of the facility on the west as mentioned in Alternative 1 which will accommodate modern operational requirements, and alleviate traffic strain in downtown San Luis.

Alternative 3—No Action Alternative. GSA will continue operations at the existing LPOE facilities as they are currently configured and will not perform any renovation nor modernization of the LPOE.

The EIS will address the potential environmental impacts of the proposed alternatives of the including aesthetics, air quality during construction and operation, geology and soils, hazards and hazardous materials, hydrology and water quality, land use, noise during construction and operation, utilities, and traffic. The EIS will also address the socioeconomic effects of the project.

Scoping Process: Scoping will be accomplished through a public scoping meeting, direct mail correspondence to appropriate federal, state, and local agencies, and to private organizations and citizens who have previously expressed, or are known to have, an interest in the project.

This meeting will be announced in the local newspaper, the *Yuma Sun.* Agencies and the public are encouraged to provide written comments regarding the scope of the EIS. Written comments must be received by Friday, December 22, 2017, and sent to the General Services Administration, Attention: Osmahn Kadri, Regional Environmental Quality Advisor/NEPA PM, 450 Golden Gate Avenue, 3rd Floor East, San Francisco, CA, 94102, or via email to *osmahn.kadri@gsa.gov.*

Dated: November 2, 2017.

Matthew Jear,

Director, Portfolio Management Division, Pacific Rim Region, Public Buildings Service.

[FR Doc. 2017–24551 Filed 11–9–17; 8:45 am]

BILLING CODE 6820–YF–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–17–1014]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled *CDC Worksite Health Scorecard* to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March 2, 2017 to obtain comments from the public and affected agencies. CDC received three comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

CDC Worksite Health Scorecard (OMB Control Number 0920–1014, expired 4/30/2017)—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) has established the Worksite Health Scorecard (Scorecard), an online organizational assessment tool, to enable employers to assess the number of evidence-based health promotion interventions or strategies in their worksites to prevent heart disease, stroke, and related conditions such as hypertension, diabetes, and obesity.

The CDC Worksite Health Scorecard will support small, mid-size, and large employer with three primary goals: (1) Assist employers in identifying gaps in their health promotion programs, and help them to prioritize high-impact strategies for health promotion at their worksites; (2) Improve the health and wellbeing of employees and their families through science-based workplace health interventions and promising practices; and (3) Support research and increase understanding of the organizational programs, policies, and practices that employers of various sizes and industry sectors have implemented to support healthy lifestyle behaviors.

The Scorecard approval under OMB Control number 0920–1014 expired at a time when it was unclear if resources would be available to continue its use. Strong commitments from internal and external stakeholders have enabled CDC to continue to offer a revised Scorecard to employers nationwide. CDC is requesting a reinstatement with change to a previously approved data collection. CDC plans to first pilot test an updated version of the Scorecard and when finalized submit a revision request to expand the number of employers the new Scorecard is offered to.

From 2014–2016, 1,531 worksites have submitted CDC Worksite Health Scorecards from employers in 40 different states. The average employer is implementing a little more than half of the recommended programmatic, policy, environmental support, and health-benefit intervention strategies assessed in the Scorecard. Additionally, those employers who have re-assessed at least once during this period have seen their Scorecard score improve from an average of 95.85 points to 139.72 points. This represents an improvement in the total number of intervention strategies being implemented as well as the number of best practice and high-impact strategies, which garner more points improving the work environment for employees to improve their health and well-being. Overall, exposure to the Scorecard is contributing to better and more effective work-place health program offerings to employees.

CDC will recruit a convenience sample of one hundred employers (each represented by two knowledgeable employees for 200 total respondents) to pilot test and evaluate the updated Scorecard. CDC will seek a diverse set of employers with respect to size and industry type who will be reached through meetings, presentations, and through gatekeeper organizations to be enrolled/registered. The updated Scorecard includes questions in four new topic areas: Sleep (8 questions); Alcohol & Other Substance Abuse (6 questions); Cancer (7 questions); and Musculoskeletal Disorders (7 questions), to include minor revisions to previously existing questions or adjustment in the associated points received for answering affirmatively to a question based on supporting evidence from the peer reviewed literature as well as sources such as the Community Guide. Additional updates also included dropping 20 questions from the prior version due to redundancy or lack of evidence to support their use. From the employers that complete the survey, CDC will conduct follow-up telephone interviews on a subset of about 16 employers (each represented by two knowledgeable employees, for 32 respondents in total). The follow-up telephone interviews will gather general impressions of the Scorecard—particularly the new modules and allow for discussion of items that presented discrepancies (and items that were left blank) to understand the respondent's interpretation and perspective of their answers these questions. This process will assess the validity and reliability of the questions, as well as allow CDC to gather suggestions for additional refinements, where necessary.

Following this pilot testing, CDC will continue to provide outreach to and register approximately 800 employers per year to use the online survey Scorecard in their workplace health program assessment, planning, and implementation efforts, which is open to employers of all sizes, industry sectors, and geographic locations across the country.

CDC requests a one-year OMB approval for this project. CDC will pilot

test the updated Scorecard in year one and create a finalized version of the instrument based on respondent feedback gathered during the pilot. After the completion of the pilot test, CDC will submit a finalized instrument as a revision request for a three-year clearance.

Participation in the CDC Worksite Health Scorecard is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 303.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Employer pilot	CDC Worksite Health Scorecard Registration Application	200	1	2/60
	CDC Worksite Health Scorecard	200	1	1.25
	CDC Worksite Health Scorecard Cognitive interview	32	1	1
	CDC Worksite Health Scorecard Pilot evaluation	200	1	5/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–24472 Filed 11–9–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–18AG; Docket No. CDC–2017–0095]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed work and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the *Evaluation of the Cancer Survivorship Demonstration Project.* This information collection aims to help CDC better understand strategies and best practices to identify and address current cancer survivorship needs and gaps.

DATES: CDC must receive written comments on or before January 12, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2017–0095 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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 submissions of responses.

5. Assess information collection costs.

Proposed Project

Evaluation of the Cancer Survivorship Demonstration Project—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Under CDC's National Comprehensive Cancer Control Program (NCCCP) Request for Applications DP5–1501, the Division of Cancer Prevention and Control (DCPC) funded six grantees to implement evidence-based and promising strategies to increase knowledge of cancer survivor needs, increase survivor knowledge of treatment and follow-up care, and increase provider knowledge of guidelines pertaining to treatment of cancer. Specifically, this initiative employs strategies that relate to increasing surveillance and community-

clinical linkages. Through this initiative, DCPC intends to help address the public health needs of cancer survivors. To facilitate evidence-informed policymaking and quality improvement of federal programs, CDC needs a comprehensive evaluation to characterize survivorship interventions and document outcomes.

CDC seeks to request OMB approval to collect information needed for this evaluation. The proposed information collection will focus on how each grantee has expanded their knowledge of cancer survivor needs, increased utilization of surveillance data to inform program planning by providers and coalition members, and enhanced partnerships to facilitate and broaden program reach. CDC will also collect data on challenges encountered and addressed, factors that facilitated implementation, and lessons learned along the way. The requested information does not currently exist for organizations and entities working to improve cancer survivorship needs. With this data, CDC will gain critical insights for improving achieving immediate strategic efforts and goals to improve the public health needs of cancer survivors.

CDC plans to collect information during two cycles of the program using a Web-based Grantee survey of NCCCP DP15–1501 grantee program directors and program managers, a Web-based Partner Survey of grantees' self-identified key partners (*e.g.,* coalition members, providers, patient navigators), and semi-structured telephone interviews with NCCCP DP15–1501 grantee program directors and program managers. The data from the survey and semi-structured interviews will provide additional insight into program efforts.

CDC is requesting OMB approval to conduct a Web-based Grantee survey using Survey Gizmo to a purposive sample of one program director and one program manager for each of the six grantee sites (12 respondents total) and to conduct a Web-based Partner Survey of 10 self-identified key partners in each of 6 grantees for a total of 60 respondents. CDC will administer the Web-based surveys to the same respondents at two time points for a total estimated burden of 8 hours for the Web-based Grantee Survey and 40 hours for the Web-based Partner Survey.

CDC will ask the respondents to provide information regarding the type of respondent; their use of surveillance data to inform survivorship interventions; communication, education, and training activities to support the implementation of survivorship interventions; partnership engagement; challenges and facilitators regarding the implementation of evidence-based cancer survivorship strategies; reach of cancer survivorship interventions; and respondent background information.

CDC intends to also seek OMB approval to conduct semi-structured interviews by telephone with a purposive sample of one program director and one program manager for each of the six grantee sites (12 respondents total). CDC will conduct the semi-structured interviews with the same respondents at two time points for a total estimated burden of 36 hours.

CDC will ask the respondents to provide information on the following: (1) Administration of the Behavioral Risk Factor Surveillance System Cancer Survivorship Module; (2) communication, education, and training activities to support the implementation of cancer survivorship interventions; (3) community clinical linkage strategies to support cancer survivors, knowledge regarding best practices for survivorship care; partnership engagement; (4) dissemination of evidence-based survivorship interventions; and (5) recommendations for improving the implementation of evidence-based survivorship interventions.

CDC will analyze the collected information and use in aggregate to inform future efforts to support cancer survivors and to initiate evidence-informed program decisions when rolling this initiative out to all NCCCP grantees. Without this data collection, CDC will not be able to provide tailored technical assistance to its grantees and communicate program efforts.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
NCCCP Grantee Program Director ..	Web-based Grantee survey	12	2	20/60	8
	Semi-structured telephone interview	12	2	1.50	36
NCCCP Grantee Partner	Web-based Partner survey	60	2	20/60	40
Total	.....	.....	.....	.....	84

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–24523 Filed 11–9–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–17AUZ; Docket No. CDC–2017–0065]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, 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. This notice invites comment on ''Project NICE: Navigating Insurance Coverage Expansion''. Project NICE will evaluate the efficacy of an in-person health insurance enrollment assistance intervention among Black and Hispanic men who have sex with

men (MSM) and Transgender persons living in the Chicago, Illinois metropolitan area.

DATES: CDC must receive written comments on or before January 12, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2017–0065 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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 submissions of responses.

5. Assess information collection costs.

Proposed Project

Project NICE: Navigating Insurance Coverage Expansion—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC seeks to request a three-year OMB approval to evaluate the efficacy of an in-person health insurance enrollment assistance intervention among 1,000 Black and Hispanic MSM and Transgender persons ages ≥18 years living in the Chicago, Illinois metropolitan area. CDC will invite individuals attending HIV testing outreach events, or seeking care in select clinics in Chicago to participate in the study after an HIV testing session. Researchers will collect study participants' sociodemographic, risk behavior, and insurance coverage information as part of study enrollment. Each quarter, researchers will abstract outcome evaluation data (linkage to and retention in HIV-related care, referrals for mental health or substance use, and other health outcomes) from study participant's electronic medical records (EMRs). Researchers will also assess intervention cost-effectiveness.

CDC funded this study through a cooperative agreement with the University of Chicago Medicine (UCM). Three partner agencies will conduct the intervention: (1) University of Chicago Medicine (UCM) (the lead partner agency), (2) Howard Brown Health, and (3) Chicago House and Social Service Agency (Chicago House). The three partner agencies each have a history of providing clinical care, HIV testing outreach, and in-person health insurance enrollment assistance for Chicago's MSM and Transgender communities.

As part of this study, CDC will evaluate the in-person health insurance enrollment assistance. Specifically, researchers will evaluate whether moving the delivery of in-person health insurance enrollment assistance, from the first clinic visit after receipt of an HIV test result, to earlier in the care continuum, during the HIV testing event, will impact health outcomes. Therefore, this study does not introduce new intervention activities or burden on the participants or the agency staff; it reorders the sequence of delivery of standard practice. Only the addition of data collection forms and procedures will be new, and the additional burden will be to partner agency staff workload and participant experience.

In 2013, MSM accounted for 81% of new HIV infections among males and 65% of all new HIV infections. In 2010, health officials reported 10,600 new HIV infections for African-American (Black) MSM, 11,200 for White MSM, and 6,700 for Hispanic MSM. Through a 2008 systematic review, researchers found HIV rates among Black and Hispanic Transgender women to be 56% and 16%, respectively.

Black and Hispanic MSM and Transgender persons face obstacles in seeking medical care and following through with referrals or appointments, including lack of health insurance.

This study will implement a structural intervention. The goal of this study is to test whether providing in-person assistance for first-time private health insurance or Medicaid enrollment, changing to a different insurance plan, or understanding how to use current insurance policies following HIV testing will: (1) Increase the proportion of participants who obtain health insurance; (2) result in better health outcomes among participants (*e.g.,* achieving viral suppression, remaining HIV negative); (3) improve the linkage and retention rates for HIV care (*i.e.,* HIV treatment, Pre-exposure Prophylaxis (PrEP)) and other HIV-associated health services (*e.g.,* mental health counseling, substance use treatment) of participants, especially those diagnosed with HIV; and (4) increase HIV care linkage and retention rates sufficiently to justify the cost of implementing the intervention (cost-benefit analysis) among Black and Hispanic MSM and Transgender persons age 18 or older in the Chicago, Illinois metropolitan area.

Randomized controlled trials (RCTs) of structural interventions are rare. Nevertheless, CDC will use a RCT design to enhance scientific validity and the policy impact of the intervention, and help researchers assess the efficacy of this intervention as an emerging practice prior to dissemination to HIV prevention service providers nationwide.

This project aligns with National HIV/AIDS Strategy 2020 and Health People 2020 objectives. This structural intervention aligns with the OMB's emphasis on application of behavioral insights in that it restructures the context (*i.e.,* after HIV testing) in which health-related decision-making (*i.e.,* health insurance enrollment) occurs in order to promote the selection of beneficial options. The proposed health insurance enrollment assistance project has the potential for widespread health improvements for Black and Hispanic MSM and Transgender persons regardless of their HIV status.

The study will enroll 1,000 participants over 12 months to reach adequate power calculations (500 into the intervention arm, and 500 into the control arm).

After an HIV testing session at an outreach event or clinic visit, a partner-agency staff person will invite an individual to participate in the study. If interested, participants will complete a consent form. Staff will screen individuals using the Eligibility Form, which will take approximately five minutes to complete. Researchers would need to screen approximately 1,500 individuals in order to identify and enroll 1,000 eligible study participants. If eligible and interested in participating, individuals will complete the Participant Enrollment Form, which will take approximately 35 minutes to complete. Researchers then will offer in-person health insurance enrollment to randomized intervention arm participants. This enrollment will take a maximum of 60 minutes to complete. The study's in-person health insurance enrollment assistance will take the same amount of time as standard practice health insurance enrollment assistance.

The total estimated annualized hourly burden anticipated for this study is 1,458 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Study participant	Consent Form	1,500	1	10/60	250
Study participant	Eligibility Form	1,500	1	5/60	125
Study participant	Participant Enrollment Form	1,000	1	35/60	583
Study participant (Intervention arm ONLY).	ACTIVITY: In-person health insurance enrollment assistance.	500	1	1	500
Total					1,458

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–24473 Filed 11–9–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–R–48 and CMS–10421]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 12, 2018.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, *Attention:* Document Identifier/OMB Control Number __, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–R–48 Hospital Conditions of Participation and Supporting Regulations

CMS–10421 Fee-for-Service Recovery Audit Prepayment Review

Demonstration and Prior Authorization Demonstration

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Hospital Conditions of Participation and Supporting Regulations; *Use:* The information collection requirements described in this information collection request are needed to implement the Medicare and Medicaid conditions of participation (CoP) for 4,890 accredited and non-accredited hospitals and an additional 101 critical access hospitals (CAHs) that have distinct part psychiatric or rehabilitation units (DPUs). CAHs that have DPUs must comply with all of the hospital CoPs on these units. Thus, this package reflects the burden for a total of 4,991 hospitals (that is, 4,890 accredited/non-accredited hospitals and 101 CAHs which include 81 CAHs that have psychiatric DPUs and 20 CAHs that have rehabilitation DPUs). The information collection requirements for the remaining 1,183 CAHs have been approved in a separate package under CMS–10239 (OMB control number: 0938–1043).

The CoPs and accompanying regulatory requirements are used by our surveyors as a basis for determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid. CMS and the health care industry believe that the availability to the facility of the type of records and general content of records is standard medical practice and is necessary to ensure the well-being and safety of patients and professional treatment accountability. *Form Number:* CMS–R–48 (OMB control number: 0938–0328); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profit); *Number of Respondents:* 4,991; *Total Annual Responses:* 1,342,424; *Total Annual Hours:* 18,840,617. (For policy questions regarding this collection contact Scott Cooper at 410–786–9465.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Fee-for-Service Recovery Audit Prepayment Review Demonstration and Prior Authorization Demonstration; *Use:* OMB approved the collections required for two demonstrations of prepayment review and prior authorization. The first demonstration allows Medicare Recovery Auditors to review claims on a pre-payment basis in certain States. The second demonstration established a prior authorization program for Power Mobility Device claims in certain States. The first demonstration has ended, so we are only extending the collection of information for the second demonstration, prior authorization of power mobility devices.

For the Prior Authorization of Power Mobility Devices (PMDs) Demonstration, we are piloting prior authorization for PMDs. Prior authorization will allow the applicable documentation that supports a claim to be submitted before the item is delivered. For prior authorization, relevant documentation for review is submitted before the item is delivered or the service is rendered. CMS will conduct this demonstration in California, Florida, Illinois, Michigan, New York, North Carolina, Texas, Pennsylvania, Ohio, Louisiana, Missouri, Maryland, New Jersey, Indiana, Kentucky, Georgia, Tennessee, Washington, and Arizona based on beneficiary address as reported to the Social Security Administration and recorded in the Common Working File (CWF). For the demonstration, a prior authorization request can be completed by the (ordering) physician or treating practitioner and submitted to the appropriate Durable Medical Equipment Medicare Administrative Contractor (DME MAC) for an initial decision. The supplier may also submit the request on behalf of the physician or treating practitioner. The physician, treating practitioner or supplier who submits the request on behalf of the physician or treating practitioner, is referred to as the ''submitter.'' Under this demonstration, the submitter will submit to the DME MAC a request for prior authorization and all relevant documentation to support Medicare coverage of the PMD item.

Form Number: CMS–10421 (OMB control number: 0938–1169); *Frequency:* Occasionally; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 50,500; *Total Annual Responses:* 50,500; *Total Annual Hours:* 25,125. (For policy questions regarding this collection contact Daniel Schwartz at 410–786–4197.)

Dated: November 7, 2017.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–24524 Filed 11–9–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Public Comment Request; Semiannual Performance Measures for the ACL Traumatic Brain Injury State Partnership Program (ICR New)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This notice solicits comments on proposed semiannual performance measures for the ACL Traumatic Brain Injury State Partnership program as reauthorized under the Traumatic Brain Injury Reauthorization Act of 2014.

DATES: Submit written or electronic comments on the collection of information by January 12, 2018.

ADDRESSES: Submit electronic comments on the collection of information to: *TBI@acl.gov.* Submit written comments to: U.S. Department of Health and Human Services, Administration for Community Living, Washington, DC 20201, Attention: Thom Campbell.

FOR FURTHER INFORMATION CONTACT: Thom Campbell by telephone: (202) 795–7263 or by email: *TBI@acl.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval.

To comply with the above requirement, ACL is publishing a notice of a new collection of information as set forth in this document. With respect to the following collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility and/or help ACL illustrate the program's return on investment; (2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (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 respondents, including through the use of automated collection techniques when appropriate and other forms of information technology.

Purpose

The purpose of the Traumatic Brain Injury (TBI) State Partnership program is to increase access to rehabilitation and other services for individuals with traumatic brain injury. Under the Traumatic Brain Injury Reauthorization Act of 2014 (Pub. L. 113–196), the Traumatic Brain Injury State Partnership program transitioned from the Health Resources and Services Administration (HRSA) to the Administration for Community Living (ACL). Under this law, the Secretary, acting through ACL, was authorized to ''make grants to States and American Indian consortia for the purpose of carrying out projects to improve access to rehabilitation and other services regarding traumatic brain injury.'' ACL seeks to collect performance measure data from state grantees consistent with the TBI State Partnership program's purpose and ACL's mission to ''Maximize the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers.''

ACL seeks data on a semi-annual basis on the types of practices, protocols, and activities performed by each grantee, as well as the cost of each activity and the number and types of people they served. ACL also seeks information about the number and types of individuals who receive TBI-related home and community based services. Finally, ACL seeks information regarding the involvement of people with TBI in advisory and program support roles.

The data collected will allow ACL to determine the extent to which the grant program is meeting its goals of expanding and improving services, generating sustainable funding streams, and enriching service systems to better serve individuals with TBI and their families. The data will also help ACL develop and expand baseline information around the nature and scope of the incidence of TBI. Additionally, this data collection will help ACL illustrate the return on investment of the TBI funds in terms of system change (*i.e.,* changes in policies and practices and the development of networks). By matching the project dollars spent against measurable improvements in state systems for delivering services and supports to people living with TBI, ACL will have a strong indicator of the effect of the TBI program on the quality of services which ultimately impact the lives of people across the country living with TBI. The proposed data collection forms may be found on the ACL Web site for review at: *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: The annual reporting burden estimates are shown below.

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
States	State Performance Report	*45	2	16	1,440

*This is the highest number of awards anticipated, but it is possible that there will be less. If less than 45 grants are awarded, the total burden hours will be adjusted proportionally.

Dated: November 7, 2017.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2017–24525 Filed 11–9–17; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5138]

S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals; International Council for Harmonisation; 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 draft guidance entitled ''S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance replaces the existing guidance entitled ''S5(R2) Detection of Toxicity to Reproduction for Human Pharmaceuticals.'' The draft guidance is intended to align with other ICH guidances, elaborate on concepts to consider when designing studies, and identify potential circumstances in which a risk assessment can be made based on preliminary studies. It also clarifies the qualification and potential use of alternative assays.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 12, 2018.

ADDRESSES: You may submit comments 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 Office, 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–2017–D–5138 for ''S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals.'' 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 Office between 9 a.m. and 4 p.m., Monday through Friday.

- *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 Office. 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.gpo.gov/fdsys/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.

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Abigail Jacobs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6474, Silver Spring, MD 20993–0002, 301–796–0174; or Martin (Dave) Green, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3270, Silver Spring, MD 20993–0002, 301–796–2640. *Regarding the ICH:* Amanda Roache, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring, MD 20993–0002, 301–796–4548.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals.'' In recent years, regulatory authorities and industry associations have participated in many important initiatives to promote international harmonization of regulatory requirements. FDA has participated in several meetings designed to enhance harmonization and is committed to seeking scientifically based, harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators around the world. The six founding members of the ICH are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CBER, FDA; and the Pharmaceutical Research and Manufacturers of America. The Standing Members of the ICH Association include Health Canada and

Swissmedic. Any party eligible to become a member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the members of the ICH Association.

The ICH Assembly is the overarching body of the Association and includes representatives from each of the ICH members and observers.

In August 2017, the ICH Assembly endorsed the draft guidance titled ''S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals'' and agreed that the guidance should be made available for public comment. The draft guidance is the product of the S5(R3) Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the S5(R3) Safety Expert Working Group.

The draft guidance replaces the existing guidance entitled ''S5(R2) Detection of Toxicity to Reproduction for Human Pharmaceuticals.'' The guidance has undergone major revisions to align with other ICH guidances, elaborate on concepts to consider when designing studies, and identify potential circumstances in which a risk assessment can be made based on preliminary studies. It also clarifies the qualification and potential use of alternative assays.

To support using alternative assays, compounds that are either positive or negative in their ability to induce embryolethality or malformations are used in the process of qualifying the assays. Although a number of compounds have been identified in the draft guidance's Annex, section 11.3.4, Tables 9–6 and 9–7, with the type of information for the compounds, the list is not complete; therefore, FDA is requesting data in the form of public comments to the docket for additional positive and negative reference compounds for potential inclusion into the list. These compounds can be either pharmaceuticals or non-pharmaceuticals and should be commercially available. For additional guidance, please refer to Endnote 3 in the S5(R3) guidance. This is not a request for data for the compounds already listed in Table 9–6, nor is this a request for examples of assays that could be used.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals.'' 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm,* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.*

Dated: November 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24483 Filed 11–9–17; 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: Voluntary Partner Surveys To Implement Executive Order 12862 in the Health Resources and Services Administration, OMB No. 0915–0212—Extension

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 must be received no later than January 12, 2018.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, 14N39, 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Voluntary Partner Surveys to Implement Executive Order 12862 in the Health Resources and Services Administration OMB No. 0915–0212—Extension.

Abstract: In response to Executive Order 12862, HRSA is proposing to conduct voluntary customer surveys of its partners to assess strengths and weaknesses in program services and processes. HRSA partners are typically state or local governments, health care facilities, health care consortia, health care providers, and researchers. HRSA is requesting continued approval for a generic clearance from OMB to conduct the partner surveys.

Partner surveys to be conducted by HRSA might include, for example, mail or telephone surveys of grantees to determine satisfaction with grant processes or technical assistance provided by a contractor, or in-class evaluation forms completed by providers who receive training from HRSA grantees to measure satisfaction with the training experience. HRSA will use the results of these surveys to plan and redirect resources and efforts as needed to improve services and processes.

HRSA may also use focus groups to gain partner input into the design of mail and telephone surveys. Focus groups, in-class evaluation forms, mail surveys, and telephone surveys are expected to be the preferred data collection methods.

A generic approval allows HRSA to conduct a limited number of partner surveys without a full-scale OMB review of each survey. If this request receives continued approval, information on each individual partner survey will not be published in the **Federal Register**.

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
In-class evaluations	40,000	1	40,000	.05	2,000
Mail/Telephone surveys	12,000	1	12,000	.25	3,000
Focus groups	250	1	250	1.5	375
Total	52,250	.....	52,250	.....	5,375

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.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2017–24492 Filed 11–9–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Assessing Client Factors Associated With Detectable HIV Viral Loads; and Models of Care and the Ryan White HIV/AIDS Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than December 13, 2017.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Assessing Client Factors Associated with Detectable HIV Viral Loads and Models of Care and the Ryan White HIV/AIDS Program.

OMB No.: 0906–xxxx—NEW.

Abstract: The Ryan White HIV/AIDS Program (RWHAP), first authorized by the U.S. Congress in 1990, is administered by HRSA's HIV/AIDS Bureau (HAB). The RWHAP provides medical services, treatment, and/or support services to 533,036 clients in 2015; 97.0 percent of these clients were living with HIV. This information collection request covers two distinct evaluation studies with RWHAP provider sites that will share components of data collection instruments through shared variables. Sharing data collection instruments will minimize burden for RWHAP provider sites collecting this data and will increase the sample size for data analysis thus resulting in more robust data and greater generalizability of results.

The first evaluation study, *Assessing Client Factors Associated with Detectable HIV Viral Loads,* will explore individuals' specific facilitators and barriers to achieving and sustaining viral suppression. Early and effective treatment for HIV has been shown to greatly reduce associated morbidity and mortality, and prevents transmission of HIV. In spite of the known benefit of treatment, many individuals remain out of care or access care only intermittently; the CDC estimated that in 2013, approximately 45 percent of people living with HIV (PLWH) in the United States were not virally suppressed, indicating a significant gap in the percentage of PLWH who are being successfully engaged and retained in care. In spite of the increased attention on retention in care and the overarching goal of viral suppression, little data exist regarding the specific individual factors that are associated with sub-optimal viral suppression. Such information is valuable for targeting programs to reach populations that are currently not achieving HIV viral suppression.

The second evaluation study, *Models of Care and the Ryan White HIV/AIDS Program,* seeks to answer the critical questions of what individual and system-wide factors, including the models of care employed among RWHAP provider sites, contribute to better health outcomes for PLWH. While advances in treatment have improved survival in patients with HIV, longer lives are associated with increased prevalence of adverse effects of HIV infection and therapeutic complications, concurrent with medical conditions related to aging processes that would occur in the absence of HIV. These long-term complications amplify chronic disease management as a major issue for the HIV population and a challenge for the delivery of effective health care. Yet little is known about how the method of health services delivery (the ''model of care'') contributes to better health outcomes, including HIV-related outcomes. For example, does it make a difference if a patient receives HIV care from a primary care provider, a

specialist, or from a care team that includes both? Understanding the most effective models of care is important for HIV specialists, primary care physicians, and other clinicians who care for PLWH as they design and coordinate a full array of primary care and support services for their patients. These primary care and support services have a direct impact on HIV viral suppression, which in turn improves life expectancy and quality of life and prevents HIV transmission.

The two studies inform each other in that the degree to which clients achieve and sustain viral suppression may be attributed partly to the model of care practiced at their clinic. Likewise, the degree to which its clients have achieved viral suppression may drive a clinic to practice a particular model of care. The two studies will collect several identical data elements through their individual collection instruments, allowing data to be aggregated across the two studies. The aggregation of data across the two studies will minimize burden for RWHAP provider sites collecting this data and will increase the sample size for data analysis thus resulting in more robust data and greater generalizability of results.

A 60-day **Federal Register** Notice was published in the **Federal Register** on May 18, 2017 (Volume 82, page 22838) which solicited comments on this data collection. Four comments were received that focused on how facilities will be selected for participation and the importance of adequate nutrition for PLWH.

Need and Proposed Use of the Information: The *Assessing Client Factors Associated with Detectable HIV Viral Loads* study will identify characteristics of RWHAP clients and health facilities that are associated with the ability to achieve and sustain an undetectable viral load as compared to the characteristics that are associated with sub-optimal viral suppression. This study will enable the development of better targeted services for improved viral suppression rates. The *Models of Care and the Ryan White HIV/AIDS Program* study will compare HIV and primary health outcomes across various models of care to determine which are most effective in responding to HIV to improve health outcomes for people living with HIV and to prevent HIV transmissions. The results from this study will enable improvements or redesigns of effective delivery of HIV care among Ryan White HIV/AIDS Program providers, which will in turn improve HIV clinical outcomes such as viral suppression.

In both studies, an analysis of the perceptions of providers and clients will further support the understanding of the impact of individual and system-wide factors on achieving health outcomes. The two studies will share data to inform both studies' objectives, allow for a larger sample size from which to generalize conclusions, and reduce the overall burden of response on RWHAP providers and clients. The objectives of both studies will be achieved through collection of the following data:

- RWHAP client records abstraction—Medical chart and administrative records (*e.g.,* service utilization and health outcomes data);
- RWHAP provider interviews—Site staff interviewees (in person);
- RWHAP client focus groups (Models of Care study sites only)—Clients at selected clinics that represent a given model of care;
- RWHAP client surveys (HIV Viral Suppression study sites only)—Clients with detectable and undetectable viral load at each clinic; and
- RWHAP client semi-structured interviews (HIV Viral Suppression study sites only)—Clients with detectable and undetectable viral load.

These studies will build upon and complement HAB's study focusing on RWHAP outcomes within the context of the changing health care landscape; and will use the RWHAP site survey and chart abstraction instruments that were submitted as part of that study. The data will be collected by a HRSA contractor.

Likely Respondents: RWHAP Administrators, RWHAP Service Providers, and RWHAP Clients.

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. Both research studies are included in the table, with burden proportional to the number of RWHAP provider sites from which each study will collect data: 25 distinct facilities for *Assessing Client Factors Associated with Detectable HIV Viral Loads* and 50 distinct facilities for *Models of Care and the Ryan White HIV/AIDS Program.* The table below provides the level of burden inclusive of both studies.

Total Estimated Annualized Burden—Hours.

12A—Estimated Annualized Burden Hours

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
RWHAP Site Administrators (Private Sector).	Medical Records Sample Selection Guide*.	75	1	75	1	75
RWHAP Service Providers (Private Sector).	Provider Interview Guide (HIV Viral Suppression).	125	1	125	2	250
RWHAP Service Providers (Private Sector).	Provider Interview Guide (Models of Care).	250	1	250	2	500
RWHAP Clients (Individual/Household).	Focus Groups Guide	240	1	240	1.5	360
RWHAP Clients (Individual/Household).	Client Survey	500	1	500	0.5	250
RWHAP Clients (Individual/Household).	Client Semi-Structured Interview.	150	1	150	0.5	75

12A—ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Total		1,340		1,340		1,510

*The medical records sample selection instrument has been previously submitted as part of the RWHAP Outcomes Study proposed data collection project.

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.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2017–24491 Filed 11–9–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Correction

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: The Health Resources and Services Administration published a notice in the **Federal Register**, FR 2017–23562 (October 31, 2017), announcing the charter renewal of the National Advisory Committee on Rural Health and Human Services (NACRHHS).

FOR FURTHER INFORMATION CONTACT: Paul Moore, Designated Federal Officer, NACRHHS, HRSA, 5600 Fishers Lane, Room 17W41C, Rockville, Maryland 20857, telephone (301) 443–0835, fax (301) 443–2803 or by email at *pmoore2@hrsa.gov*.

Correction

In the **Federal Register**, FR 2017–23562 (October 31, 2017), please make the following correction:

In the Summary section, correct to read: The effective date of the renewed charter is October 29, 2017.

Amy McNulty,

Acting Director, Division of Executive Secretariat.

[FR Doc. 2017–24490 Filed 11–9–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Be The Match® Patient Services Survey, OMB No. 0906–0004—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than December 13, 2017.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Be The Match® Patient Services Survey.

OMB No.: 0906–0004—Revision.

Abstract: The National Marrow Donor Program®/Be The Match® is a HRSA contractor dedicated to helping patients and families get the support and information they need to learn about their disease and treatment options, prepare for a blood stem cell transplant, and thrive after a transplant procedure. The information and resources provided help individuals navigate the bone marrow or cord blood transplant process. Participant feedback is essential to understand the needs for transplant support services and educational information across a diverse population. This information is used to determine the helpfulness of existing services and resources. Feedback is also used to identify areas for improvement and develop future programs.

Need and Proposed Use of the Information: Barriers to access to bone marrow or cord blood transplant related care and educational information are multi-factorial. Feedback from participants is essential to understand the changing needs for services and information as well as to demonstrate the effectiveness of existing services. The primary use for information gathered through the survey is to determine helpfulness of participants' initial contact with Be The Match® Patient Services Coordinators (PSC) and to identify areas for improvement in the delivery of services. In addition, stakeholders use this evaluation data to make program and resource allocation decisions.

The survey includes the following items to measure: (1) Reason for contacting Be The Match®, (2) if the PSC was able to answer questions and easy to understand, (3) if the contact helped the participant to feel better prepared to discuss transplant with their care team, (4) increase in awareness of available resources, (5) timeliness of response, and (6) overall satisfaction.

Proposed changes to the survey instrument include updated references to the survey title and staff titles. Changes to the questions include minor changes to question one, changes to the instructions for questions three and four, and minor rewording of question

six. Question eight is simplified. References to race and ethnicity are updated to better match preliminary U.S. Census Bureau question format and statements from the U.S. Department of Education to allow individuals to self-identify their ethnicity and race and permit individuals to select more than one race and/or ethnicity. These changes will not increase respondent burden.

Likely Respondents: Respondents will include all patients, caregivers, and family members who have contact with Be The Match® Patient Services Coordinators via phone or email for transplant navigation services and support. The decision to survey all participants was made based on historic evidence of patients' unavailability due to frequent transitions in health status as well as transfer between home and the hospital for initial treatment and care for complications.

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: (1) Review instructions; (2) 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; (3) train personnel; (4) be able to respond to a collection of information; (5) search data sources; (6) to complete and review the collection of information; (7) and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request 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
Be The Match® Patient Services Survey	420	1	420	0.25	105
Total	420		420		105

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2017–24494 Filed 11–9–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0915–0172—Revision]

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than December 13, 2017.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report.

OMB No.: 0915–0172—Revision.

Abstract: HRSA is updating the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report.* This guidance is used annually by the 50 states and 9 jurisdictions in applying for Block Grants under Title V of the Social Security Act and in preparing the required annual report. The updates proposed by HRSA's Maternal and Child Health Bureau (MCHB) for this edition of the guidance are intended to reinforce the reporting structure and vision outlined in the previous edition and to reinforce the role of the state in developing a Title V Maternal and Child Health (MCH) Action Plan that responds to its unique priority needs. These updates are intended to enable a state to present an articulate and comprehensive description of its Title V program activities and leadership role in assuring a public health system for serving the MCH population. The proposed updates to the next edition of the guidance were informed by comments received from state Title V MCH program leadership, national MCH leaders, family-led organizations, other MCH stakeholders and the public. Publication of a 60-day **Federal Register** notice on June 9, 2017 at 82 FR 26810, generated comments on the proposed changes to the narrative reporting requirements, reporting forms, definitions, consolidation of the 15 National Performance Measures (NPMs) into five domains, re-titling of a sixth domain to ''Cross-cutting and Systems Building,'' reduction in the required number of state-selected NPMs and description of family partnerships.

Specific updates to this edition of the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report* include the following:

(1) The current performance measure framework is maintained, but the 15 National Performance Measures (NPMs) are now distributed within five population domains (*i.e.,* (Women/Maternal Health; Perinatal/Infant Health; Child Health; Adolescent Health; and Children with Special Health Care Needs (CSHCN)).

(2) The Cross-cutting/Life Course domain is replaced by the Cross-cutting and Systems Building Domain, which is an optional domain for states to include as a State Performance Measure (SPM) for addressing an identified priority

need that is not aligned with one or more of the five population health domains. The compound NPMs formerly included in the Cross-cutting/Life Course domain (*i.e.,* NPM #13 and NPM #14), along with NPM #15, are incorporated into the most relevant population health domain(s).

(3) The required minimum number of NPMs to be selected by a state is reduced from eight to five. A state will select at least one NPM in each of the five population health domains, but a state can choose to select additional NPMs based on its current State Action Plan and identified priority needs.

(4) A state has flexibility in the number of SPMs it develops, provided each identified MCH priority need is addressed by either a NPM and/or SPM.

(5) The development and implementation of evidence-based and/or evidence–informed strategies and measures continues to be a point of focus and an enhanced definition of ''evidence-based,'' clarifying instructions and state examples of Evidence-based or -informed Strategy Measures are included.

(6) Clearer expectations around state Title V reporting on family are outlined, which include enhanced discussion of specific program activities, their impact on all sectors of the MCH population and their demonstrated value in improving MCH outcomes.

(7) Narrative reporting requirements around services for CSHCN are enhanced to allow each state to identify and define the components of its system of services. States are also encouraged to reflect on the impact of these services within the context of the identified priority needs and the measures selected for the State Action Plan.

(8) Further anticipated reductions to state burden are attained through more streamlined narrative reporting, particularly between the State Overview, Needs Assessment and State Action Plan sections; clearer descriptions of expected content in each of the narrative sections; and refined instructions for completing the data reporting forms. Notable among these updates is the restructuring of the State Action Plan narrative discussion to allow a state Title V program greater flexibility in describing its public health framework (*e.g.,* life course model), leadership and partnership roles, cross-cutting strategies and the leveraging of resources.

It is recognized that the full extent of the anticipated burden reduction will be realized over time as states become more familiar with the updated instructions and reporting requirements. The burden estimates presented in the table below are based on previous burden estimates and consultations with a few states on the proposed updates. Once implemented, HRSA will explore opportunities for soliciting additional information from no more than nine states to derive accurate estimates.

Need and Proposed Use of the Information: Each year, all states and jurisdictions are required to submit an Application/Annual Report for Federal funds for their Title V MCH Services Block Grant to States Program to HRSA's MCHB (Section 505(a) of Title V of the Social Security Act). In addition, each state is required to conduct a statewide, comprehensive Needs Assessment every five years. The information and instructions for the preparation and submission of this Application/Annual Report are contained in the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report.*

Likely Respondents: By legislation (Section 505(a) of Title V of the Social Security Act), the MCH Block Grant application/annual report must be developed by, or in consultation with, the state MCH Health agency.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This estimate 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	Burden per response (in hours)	Total burden hours
Application and Annual Report without 5-Year Needs Assessment Summary	59	1	59	120	7,080
Application and Annual Report with 5-Year Needs Assessment Summary	59	1	59	189	11,151
Average Total Annual Burden	59		59		*8,437

*Reflects the average of one Application/Annual Report with a Five-Year Needs Assessment Summary and two Applications/Annual Reports without a Five-Year Needs Assessment Summary.

In fiscal year (FY) 2019 and FY 2020, states and jurisdictions will be submitting an application and annual report without a Five-year Needs Assessment Summary for a total estimated burden of 14,160 hours. In FY 2021, states and jurisdictions will be submitting an application and annual report with a five-year Needs Assessment Summary for a total estimated burden of 11,151 hours.

In deriving these estimates, HRSA contacted fewer than 10 states to discuss the level of burden associated with the development and submission of an application/annual Report under the current guidance. The burden estimates reflect the average level of burden necessary to meet the specified reporting requirements. States often report a range of burden hours due to the differences in their population size, program resources and the extensiveness of the processes they use to conduct their five-year Needs Assessment and to prepare the yearly MCH Block Grant Applications/Annual Reports. Continued enhancements to the electronic data entry system also contribute to reductions in state burden associated with the yearly preparation/submission of an application/annual Report.

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.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2017–24495 Filed 11–9–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA), notice is hereby given that a meeting is scheduled for the Advisory Commission on Childhood Vaccines (ACCV). This meeting will be open to the public. Information about the ACCV and the agenda for this meeting can be obtained by accessing the following Web site: *http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html.*

DATES: The meeting will be held on December 8, 2017, at 9:00 a.m. ET.

ADDRESSES: The address for the meeting is 5600 Fishers Lane, Rockville, MD, Conference Room 5N54. The public can join the meeting by:

1. (In Person) Persons interested in attending the meeting in person are encouraged to submit a written notification to: Annie Herzog, Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau (HSB), HRSA, Room 08N146B, 5600 Fishers Lane, Rockville, Maryland 20857 or email: *aherzog@hrsa.gov.* Since this meeting is to be held in a federal government building, attendees will need to go through a security check to enter the building and participate in the meeting. Written notification is encouraged so that a list of attendees can be provided to make entry through security quicker. Persons may attend in person without providing written notification, but their entry into the building may be delayed due to security checks and the requirement to be escorted to the meeting by a federal government employee. To request an escort to the meeting after entering the building, call Amber Johnson at (301) 443–0129.

2. (Audio Portion) Calling the conference phone number 1–800–369–1833 and providing the following information:

Leader Name: Dr. Narayan Nair.

Password: 6706374.

3. (Visual Portion) Connecting to the ACCV Adobe Connect Pro Meeting using the following URL: *https://hrsa.connectsolutions.com/accv/* (copy and paste the link into your browser if it does not work directly, and enter as a guest). Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: *https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm* and get a quick overview by following URL: *http://www.adobe.com/go/connectpro_overview.*

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding the ACCV should contact Annie Herzog, Program Analyst, DICP, HRSA in one of three ways: (1) Send a request to the following address: Annie Herzog, Program Analyst, DICP, HSB, HRSA, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857; (2) call (301) 443–6593; or (3) send an email to *aherzog@hrsa.gov.*

The ACCV will meet on Friday, December 8, 2017, beginning at 9:00 a.m. ET in the 5600 Fishers Lane Building, Conference Room 5N54, Rockville, Maryland 20857; however, meeting times and locations could change. For the latest information regarding meeting start time and location, please check the ACCV Web site: *http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html.*

SUPPLEMENTARY INFORMATION: The ACCV was established by section 2119 of the Public Health Service Act (the Act) (42 U.S.C. 300aa–19), as enacted by Public Law (Pub. L.) 99–660, and as subsequently amended, and advises the Secretary of HHS (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

Other activities of the ACCV include: Recommending changes to the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 of the Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b) of the Act; advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; consulting on the development or revision of Vaccine Information Statements; and recommending to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the VICP.

The agenda items for the December 8, 2017, meeting will include, but are not limited to, review of petitions to add injuries to the vaccine injury table, and updates from DICP, Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics, Evaluation and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (*http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html*) prior to the meeting. Agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the ACCV should be sent to Annie Herzog using the address and phone number above by December 4, 2017. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Annie Herzog, using the address and phone number above at least 10 days prior to the meeting.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2017–24493 Filed 11–9–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel; Developmental Centers for AIDS Research (P30).

Date: December 4–5, 2017.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select) 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jay R. Radke, Ph.D., AIDS Review Branch, Scientific Review Program, Division of Extramural Activities, Room #3G11B, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC–9823, Bethesda, MD 20892–9823, (240) 669–5046, *jay.radke@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Cellular Therapies for Treatment of Radiation Injuries (U01).

Date: December 5, 2017.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Thomas F. Conway, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G51, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, 240–507–9685, *thomas.conway@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; AIDSRRC Independent SEP.

Date: December 5, 2017.

Time: 2:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Peter R. Jackson, Ph.D., Chief, AIDS Research Review Branch, Scientific Review Program, Division of Extramural Activities, Room #3G20, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5049, *pjackson@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 6, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–24435 Filed 11–9–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Grant (R01).

Date: December 7, 2017.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Dharmendar Rathore, Ph.D., Senior Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G30, National Institutes of Health/NIAID, 5601 Fishers Lane, Drive, MSC 9823, Bethesda, MD 20892–9823, 240–669–5058, *rathored@mail.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (R13).

Date: December 11–15, 2017.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Amir E. Zeituni, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9834, Rockville, MD 20852, 301–496–2550, *amir.zeituni@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 6, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–24436 Filed 11–9–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2017–0954]

Information Collection Request to Office of Management and Budget; OMB Control Number[s]: 1625–0085

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information without change: 1625–0085, Streamlined Inspection Program. Our ICR describe the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before January 12, 2018.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2017–0954] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov*. See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov*. Additionally, copies are available from: Commandant (CG–612), ATTN: Paperwork Reduction

Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2017–0954], and must be received by January 12, 2018.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Information Collection Request

Title: Streamlined Inspection Program.

OMB Control Number: 1625–0085.

Summary: The Coast Guard established an optional Streamlined Inspection Program (SIP) to provide owners and operators of U.S. vessels an alternative method of complying with inspection requirements of the Coast Guard.

Need: The SIP regulations under 46 CFR part 8, subpart E, offer owners and operators of inspected vessels an alternative to traditional Coast Guard inspection procedures. Title 46 U.S.C. 3306 of authorizes the Coast Guard to prescribe regulations necessary to carry out the inspections of vessels required to be inspected under 46 U.S.C. 3103, and 46 U.S.C. 3301 allows the Coast Guard to rely on reports, documents, and records of other persons who have been determined to be reliable, and other methods that have been determined to be reliable to ensure compliance with vessels and seamen requirements under 46 U.S.C. subtitle II.

Forms: None.

Respondents: Owners and operators of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 2,334 hours to 8,254 hours a year due to an increase in the number of SIP participants (*i.e.,* companies and vessels).

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: November 2, 2017.

James D. Roppel,

U.S. Coast Guard, Acting Chief, Office of Information Management.

[FR Doc. 2017–24489 Filed 11–9–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR957000.L63100000. HD0000. 18XL1109AF. HAG 18–0029]

Filing of Plats of Survey: Oregon/Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management (BLM), Oregon/Washington State Office, Portland, Oregon, 30 calendar days from the date of this publication. The surveys, which were executed at the request of the BLM, are necessary for the management of these lands.

DATES: Protests must be received by the BLM by December 13, 2017.

ADDRESSES: A copy of the plats may be obtained from the Public Room at the BLM, Oregon/Washington State Office, 1220 SW 3rd Avenue, Portland, Oregon 97204, upon required payment. The plats may be viewed at this location at no cost. Please use this address when filing written protests.

FOR FURTHER INFORMATION CONTACT: Kyle Hensley, (503) 808–6132, Branch of Geographic Sciences, BLM, 1220 SW 3rd Avenue, Portland, Oregon 97204. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The plats of survey of the following described lands are scheduled to be officially filed in the BLM, Oregon/Washington State Office, Portland, Oregon:

Willamette Meridian, Oregon

T. 11 S., R. 4 E., accepted September 22, 2017

A person or party who wishes to protest one or more plats of survey identified above must file a written notice of protest with the State Director for Oregon/Washington, BLM. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. The notice of protest must be filed before the scheduled date of official filing for the plat(s) of survey being protested. Any notice of protest filed after the scheduled date of official filing will not be considered. A notice

of protest is considered filed on the date it is received by the State Director for Oregon/Washington during regular business hours; if received after regular business hours, a notice of protest will be considered filed the next business day. A written statement of reasons in support of a protest, if not filed with the notice of protest, must be filed with the State Director for Oregon/Washington within 30 calendar days after the notice of protest is filed. If a notice of protest against a plat of survey is received prior to the scheduled date of official filing, the official filing of the plat of survey identified in the notice of protest will be stayed pending consideration of the protest. A plat of survey will not be officially filed until the next business day following dismissal or resolution of all protests of the plat.

Before including your address, phone number, email address, or other personal identifying information in a notice of protest or statement of reasons, you should be aware that the documents you submit—including your personal identifying information—may be made publicly available in their entirety at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. Chap. 3.

Mary J.M. Hartel,

Chief Cadastral Surveyor of Oregon/Washington.

[FR Doc. 2017–24529 Filed 11–9–17; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAK930000.L13100000.FF0000.241A]; OMB Control No. 1004–0201

Agency Information Collection Activities; Oil Shale Management

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, we, the Bureau of Land Management (BLM) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 12, 2018.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to the Jean Sonneman, U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW., Room 2134LM, Washington, DC 20240; or by email to *jesonnem@blm.gov.* Please reference OMB Control Number 1004–0201 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, please contact Mary Linda Ponticelli by email at *mpontice@blm.gov* or, by phone at 202–912–7115. Persons who use a telecommunication device for the deaf may call the Federal Information Relay Service at 1–800–877–8339 to leave a message for the above person.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the BLM; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BLM enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BLM minimize the burden of the collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

The following information is provided for the information collection:

Abstract: This control number applies to the exploration, development, and utilization of oil shale resources on the BLM-managed public lands. Currently, the only oil shale leases issued by the BLM are for research, development, and demonstration (RD&D) leases. However, the BLM regulations provide a framework for commercial oil shale leasing and additionally include provisions for conversion of RD&D leases to commercial leases.

Title of Collection: Oil Shale Management (43 CFR parts 3900, 3910, 3920, and 3930).

OMB Control Number: 1004–0201.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Applicants for oil shale leases, oil shale lessees and oil shale operators.

Total Estimated Number of Annual Respondents: 24.

Total Estimated Number of Annual Responses: 24.

Estimated Completion Time per Response: Varies from the number of minutes/hours per response.

Total Estimated Number of Annual Burden Hours: 1,795.

Respondent's Obligation: Required to obtain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Non Hour Burden Cost: $526,632.

The estimated burdens are itemized in the following table:

Type of response	Number of responses	Hours per response	Total time (column B × column C)
A	B.	C	D
Application for Waiver, Suspension, or Reduction of Rental or Payment In Lieu of Production; Application for Reduction in Royalty; or Application for Waiver of Royalty, 43 CFR 3903.54(b)	1	1	1
Bonding Requirements, 43 CFR Subpart 3904	1	1	1
Application for an Exploration License, 43 CFR 3910.31(a) through (e)	1	24	24

Type of response	Number of responses	Hours per response	Total time (column B × column C)
A	B.	C	D
Notice Seeking Participation in an Exploration License, 43 CFR 3910.31(f)	1	1	1
Data Obtained Under an Exploration License, 43 CFR 3910.44	1	8	8
Response to Call for Expression of Leasing Interest, 43 CFR 3921.30	1	4	4
Application for a Lease — Individuals, 43 CFR 3902.23, 3922.20, and 3922.30	1	308	308
Application for a Lease — Associations, 43 CFR 3902.24, 3922.20, and 3922.30	1	308	308
Application for a Lease — Corporations, 43 CFR 3902.25, 3922.20, and 3922.30	1	308	308
Sealed Bid, 43 CFR 3924.10	1	8	8
Application to Convert Research, Development, and Demonstration Lease to Commercial Lease, 43 CFR 3926.10(c)	1	308	308
Drill and Geophysical Logs, 43 CFR 3930.11(b)	1	19	19
New Geologic Information, 43 CFR 3930.20(b)	1	19	19
Plan of Development, 43 CFR 3931.11	1	308	308
Application for Suspension of Lease Operations and Production, 43 CFR 3931.30	1	24	24
Exploration Plan, 43 CFR 3931.41	1	24	24
Modification of Approved Exploration Plan or Plan of Development, 43 CFR 3931.50	1	24	24
Production Maps and Production Reports, 43 CFR 3931.70	1	16	16
Records of Core or Test Hole Samples and Cuttings, 43 CFR 3931.80	1	16	16
Application for Modification of Lease Size, 43 CFR 3932.10, 3930.20, and 3932.30	1	12	12
Request for Approval of Assignment of Record Title or Sublease or Notice of Overriding Royalty Interest Assignment, 43 CFR Subpart 3933	2	10	20
Relinquishment of Lease or Exploration License, 43 CFR 3934.10	1	18	18
Production and Sale Records, 43 CFR 3935.10	1	16	16
Totals	24		1,795

The authorities for this action are the Mineral Leasing Act of 1920, the Mineral Leasing Act for Acquired Lands Act of 1947, the Federal Land Policy and Management Act of 1976 and the EP Act and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*).

Jean Sonneman,

Information Collection Clearance Officer, Bureau of Land Management.

[FR Doc. 2017–24528 Filed 11–9–17; 8:45 am]

BILLING CODE 4310–84–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–945 (Modification Proceeding)]

Certain Network Devices, Related Software and Components Thereof (II); Notice of Correction Concerning the Institution of Modification Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Correction of notice.

SUMMARY: Correction is made to notice 82 FR 50678, which was published on Wednesday, November 1, 2017, to clarify that the Office of Unfair Import Investigations is not named as a party in this modification proceeding. Any inclusion of the Office of Unfair Import Investigations as a named party in this proceeding is hereby corrected in the Notice of Institution.

By order of the Commission.

Issued: November 7, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–24530 Filed 11–9–17; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Pistoia Alliance, Inc.

Notice is hereby given that, on October 3, 2017, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Pistoia Alliance, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Luxoft Global Operations GmbH, Zug, SWITZERLAND; Congenica Limited, Hinxton, UNITED KINGDOM; Jeremy G. Frey (individual member), Highfield, UNITED KINGDOM; The HDF Group, Champaign, IL; BioRAFT, Cambridge, MA; Cyclica, Toronto, CANADA; and AbbVie Inc., North Chicago, IL, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Pistoia Alliance, Inc. intends to file additional written notifications disclosing all changes in membership.

On May 28, 2009, Pistoia Alliance, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 15, 2009 (74 FR 34364).

The last notification was filed with the Department on July 12, 2017. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 16, 2017 (82 FR 38939).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2017–24544 Filed 11–9–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on ROS-Industrial Consortium-Americas

Notice is hereby given that, on October 18, 2017, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on ROS-Industrial Consortium-Americas (''RIC-Americas'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its Membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Tormach, Inc., Waunakee, WI, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open and RIC-Americas intends to file additional written notifications disclosing all changes in membership or planned activities.

On April 30, 2014, RIC-Americas filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 9, 2014 (79 FR 32999).

The last notification was filed with the Department on April 7, 2017. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on May 2, 2017 (82 FR 20488).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2017–24545 Filed 11–9–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Entercom Communications Corp., et al.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America* v. *Entercom Communications Corp.,* Case No. 1:17–cv–02268. On November 1, 2017, the United States filed a Complaint alleging that Entercom Communications Corp.'s proposed acquisition of CBS Radio, Inc. would violate Section 7 of the Clayton Act, 15 U.S.C. 18. The proposed Final Judgment, filed on the same day as the Complaint, resolves the case by requiring Entercom to divest certain broadcast television stations in Boston, Massachusetts; San Francisco, California; and Sacramento, California. A Competitive Impact Statement filed by the United States describes the Complaint, the proposed Final Judgment, and the industry.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be directed to Owen M. Kendler, Chief, Media, Entertainment, and Professional Services Section, Antitrust Division, Department of Justice, Washington, DC 20530, (telephone: 202–305–8376).

Patricia A. Brink,

Director of Civil Enforcement.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, United States Department of Justice, Antitrust Division, 450 Fifth Street NW., Suite 4000, Washington, DC 20530 Plaintiff, v. *ENTERCOM COMMUNICATIONS CORP., 401 E. City Avenue, Suite 809, Bala Cynwyd, PA 19004* and *CBS CORPORATION, 51 W. 52nd Street, New York, NY 10019*

Case No: 1:17–cv–02268

Judge: Boasberg

Defendants.

COMPLAINT

The United States of America brings this civil action to enjoin the proposed acquisition of CBS Radio, Inc. by Entercom Communications Corporation, and to obtain other equitable relief. The acquisition likely would substantially lessen competition for the sale of radio advertising to advertisers targeting English-language listeners in the Boston, Sacramento, and San Francisco Designated Market Areas (''DMAs''), in violation of Section 7 of the Clayton Act, 15 U.S.C. 18. The United States alleges as follows:

I. NATURE OF THE ACTION

1. Pursuant to an Agreement and Plan of Merger dated February 2, 2017, between Entercom, CBS Radio, Inc. and CBS Corporation, Entercom agreed to acquire CBS Radio in a Reverse Morris Trust transaction valued at over $1.6 billion. CBS Radio is a subsidiary of CBS Corporation.

2. Entercom and CBS Radio own and operate broadcast radio stations in various locations throughout the United States, including multiple stations in Boston, Massachusetts, Sacramento, California, and San Francisco, California. Entercom and CBS Radio compete head-to-head for the business of local and national companies that seek to advertise on English-language broadcast radio stations in these three DMAs.

3. As alleged in greater detail below, the proposed acquisition would eliminate this substantial head-to-head competition in Boston, Sacramento, and San Francisco, and likely would result in advertisers paying higher prices for radio advertising. Therefore, the proposed acquisition would violate Section 7 of the Clayton Act, 15 U.S.C. 18, and should be enjoined.

II. JURISDICTION, VENUE, AND COMMERCE

4. The United States brings this action under the direction of the Attorney General and pursuant to Section 15 of the Clayton Act, as amended, 15 U.S.C. 25, to prevent and restrain Entercom and CBS Corp. from violating Section 7 of the Clayton Act, 15 U.S.C. 18. The Court has subject-matter jurisdiction over this action pursuant to Section 15 of the Clayton Act, 15 U.S.C. 25, and 28 U.S.C. 1331, 1337(a), and 1345.

5. Entercom and CBS Corporation are engaged in interstate commerce and in activities substantially affecting interstate commerce. They own and operate broadcast radio stations in various locations throughout the United States and sell radio advertising time on those stations to advertisers located throughout the United States. Defendants' radio advertising sales have a substantial effect upon interstate commerce.

6. Defendants Entercom and CBS Corporation transact business in the District of Columbia and have consented to venue and personal jurisdiction in this District. Venue is proper in this District under Section 12 of the Clayton Act, 15 U.S.C. 22 and 28 U.S.C. 1391(c).

III. THE DEFENDANTS

7. Entercom, a Pennsylvania corporation with its headquarters in Bala Cynwyd, Pennsylvania, is the fourth-largest broadcast radio company in the United States. It has a portfolio of 127 stations in 27 markets. In 2016, Entercom reported net revenues of approximately $460 million.

8. CBS Corporation is incorporated in Delaware and maintains its headquarters in New York, New York. Its wholly-owned subsidiary, CBS Radio, owns 117 stations in 26 DMAs. In 2016, CBS Radio reported net revenues of approximately $1.2 billion.

IV. RELEVANT MARKETS

9. Entercom and CBS Radio sell radio advertising time to local and national advertisers that target English-language listeners in the Boston, Sacramento, and San Francisco DMAs. A DMA is a geographical unit in which the Nielsen Company surveys radio listeners in order to furnish radio stations, advertisers, and advertising agencies with data to aid in evaluating radio audiences. DMAs are widely accepted by industry participants as the standard geographic boundaries to use in evaluating radio audience size and demographic composition. A radio station's advertising rates are directly related to the station's ability, relative to competing radio stations, to attract listeners within a DMA that have demographic characteristics that advertisers want to reach.

10. The primary source of revenue for Entercom and CBS Radio is the sale of advertising time to local and national advertisers who want to reach listeners in one or more DMAs. Advertising placed on radio stations in a DMA is aimed at reaching listening audiences located in that DMA, and radio stations outside that DMA do not provide effective access to these audiences.

11. Local and national advertisers purchase radio advertising time because they find such advertising valuable, either by itself or as part of a broader mix of advertising on other media platforms. Advertisers use broadcast radio for many reasons, including that radio advertising offers a high level of audience reach, as well as a stable listenership, and it is often a more efficient means than other advertising platforms to reach an advertiser's target audience at the desired frequency. In addition, radio stations offer certain promotional opportunities to advertisers, such as on-air endorsements by local radio personalities, that advertisers cannot obtain as effectively using other media.

12. Many local and national advertisers consider English-language broadcast radio to be a particularly effective or important means to reach their desired customers, and do not consider advertisements on other media, including non-English-language broadcast radio, digital music streaming services (such as Pandora), and television, to be reasonable substitutes.

13. In addition, radio stations negotiate prices individually with advertisers; consequently, radio stations can charge different advertisers different prices. Radio stations generally can identify advertisers with strong preferences to advertise on radio in a particular language in a specific DMA. Because of this ability to price discriminate among customers, radio stations may charge higher prices to advertisers that view English-language radio advertising in a specific DMA as particularly effective for their needs, while maintaining lower prices for more price-sensitive advertisers. As a result, Entercom and CBS Radio could profitably raise prices to those advertisers that view English-language radio targeting listeners in the Boston, Sacramento, or San Francisco DMAs as an important advertising medium.

14. If there were a small but significant and non-transitory increase in the price of radio advertising time on English-language stations in the Boston, Sacramento, and San Francisco DMAs, advertisers would not reduce their purchases sufficiently to render the price increase unprofitable. Advertisers would not switch enough purchases of advertising time to radio stations outside the DMA, to other media, or to non-English-language radio stations to render the price increase unprofitable.

15. Accordingly, the sale of broadcast radio advertising time to advertisers targeting English-language listeners is a line of commerce and a relevant product market within the meaning of Section 7 of the Clayton Act. The Boston, Sacramento, and San Francisco DMAs constitute relevant geographic markets within the meaning of Section 7 of the Clayton Act.

V. ANTICOMPETITIVE EFFECTS

16. Post merger, radio station ownership in the Boston, Sacramento and San Francisco DMAs would be highly concentrated. In each of these markets, a small number of station-group owners account for the bulk of the advertising revenues. Entercom's and CBS Radio's combined advertising revenue shares would exceed 40% in San Francisco, 50% in Boston, and 55% in Sacramento.

17. As articulated in the Horizontal Merger Guidelines issued by the Department of Justice and the Federal Trade Commission, the Herfindahl-Hirschman Index (''HHI'') is a measure of market concentration.[1] Market concentration is often one useful indicator of the likely competitive effects of a merger. The more concentrated a market, and the more a transaction would increase concentration in a market, the more likely it is that a transaction would result in a meaningful reduction in competition harming consumers. Mergers resulting in highly concentrated markets (with an HHI in excess of 2,500) that involve an increase in the HHI of more than 200 points are presumed to be likely to enhance market power.

18. Concentration in the Boston DMA would increase substantially as a result of the proposed acquisition: the post-acquisition HHI would exceed 3,600 for English-language broadcast radio stations, with an increase of over 1,200 points.

19. Concentration in the Sacramento DMA would increase substantially as a result of the proposed acquisition: the post-acquisition HHI would exceed 4,300 for English-language broadcast radio stations, with an increase of over 1,600 points.

20. Concentration in the San Francisco DMA would increase substantially as a result of the proposed acquisition: the post-acquisition HHI would exceed 2,800 for English-language broadcast radio stations, with an increase of over 800 points.

21. In addition to increasing concentration, the merger also combines stations that are close substitutes and vigorous head-to-head competitors. Advertisers that use radio to reach their target audiences select radio stations on which to advertise based upon a number of factors including, among others, the

[1] *See* U.S. Dep't of Justice, Horizontal Merger Guidelines § 5.3 (2010), available at *http://www.justice.gov/atr/public/guidelines/hmg-2010.html.* The HHI is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. For example, for a market consisting of four firms with shares of 30, 30, 20, and 20 percent, the HHI is 2,600 ($30^2 + 30^2 + 20^2 + 20^2 = 2,600$). It approaches zero when a market is occupied by a large number of firms of relatively equal size and reaches a maximum of 10,000 points when a market is controlled by a single firm. The HHI increases both as the number of firms in the market decreases and as the disparity in size between those firms increases.

size of a station's audience, its demographic composition, and the geographic reach of its broadcast signal. Many advertisers select stations whose listening audiences best correlate to their target audience. If a number of stations, or combinations of stations, broadcasting in the same DMA efficiently reach a particular target audience, advertisers benefit from the competition among those stations to offer better prices and other terms.

22. Entercom and CBS Radio, each of which operates multiple highly-rated radio stations in the Boston, Sacramento, and San Francisco DMAs, are important competitors for listeners and advertisers in those DMAs. From the perspective of many local and national advertisers buying radio advertising time in those DMAs, Entercom and CBS Radio are two of a limited number of station groups whose large and diverse listenership allows advertisers to meet their reach and frequency goals with respect to their target audience. Entercom and CBS Radio compete vigorously to win business from advertisers and substantially constrain each other's prices.

23. During individual negotiations between advertisers and radio stations, advertisers often provide the stations with information about their advertising needs, including their target audience and the desired frequency and timing of ads. Radio stations have the ability to charge advertisers differing rates based in part on the number and attractiveness of competitive radio stations that can meet a particular advertiser's specific target needs. During negotiations, advertisers can gain more competitive rates and other terms by ''playing off'' Entercom stations against CBS Radio stations, either individually or as a cluster. The proposed acquisition would end that competition, resulting in harm to advertisers.

24. Post-acquisition, if Entercom raised prices to those advertisers that buy advertising time on Entercom stations in the Boston, Sacramento and San Francisco DMAs, non-Entercom stations in those DMAs would likely respond with higher prices of their own rather than alter their existing formats to attract the Entercom stations' listeners and advertisers. Repositioning a station by changing format is costly and risky, with the potential to lose substantial numbers of existing listeners and advertisers. In addition, re-formatting is unlikely to attract in a timely manner sufficient listeners and advertisers to make a price increase unprofitable for Entercom.

25. Due to FCC regulation, the lack of available spectrum, and other significant barriers, the entry of new broadcast radio stations into the Boston, Sacramento, and San Francisco DMAs would not be timely, likely, or sufficient to deter the exercise of market power.

26. For all of these reasons, the effect of the proposed acquisition of CBS Radio by Entercom would likely be to lessen competition substantially in violation of Section 7 of the Clayton Act.

VI. VIOLATION ALLEGED

27. Entercom's proposed acquisition of CBS Radio would likely substantially lessen competition in interstate trade and commerce in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and would likely have the following effects, among others:

a) competition in the sale of advertising time on English-language broadcast radio stations in the Boston, Sacramento, and San Francisco DMAs would be substantially lessened;

b) competition between Entercom broadcast radio stations and CBS broadcast radio stations in the sale of radio advertising time in the Boston, Sacramento, and San Francisco DMAs would be eliminated; and

c) prices for advertising time on English-language radio stations in the Boston, Sacramento, and San Francisco DMAs would likely increase.

VII. REQUESTED RELIEF

28. The United States requests that this Court:

a) adjudge and decree Entercom's proposed acquisition of CBS Radio to be unlawful and in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18;

b) permanently enjoin and restrain the Defendants from carrying out the proposed acquisition or from entering into or carrying out any other contract, agreement, plan, or understanding, the effect of which would be to combine CBS Radio with Entercom;

c) award the United States the costs of this action; and

d) award such other relief to the United States as the Court may deem just and proper.

Dated: November 1, 2017

Respectfully submitted,

FOR PLAINTIFF UNITED STATES:

/s/

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**Attorney of Record*

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA Plaintiff, v. *ENTERCOM COMMUNICATIONS CORP. and CBS CORPORATION* Defendants.

Case No. 1:17–cv–02268

Judge: Boasberg

COMPETITIVE IMPACT STATEMENT

Pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (''APPA'' or ''Tunney Act''), 15 U.S.C. § 16(b)–(h), plaintiff United States of America (''United States'') files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. NATURE AND PURPOSE OF THE PROCEEDING

The United States filed a civil antitrust Complaint on November 1, 2017 seeking to enjoin Entercom Communications Corporation's (''Entercom'') proposed acquisition of broadcast radio stations from CBS Corporation (''CBS''). The Complaint alleges that the acquisition's likely effect would be to increase English-language broadcast radio advertising prices in the following Designated Market Areas (''DMAs'') in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18: Boston, Massachusetts; San Francisco, California; and Sacramento, California (collectively ''the Divestiture Markets'').

At the same time the Complaint was filed, the United States also filed a Hold Separate Stipulation and Order (''Hold Separate'') and a proposed Final

Judgment, which are designed to eliminate the anticompetitive effects of the proposed acquisition in the Divestiture Markets. The proposed Final Judgment, which is explained more fully below, requires defendants to divest the following broadcast radio stations (the ''Divestiture Stations'') to acquirers approved by the United States in a manner that preserves competition: (1) in the Boston DMA: WBZ AM, WBZ FM, WKAF FM, WZLX FM, and WRKO AM; (2) in the San Francisco DMA: KOIT FM, KMVQ FM, KUFX FM, and KBLX FM; and (3) in the Sacramento DMA: KNCI FM, KYMX FM, KZZO FM and KHTK AM. The Hold Separate also requires defendants to take certain steps to ensure that the Divestiture Stations are operated as competitively independent, economically viable and ongoing business concerns, uninfluenced by Entercom, so that competition is maintained until the required divestitures occur.

The United States and defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment would terminate this action, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

II. DESCRIPTION OF THE EVENTS GIVING RISE TO THE ALLEGED VIOLATION

A. The Defendants and the Proposed Acquisition

Entercom is incorporated in Pennsylvania and headquartered in Bala Cynwyd, Pennsylvania. Entercom owns and operates 126 broadcast radio stations in 28 metropolitan areas.

CBS is organized under the laws of Delaware, with headquarters in New York, New York. CBS owns and operates 116 broadcast radio stations in 26 metropolitan areas.

Pursuant to an Agreement and Plan of Merger, dated February 2, 2017, Entercom agreed to acquire all of CBS's broadcast radio stations.

Entercom and CBS compete against one another to win business from local and national advertisers that seek to purchase English-language radio advertising time that targets listeners located in certain DMAs. The proposed transaction between Entercom and CBS would eliminate that competition in the Divestiture Markets.

B. Anticompetitive Consequences of the Transaction

1. Broadcast Radio Advertising

The Complaint alleges that the sale of English-language broadcast radio advertising time to advertisers targeting listeners located in the Divestiture Markets constitutes a relevant market for analyzing this acquisition under Section 7 of the Clayton Act. Each of the Divestiture Markets constitutes a distinct DMA. A DMA is a geographical unit defined by the Nielsen Company, which surveys radio listeners in order to furnish radio stations, advertisers, and advertising agencies with data to aid in evaluating radio audiences. DMAs are widely accepted by radio stations, advertisers, and advertising agencies as the standard geographic area to use in evaluating radio audience size and demographic composition (primarily age and gender). A radio station's advertising rates typically are based on the station's ability, relative to competing radio stations, to attract listening audiences that have certain demographic characteristics that advertisers want to reach.

Entercom and CBS broadcast radio stations generate most of their revenues by selling English-language advertising time in particular DMAs to local and national advertisers. Advertising placed on radio stations in a DMA is aimed at reaching listening audiences located in that DMA, and broadcast radio stations outside that DMA do not provide effective access to those audiences.

Many local and national advertisers purchase radio advertising time because they find such advertising valuable, either by itself or as part of a mix of media platforms, including television, digital music services, like Pandora Media, Inc. (''Pandora''), and other advertising platforms. For such advertisers, radio time (a) may be less expensive and more cost-efficient than other media in reaching the advertiser's target audience (individuals most likely to purchase the advertiser's products or services) at the desired frequency; or (b) may offer promotional and on-air endorsement opportunities to advertisers that cannot be replicated as effectively using other media. For these and other reasons, many local and national advertisers who purchase radio advertising time view radio as a necessary advertising medium for them or as an important part of advertising campaigns that include other media platforms.

Many local and national advertisers also consider English-language radio to be particularly effective or important to reach their desired customers. The advertisers that use English-language radio, either alone or as a mix with other media platforms to reach their target audience, generally do not consider other media, including non-English-language radio, such as Spanish-language radio, for example, to be a reasonable substitute.

If there were a small but significant and non-transitory increase in the price (''SSNIP'') of advertising time on English-language broadcast radio stations in the Divestiture Markets, advertisers would not reduce their purchases sufficiently to render the price increase unprofitable. Advertisers would not switch enough purchases of advertising time to radio stations located outside the Divestiture Markets, to other media, including digital music services, like Pandora, that offer advertising time, or to non-English-language stations to render the price increase unprofitable.

In addition, radio stations negotiate prices individually with advertisers; consequently, radio stations can charge different advertisers different prices. Radio stations generally can identify advertisers with strong preferences to advertise on radio in a specific language and in a specific DMA. Because of this ability to price discriminate among customers, radio stations may charge higher prices to advertisers that view radio in a specific DMA as particularly effective for their needs, while maintaining lower prices for more price-sensitive advertisers in that same DMA. As a result, Entercom and CBS could profitably raise prices to those advertisers that view broadcast radio that targets listeners in the Divestiture Markets as an important advertising medium.

2. Harm to Competition

The Complaint alleges that the proposed acquisition likely would lessen competition substantially in interstate trade and commerce, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18, and likely would have the following effects, among others:

a) Competition in the sale of advertising time on English-language broadcast radio stations in the Divestiture Markets would be lessened substantially;

b) competition between Entercom broadcast radio stations and CBS broadcast radio stations in the sale of radio advertising time in the Divestiture Markets would be eliminated; and

c) the prices for advertising time on English-language broadcast radio stations in the Divestiture Markets likely would increase.

In the Divestiture Markets, combining the Entercom and CBS broadcast radio stations would give Entercom the following estimated percentages of advertising sales on English-language broadcast radio stations: In Boston, over 50 percent; in San Francisco, over 40 percent; and in Sacramento, over 55 percent. In addition, Entercom's acquisition of CBS's broadcast radio stations located in the Divestiture Markets would result in each Divestiture Market becoming highly concentrated. Using the Herfindahl-Hirschman Index (''HHI''), a standard measure of market concentration,[2] the estimated post-acquisition HHIs and the changes in those HHIs in each of the Divestiture Markets based on revenues can be stated as follows: In Boston, the post-merger HHI would be over 3,600 with an increase in the HHI of over 1,200; in San Francisco, the post-merger HHI would be over 2,800 with an increase of over 800; and in Sacramento, the post-merger HHI would be over 4,300 with an increase of over 1,600. As can be seen, Entercom's proposed acquisition of CBS's broadcast radio stations in the Divestiture Markets would result in substantial increases in the HHIs of each market in excess of the 200 points presumed likely to enhance market power under the Horizontal Merger Guidelines issued by the Department of Justice and Federal Trade Commission.

The transaction also combines stations that are close substitutes and vigorous head-to-head competitors for advertisers seeking to reach audiences in the Divestiture Markets. Advertisers select radio stations to reach a large percentage of their target audience based upon a number of factors, including, *inter alia,* the size of the station's audience, the demographic characteristics of its audience, and the geographic reach of a station's broadcast signal. Many advertisers seek to reach a large percentage of their target listeners by selecting those stations whose audience best correlates to their target listeners. As stated above, radio stations have the ability to charge different advertisers differing prices, but that ability is circumscribed in part by the number and attractiveness of competitive radio stations and station groups in the market that can meet a particular advertiser's audience reach and frequency needs. When such competition exists, advertisers can negotiate lower prices by ''playing off'' stations and station groups against each other. Entercom and CBS, each of which operates highly-rated radio stations and clusters of stations in the Divestiture Markets, are important competitors for listeners and advertisers in each of those markets. For many local and national advertisers buying radio advertising time in the Divestiture Markets, Entercom and CBS are two of a limited number of station groups whose large and diverse listenership allows advertisers to meet their reach and frequency goals with respect to their targeted audience. The transaction would end the head-to-head competition between Entercom and CBS station groups in each of the Divestiture Markets.

In addition, the loss of head-to-head competition between specific Entercom and CBS radio stations can exacerbate the harm to advertisers for whom those stations are particularly close substitutes. For example, in Boston, Entercom's WEEI FM, which broadcasts in a sports talk format, is a close substitute for CBS's WBZ FM, which also broadcasts in a sports talk format. Both stations are among the highest-rated in Boston. They share many of the same listeners and have audiences with very similar demographic characteristics that are valuable to many advertisers. Prior to the transaction, if Entercom had increased prices for advertising time on WEEI FM, it likely would have lost sufficient revenues and profits to CBS's WBZ FM to outweigh the gain from customers willing to accept the price increase. Following the transaction, however, it would recapture the revenues and profits from those advertisers switching to WBZ FM because of a WEEI FM price increase. As a consequence, the transaction would make such a price increase profitable. Entercom could also effect this strategy by increasing WBZ FM's prices, which could be recaptured to some extent through increased WEEI FM's sales. Therefore, Entercom likely would raise advertising prices as a result of the transaction.

Post-acquisition, if Entercom raised prices to those advertisers that buy advertising time on the Entercom and CBS broadcast radio stations in the Divestiture Markets, non-Entercom stations in those markets would likely respond with higher prices of their own, rather than reposition their stations to induce Entercom's listeners and advertisers to switch. Repositioning, by changing a station's format, is costly and risky, with the potential to lose substantial numbers of existing listeners and advertisers. In addition, reformatting is unlikely to attract in a timely manner enough listeners or advertisers to make a price increase unprofitable for Entercom. Finally, the entry of new radio stations into the Divestiture Markets would not be timely, likely, or sufficient to deter the exercise of market power.

For all these reasons, the Complaint alleges that Entercom's proposed acquisition of CBS' broadcast radio stations would lessen competition substantially in the sale of radio advertising time to advertisers targeting listeners in each of the Divestiture Markets, eliminate head-to-head competition between Entercom and CBS broadcast radio stations in those three markets, and result in increased prices for radio advertisers in those markets, all in violation of Section 7 of the Clayton Act.

III. EXPLANATION OF THE PROPOSED FINAL JUDGMENT

The proposed Final Judgment requires significant divestitures that will eliminate the anticompetitive effects of the transaction in the Divestiture Markets by maintaining the Divestiture Stations as independent, economically viable competitors. The proposed Final Judgment requires Entercom to divest the Boston broadcast radio stations WBZ AM, WRKO AM, WZLX FM, and WKAF FM to iHeartMedia, and WBZ FM to Beasley Broadcasting. The proposed Final Judgment also requires Entercom to place certain broadcast radio stations into a trust to be operated independent from and in competition with Entercom: In San Francisco, KOIT FM, KMVQ FM, KUFX FM, and KBLX FM; and in Sacramento, KNCI FM, KYMX FM, KZZO FM, and KHTK AM. With respect to those stations, the proposed Final Judgment provides that Entercom can enter into local marketing agreement(s) (''LMAs'') with Bonneville International. During the term of the LMAs, Bonneville will program each of those radio stations as an independent, ongoing, economically viable, competitive business, with programming and advertising sales of each station held entirely separate, distinct, and apart from those of defendants' other operations. The LMAs cannot be amended without the prior approval of the United States at its sole discretion. Each LMA will expire with

[2] *See* U.S. Dep't of Justice, Horizontal Merger Guidelines § 5.3 (2010), available at *http://www.justice.gov/atr/public/guidelines/hmg-2010.html*. The HHI is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. For example, for a market consisting of four firms with shares of 30, 30, 20, and 20 percent, the HHI is 2,600 ($30^2 + 30^2 + 20^2 + 20^2 = 2,600$). It approaches zero when a market is occupied by a large number of firms of relatively equal size and reaches a maximum of 10,000 points when a market is controlled by a single firm. The HHI increases both as the number of firms in the market decreases and as the disparity in size between those firms increases.

respect to each LMA station upon the consummation of a final agreement to divest that station to an acquirer. The United States has approved iHeartMedia and Beasley as divestiture buyers in Boston, and has approved the LMAs with Bonneville.

The divestitures target the loss of competition between Entercom and CBS in each of the Divestiture Markets.

Because of the unique positioning of radio stations in Boston, the divestitures will strengthen the ability of each of the remaining major station groups to offer a wider range of attractive demographics to advertisers that seek to target specific demographic groups of listeners on English-language broadcast radio stations in the Boston market. Further, the divestiture of WBZ FM to Beasley Broadcasting preserves the competition for advertisers and listeners between the two important sports radio stations, WEEI FM and WBZ FM.

In San Francisco, the divestitures prevent any significant lessening of competition in the San Francisco broadcast radio market.

In Sacramento, the divestitures prevent any significant lessening of competition in the Sacramento broadcast radio market.

The ''Divestiture Assets'' are defined in Paragraph II.I of the proposed Final Judgment to cover all assets, tangible or intangible, necessary for the operation of the Divestiture Stations as viable, ongoing commercial broadcast radio stations. With respect to each Divestiture Station, the divestiture will include assets sufficient to satisfy the United States, in its sole discretion, that such assets can and will be used to operate each station as a viable, ongoing, commercial radio business.

To ensure that the Divestiture Stations are operated independently from Entercom after the divestiture, Section V and Section XII of the proposed Final Judgment prohibit Entercom from entering into any agreements during the term of the Final Judgment that create a long-term relationship with or any entanglements that affect competition between either Entercom and the acquirers of the Divestiture Stations concerning the Divestiture Assets after the divestiture is completed. Examples of prohibited agreements include agreements to reacquire any part of the Divestiture Assets, agreements to acquire any option to reacquire any part of the Divestiture Assets or to assign the Divestiture Assets to any other person, agreements to enter into any time brokerage agreement, local marketing agreement, joint sales agreement, other cooperative selling arrangement, shared services agreement, or agreements to conduct other business negotiations jointly with the acquirer(s) with respect to the Divestiture Assets, or providing financing or guarantees of financing with respect to the Divestiture Assets, during the term of this Final Judgment. The shared services prohibition does not preclude defendants from continuing or entering into any non-sales-related shared services agreement that is approved in advance by the United States in its sole discretion. The time brokerage agreement prohibition does not preclude defendants from entering into an agreement pursuant to which the acquirers can begin programming the Divestiture Stations immediately after the Court's approval of the Hold Separate Stipulation and Order in this matter, so long as any agreement with an acquirer expires upon the consummation of a final agreement to divest the Divestiture Assets to the acquirer.

Defendants are required to take all steps reasonably necessary to accomplish the divestiture quickly and to cooperate with prospective purchasers. Because transferring the broadcast license for each of the Divestiture Stations requires FCC approval, defendants are specifically required to use their best efforts to obtain all necessary FCC approvals as expeditiously as possible. The divestiture of each of the Divestiture Stations must occur within ninety (90) calendar days after the filing of the Hold Separate Stipulation and Order in this matter or five (5) calendar days after notice of the entry of the Final Judgment by the Court, whichever is later, subject to extension during the pendency of any necessary FCC order pertaining to the divestiture. The United States, in its sole discretion, may agree to one or more extensions of the ninety-day time period not to exceed ninety (90) calendar days in total, and shall notify the Court in such circumstances.

In the event that defendants do not accomplish the divestitures within the periods prescribed in the proposed Final Judgment, the proposed Final Judgment provides that the Court, upon application of the United States, will appoint a trustee selected by the United States to effect the divestitures. If a trustee is appointed, the proposed Final Judgment provides that Entercom will pay all costs and expenses of the trustee. The trustee's commission will be structured to provide an incentive for the trustee based on the price obtained and the speed with which the divestiture is accomplished. After his or her appointment becomes effective, the trustee will file monthly reports with the Court and the United States describing his or her efforts to accomplish the divestiture of any remaining stations. If the divestiture has not been accomplished after six (6) months, the trustee and the United States will make recommendations to the Court, which shall enter such orders as appropriate, to carry out the purpose of the trust, including extending the trust or the term of the trustee's appointment.

IV. REMEDIES AVAILABLE TO POTENTIAL PRIVATE LITIGANTS

Section 4 of the Clayton Act, 15 U.S.C. § 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. § 16(a), the proposed Final Judgment has no prima facie effect in any subsequent private lawsuit that may be brought against defendants.

V. PROCEDURES AVAILABLE FOR MODIFICATION OF THE PROPOSED FINAL JUDGMENT

The United States and defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the Federal Register, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of the United States will be filed with the Court. In addition, comments will be posted on the United States Department of Justice, Antitrust Division's Internet

website and, under certain circumstances, published in the Federal Register.

Written comments should be submitted to: Owen M. Kendler, Chief, Media, Entertainment, and Professional Services Section, Antitrust Division, United States Department of Justice, 450 5th Street, N.W. Suite 4000, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and defendants may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. ALTERNATIVES TO THE PROPOSED FINAL JUDGMENT

The United States considered, as an alternative to the proposed Final Judgment, a full trial on the merits against defendants. The United States could have continued the litigation and sought preliminary and permanent injunctions against Entercom's acquisition of CBS's broadcast radio stations. The United States is satisfied, however, that the divestiture of assets described in the proposed Final Judgment will preserve competition for the sale of broadcast radio advertising in the Boston, San Francisco, and Sacramento DMAs. Thus, the proposed Final Judgment would achieve all or substantially all of the relief the United States would have obtained through litigation, but avoids the time, expense, and uncertainty of a full trial on the merits of the Complaint.

VII. STANDARD OF REVIEW UNDER THE APPA FOR THE PROPOSED FINAL JUDGMENT

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty-day comment period, after which the court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. § 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

(A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *see generally United States* v. *SBC Commc'ns, Inc.,* 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing public interest standard under the Tunney Act); *United States v, U.S. Airways Group, Inc.,* No. 13–cv–1236 (CKK), 2014–1 Trade Cas. (CCH) ¶ 78, 748, 2014 U.S. Dist. LEXIS 57801, at *7 (D.D.C. Apr. 25, 2014) (noting the court has broad discretion of the adequacy of the relief at issue); *United States* v. *InBev N.V./S.A.,* No. 08-1965 (JR), 2009-2 Trade Cas. (CCH) ¶ 76,736, 2009 U.S. Dist. LEXIS 84787, at *3, (D.D.C. Aug. 11, 2009) (noting that the court's review of a consent judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable.'').[3]

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See Microsoft,* 56 F.3d at 1458-62. With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States* v. *BNS, Inc.,* 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft,* 56 F.3d at 1460-62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Courts have held that:

[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is ''*within the reaches of the public interest.*'' More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[4] In determining whether a proposed settlement is in the public interest, a district court ''must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17; *see also U.S. Airways,* 2014 U.S. Dist. LEXIS 57801, at *16 (noting that a court should not reject the proposed remedies because it believes others are preferable); *Microsoft,* 56 F.3d at 1461 (noting the need for courts to be ''deferential to the government's predictions as to the effect of the proposed remedies''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the United States' prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case).

Courts have greater flexibility in approving proposed consent decrees than in crafting their own decrees following a finding of liability in a litigated matter. ''[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.''' *United States* v. *Am. Tel. & Tel. Co.,* 552 F. Supp. 131, 151 (D.D.C. 1982) (citations omitted) (quoting *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975)), *aff'd sub nom. Maryland* v. *United States,* 460 U.S. 1001 (1983); *see also U.S. Airways,* 2014 U.S. Dist.

[3] The 2004 amendments substituted ''shall'' for ''may'' in directing relevant factors for court to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. § 16(e) (2004) *with* 15 U.S.C. § 16(e)(1) (2006); *see also SBC Commc'ns,* 489 F. Supp. 2d at 11 (concluding that the 2004 amendments ''effected minimal changes'' to Tunney Act review).

[4] *Cf. BNS,* 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass''). *See generally Microsoft,* 56 F.3d at 1461 (discussing whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest'''').

LEXIS 57801, at *8 (noting that room must be made for the government to grant concessions in the negotiation process for settlements (citing *Microsoft,* 56 F.3d at 1461)); *United States* v. *Alcan Aluminum Ltd.,* 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy). To meet this standard, the United States ''need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17.

Moreover, the court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint, and does not authorize the court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 2014 U.S. Dist. LEXIS 57801, at *9 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''the 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459-60. As this Court recently confirmed in *SBC Communications,* courts ''cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power.'' *SBC Commc'ns,* 489 F. Supp. 2d at 15.

In its 2004 amendments, Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. § 16(e)(2); *see also U.S. Airways,* 2014 U.S. Dist. LEXIS 57801, at *9 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). The language wrote into the statute what Congress intended when it enacted the Tunney Act in 1974, as Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Senator Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns,* 489 F. Supp. 2d at 11.[5] A court can make its public interest determination based on the competitive impact statement and response to public comments alone. *U.S. Airways,* 2014 U.S. Dist. LEXIS 57801, at *9.

VIII. DETERMINATIVE DOCUMENTS

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: November 1, 2017

Respectfully Submitted,

/s/

Bennett J. Matelson*
Mark A. Merva
Trial Attorneys

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* Attorney of Record

United States District Court for the District of Columbia

United States of America, Plaintiff, v. *Entercom Communications Corp. and CBS Corporation,* Defendants.

Case No: 1:17–cv–02268
Judge: Boasberg

PROPOSED FINAL JUDGMENT

WHEREAS, Plaintiff, United States of America, filed its Complaint on November 1, 2017, the United States and defendants Entercom Communications Corp. and CBS Corporation, by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party regarding any issue of fact or law;

AND WHEREAS, defendants agree to be bound by the provisions of this Final Judgment pending its approval by the Court;

AND WHEREAS, the essence of this Final Judgment is the prompt and certain divestiture of certain rights or assets by the defendants to assure that competition is not substantially lessened;

AND WHEREAS, the United States requires defendants to make certain divestitures for the purpose of remedying the loss of competition alleged in the Complaint;

AND WHEREAS, defendants have represented to the United States that the divestitures required below can and will be made, and that defendants will later raise no claim of hardship or difficulty as grounds for asking the Court to modify any of the divestiture provisions contained below;

NOW THEREFORE, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is ORDERED, ADJUDGED, AND DECREED:

I. Jurisdiction

This Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against defendants under Section 7 of the Clayton Act, as amended (15 U.S.C. § 18).

II. Definitions

As used in this Final Judgment:

A. ''Entercom'' means defendant Entercom Communications Corp., a Pennsylvania corporation headquartered in Bala Cynwyd, Pennsylvania, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

B. ''CBS'' means defendant CBS Corporation, a Delaware corporation headquartered in New York City, New York, its successors and assigns, and its

[5] *See United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); *United States* v. *Mid-Am. Dairymen, Inc.,* 1977-1 Trade Cas. (CCH) ¶ 61,508, at 71,980 (W.D. Mo. 1977) (''Absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should . . . carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.''); S. Rep. No. 93-298, 93d Cong., 1st Sess., at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

subsidiaries, including CBS Radio, Inc., divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

C. ''Acquirers'' means Beasley, iHeartMedia, or another entity to which Entercom divests any Divestiture Assets.

D. ''Beasley'' means Beasley Broadcast Group, Inc., a Delaware Corporation, headquartered in Naples, Florida, its successor and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

E. ''Bonneville'' means Bonneville International Corporation, headquartered in Salt Lake City, Utah, its successor and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

F. ''iHeartMedia'' means iHeartMedia, Inc., a Delaware Corporation, headquartered in San Antonio, Texas, its successor and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

G. ''DMA'' means Designated Market Area as defined by A.C. Nielsen Company and used by the *Investing in Radio BIA Market Report 2016* (1st edition). DMAs are ranked according to the number of households therein and are used by broadcasters, advertisers, and advertising agencies to aid in evaluating radio audience size and composition.

H. ''LMA'' means a local marketing agreement.

I. ''Divestiture Assets'' means

1. The following broadcast radio stations owned by CBS:

a. WBZ AM, located in the Boston, Massachusetts DMA (''WBZ AM'');

b. WBZ FM, located in the Boston, Massachusetts DMA (''WBZ FM'');

c. WZLX FM, located in the Boston, Massachusetts DMA (''WZLX FM'');

d. KMVQ FM, located in the San Francisco, California DMA (''KMVQ FM'');

e. KNCI FM, located in the Sacramento, California DMA (''KNCI FM'');

f. KYMX FM, located in the Sacramento, California DMA (''KYMX FM'');

g. KZZO FM, located in the Sacramento, California DMA (''KZZO FM''); and

h. KHTK AM, located in the Sacramento, California DMA (''KHTK AM'').

2. The following broadcast radio stations owned by Entercom:

a. WRKO AM, located in the Boston, Massachusetts DMA (''WRKO AM'');

b. WKAF FM, located in the Boston, Massachusetts DMA (''WKAF FM'');

c. KOIT FM, located in the San Francisco, California DMA (''KOIT FM'')

d. KUFX FM, located in the San Francisco, California DMA (''KUFX FM''); and

e. KBLX FM, located in the San Francisco, California DMA (''KBLX FM'').

3. All of the assets, tangible or intangible, necessary for the operations of the Divestiture Radio Stations and LMA Radio Stations as viable, ongoing commercial broadcast radio stations, except as otherwise agreed to in writing by the United States Department of Justice, including, but not limited to, all real property (owned or leased), all broadcast equipment, office equipment, office furniture, fixtures, materials, supplies, and other tangible property; all licenses, permits, authorizations, and applications therefore issued by the Federal Communications Commission (''FCC'') and other government agencies related to the stations; all contracts (including programming contracts and rights), agreements, network agreements, leases, and commitments and understandings of defendants; all trademarks, service marks, trade names, copyrights, patents, slogans, programming materials, and promotional materials relating to the stations (subject to the CBS Brands License Agreements contained in the Agreement and Plan of Merger, dated February 2, 2017, between CBS, CBS Radio, Inc., and Entercom); all customer lists, contracts, accounts, credit records, and all logs and other records maintained by defendants in connection with the stations.

J. ''Divestiture Radio Stations'' means WBZ AM, WBZ FM, WRKO AM, WKAF FM and WZLX FM.

K. ''LMA Radio Stations'' means KOIT FM, KMVQ FM, KUFX FM, KBLX FM, KNCI FM, KYMX FM, KZZO FM and KHTK AM.

L. ''Relevant Employee'' means the personnel involved in the operations of the Divestiture Assets.

III. Applicability

A. This Final Judgment applies to Entercom and CBS as defined above, and all other persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

B. If, prior to complying with Section V and Section VI of this Final Judgment, defendants sell or otherwise dispose of all or substantially all of their assets or of lesser business units that include the Divestiture Assets, defendants shall require the purchaser to be bound by the provisions of this Final Judgment. Entercom need not obtain such an agreement from the acquirers of the assets divested pursuant to this Final Judgment.

IV. LMA

Entercom is ordered and directed, after the Court's approval of the Hold Separate Stipulation and Order in this matter, to enter into an LMA(s) with respect to the LMA Radio Stations with Bonneville, the terms of which are subject to the approval of the United States in its sole discretion. Pursuant to the terms of the LMA(s), Entercom will cede to Bonneville the sole right and ability to program and sell advertising on the LMA Radio Stations. The LMA(s) shall last no longer than one year or, with respect to each LMA Radio Station, upon the consummation of a final agreement to divest that station to an Acquirer. Without limiting defendants' obligations under Section IX, Bonneville will program each of those radio stations as an independent, ongoing, economically viable, competitive business, with programming and advertising sales held entirely separate, distinct, and apart from those of defendants' other operations. Entercom and Bonneville may not amend the LMA(s) without the prior approval of the United States, in its sole discretion.

V. Divestitures

A. Entercom is ordered and directed, within ninety (90) calendar days after the signing of the Hold Separate Stipulation and Order in this matter or five (5) calendar days after notice of the entry of this Final Judgment by the Court, whichever is later, to divest the Divestiture Radio Stations in a manner consistent with this Final Judgment to an Acquirer or Acquirers acceptable to the United States, in its sole discretion. The United States, in its sole discretion, may agree to one or more extensions of this time period not to exceed ninety (90) calendar days in total, and shall notify the Court in such circumstances.

B. Entercom is ordered and directed, within one hundred and eighty (180) calendar days after the signing of the Hold Separate Stipulation and Order in this matter, to divest the LMA Radio Stations in a manner consistent with this Final Judgment to an Acquirer or Acquirers acceptable to the United States, in its sole discretion. The United States, in its sole discretion, may agree to one or more extensions of this time period not to exceed one hundred and eighty (180) calendar days in total, and

shall notify the Court in such circumstances.

C. With respect to divestiture of the Divestiture Assets by Entercom or the trustee appointed pursuant to Section VI of this Final Judgment, if applications have been filed with the FCC within the period permitted for divestiture, seeking approval to assign or transfer licenses to the Acquirer(s) of the Divestiture Assets, but no order or other dispositive action by the FCC on such applications has been issued before the end of the period permitted for divestiture, the period permitted for divestiture shall be extended no later than ten (10) business days after the FCC order consenting to the assignment of the Divestiture Assets to the Acquirers has become final.

D. Entercom shall use its best efforts to accomplish the divestitures ordered by this Final Judgment as expeditiously as possible, including using their best efforts to obtain all necessary FCC approvals as expeditiously as possible. This Final Judgment does not limit the FCC's exercise of its regulatory powers and process with respect to the Divestiture Assets. Authorization by the FCC to conduct the divestiture of a Divestiture Asset in a particular manner will not modify any of the requirements of this Final Judgment.

E. In the event that Entercom is attempting to divest any of the Divestiture Assets to an Acquirer other than Beasley (WBZ FM) or iHeartMedia (WBZ AM, WRKO AM, WKAF FM, and WZLX FM):

(1) Entercom promptly shall make known, by usual and customary means, the availability of the Divestiture Assets;

(2) Entercom shall inform any person making inquiry regarding a possible purchase of the Divestiture Assets that they are being divested pursuant to this Final Judgment and provide that person with a copy of this Final Judgment;

(3) Except with written permission from the United States, Entercom shall offer to furnish to all prospective acquirers, subject to customary confidentiality assurances, all information and documents relating to the Divestiture Assets customarily provided in a due diligence process except such information or documents subject to the attorney-client privilege or work-product doctrine; and

(4) Entercom shall make available such information to the United States at the same time that such information is made available to any other person.

F. Defendants shall provide the Acquirer(s) and the United States information relating to the personnel necessary to the operation or management of the Divestiture Assets to enable the Acquirer(s) to make offers of employment. Defendants will not interfere with any negotiations by the Acquirer(s) to employ any defendant employee whose primary responsibility is the operation or management of the Divestiture Assets.

G. From the date of the filing of the Complaint in this matter, defendants may enter into an agreement with an Acquirer or Bonneville pursuant to which defendants may not solicit to hire, or hire, certain Relevant Employees. Any such agreement is subject to the approval of the United States, in its sole discretion.

H. Entercom shall permit prospective acquirers of the Divestiture Assets to have reasonable access to personnel and to make inspections of the physical facilities of each of the Divestiture Radio Stations; access to any and all environmental, zoning, and other permit documents and information; and access to any and all financial, operational, or other documents and information customarily provided as part of a due diligence process.

I. Entercom shall warrant to the Acquirer(s) that each Divestiture Radio Station or LMA Radio Station will be operational on the date of sale.

J. Defendants shall not take any action that will impede in any way the permitting, operation, or divestiture of each of the Divestiture Radio Stations or LMA Radio Stations.

K. Entercom shall warrant to the Acquirers that there are no material defects in the environmental, zoning, or other permits pertaining to the operation of each Divestiture Radio Station or LMA Radio Station, and that, following the sale of each of the Divestiture Assets, defendants will not undertake, directly or indirectly, any challenges to the environmental, zoning, or other permits relating to the operation of each Divestiture Radio Station or LMA Radio Station.

L. Unless the United States otherwise consents in writing, the divestiture pursuant to Section V, or by Divestiture Trustee appointed pursuant to Section VI of this Final Judgment, shall include the entire Divestiture Assets and shall be accomplished in such a way as to satisfy the United States, in its sole discretion, that each Divestiture Radio Station or LMA Radio Station can and will be used by the Acquirer(s) as part of a viable, ongoing commercial radio broadcasting business. Divestiture of the Divestiture Assets may be made to one or more Acquirers, provided that in each instance it is demonstrated to the sole satisfaction of the United States that the Divestiture Assets will remain viable, and the divestiture of such assets will achieve the purposes of this Final Judgment and remedy the competitive harm alleged in the Complaint. The divestitures, whether pursuant to Section V or Section VI of this Final Judgment:

(1) shall be made to Acquirers that, in the United States' sole judgment, has the intent and capability (including the necessary managerial, operational, technical, and financial capability) of competing effectively in the commercial radio broadcasting business; and

(2) shall be accomplished so as to satisfy the United States, in its sole discretion, that none of the terms of any agreement between an Acquirer and defendants gives defendants the ability unreasonably to raise any Acquirer's costs, to lower any Acquirer's efficiency, or otherwise to interfere in the ability of any Acquirer to compete effectively.

VI. Appointment of Divestiture Trustee

A. If defendants have not divested each of the Divestiture Radio Stations within the time period specified in Section V(A) or each of the LMA Radio Stations within the time period specified in Section V(B), defendants shall notify the United States of that fact in writing. Upon application of the United States, the Court shall appoint a Divestiture Trustee selected by the United States and approved by the Court to effect the divestiture of the Divestiture Assets.

B. After the appointment of a Divestiture Trustee becomes effective, only the Divestiture Trustee shall have the right to sell the Divestiture Assets. The Divestiture Trustee shall have the power and authority to accomplish the divestiture to an Acquirer(s) acceptable to the United States at such price and on such terms as are then obtainable upon reasonable effort by the Divestiture Trustee, subject to the provisions of Sections V, VI, and VII of this Final Judgment, and shall have such other powers as this Court deems appropriate. Subject to Section VI(D) of this Final Judgment, the Divestiture Trustee may hire at the cost and expense of Entercom any investment bankers, attorneys, or other agents, who shall be solely accountable to the Divestiture Trustee, reasonably necessary in the Divestiture Trustee's judgment to assist in the divestiture. Any such investment bankers, attorneys, or other agents shall serve on such terms and conditions as the United States approves, including confidentiality requirements and conflict of interest certifications.

C. Defendants shall not object to a sale by the Divestiture Trustee on any ground other than the Divestiture Trustee's malfeasance. Any such

objections by defendants must be conveyed in writing to the United States and the Divestiture Trustee within ten (10) calendar days after the Divestiture Trustee has provided the notice required under Section VII.

D. The Divestiture Trustee shall serve at the cost and expense of Entercom pursuant to a written agreement, on such terms and conditions as the United States approves, including confidentiality requirements and conflict of interest certifications. The Divestiture Trustee shall account for all monies derived from the sale of the assets sold by the Divestiture Trustee and all costs and expenses so incurred. After approval by the Court of the Divestiture Trustee's accounting, including fees for its services yet unpaid and those of any professionals and agents retained by the Divestiture Trustee, all remaining money shall be paid to Entercom and the trust shall then be terminated. The compensation of the Divestiture Trustee and any professionals and agents retained by the Divestiture Trustee shall be reasonable in light of the value of the Divestiture Assets and based on a fee arrangement providing the Divestiture Trustee with an incentive based on the price and terms of the divestiture and the speed with which it is accomplished, but timeliness is paramount. If the Divestiture Trustee and Entercom are unable to reach agreement on the Divestiture Trustee's or any agents' or consultants' compensation or other terms and conditions of engagement within 14 calendar days of appointment of the Divestiture Trustee, the United States may, in its sole discretion, take appropriate action, including making a recommendation to the Court. The Divestiture Trustee shall, within three (3) business days of hiring any other professionals or agents, provide written notice of such hiring and the rate of compensation to Entercom and the United States.

E. Defendants shall use their best efforts to assist the Divestiture Trustee in accomplishing the required divestitures. The Divestiture Trustee and any consultants, accountants, attorneys, and other agents retained by the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities of the business to be divested, and defendants shall develop financial and other information relevant to such business as the Divestiture Trustee may reasonably request, subject to reasonable protection for trade secret or other confidential research, development, or commercial information or any applicable privileges. Defendants shall take no action to interfere with or to impede the Divestiture Trustee's accomplishment of the divestitures.

F. After its appointment, the Divestiture Trustee shall file monthly reports with the United States and, as appropriate, the Court setting forth the Divestiture Trustee's efforts to accomplish the divestitures ordered under this Final Judgment. To the extent such reports contain information that the Divestiture Trustee deems confidential, such reports shall not be filed in the public docket of the Court. Such reports shall include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in and of the Divestiture Radio Stations or LMA Radio Stations, and shall describe in detail each contact with any such person. The Divestiture Trustee shall maintain full records of all efforts made to divest the Divestiture Assets.

G. If the Divestiture Trustee has not accomplished the divestitures ordered under this Final Judgment within six months after its appointment, the Divestiture Trustee shall promptly file with the Court reports setting forth (1) the Divestiture Trustee's efforts to accomplish the required divestitures, (2) the reasons, in the Divestiture Trustee's judgment, why the required divestitures have not been accomplished, and (3) the Divestiture Trustee's recommendations. To the extent such reports contain information that the Divestiture Trustee deems confidential, such reports shall not be filed in the public docket of the Court. The Divestiture Trustee shall at the same time furnish such reports to the United States, which shall have the right to make additional recommendations consistent with the purpose of the trust. The Court thereafter shall enter such orders as it shall deem appropriate to carry out the purpose of the Final Judgment, which may, if necessary, include extending the trust and the term of the Divestiture Trustee's appointment by a period requested by the United States.

H. If the United States determines that the Divestiture Trustee has ceased to act or failed to act diligently or in a reasonably cost-effective manner, it may recommend the Court appoint a substitute Divestiture Trustee.

VII. Notice of Proposed Divestitures

A. Within two (2) business days following execution of a definitive divestiture agreement, Entercom or the Divestiture Trustee, whichever is then responsible for effecting the divestiture required herein, shall notify the United States of any proposed divestiture required by Section V or Section VI of this Final Judgment. If the Divestiture Trustee is responsible, it shall similarly notify defendants. The notice shall set forth the details of the proposed divestiture and list the name, address, and telephone number of each person not previously identified who offered or expressed an interest in or desire to acquire any ownership interest in the Divestiture Assets, together with full details of the same.

B. Within fifteen (15) calendar days of receipt by the United States of such notice, the United States may request from defendants, the proposed Acquirer(s), any other third party, or the Divestiture Trustee, if applicable, additional information concerning the proposed divestiture(s), the proposed Acquirer(s), and any other potential Acquirer. Defendants and the Divestiture Trustee shall furnish any additional information requested within fifteen (15) calendar days of the receipt of the request, unless the parties shall otherwise agree.

C. Within thirty (30) calendar days after receipt of the notice or within twenty (20) calendar days after the United States has been provided the additional information requested from defendants, the proposed Acquirer(s), any third party, and the Divestiture Trustee, whichever is later, the United States shall provide written notice to defendants and the Divestiture Trustee, if there is one, stating whether or not it objects to the proposed divestiture. If the United States provides written notice that it does not object, the divestiture may be consummated, subject only to defendants' limited right to object to the sale under Section VI(C) of this Final Judgment. Absent written notice that the United States does not object to the proposed Acquirer(s) or upon objection by the United States, a divestiture proposed under Section V or Section VI shall not be consummated. Upon objection by defendants under Section VI(C), a divestiture proposed under Section VI shall not be consummated unless approved by the Court.

VIII. Financing

Defendants shall not finance all or any part of any purchase made pursuant to Section V or Section VI of this Final Judgment.

IX. Hold Separate

Until the divestitures required by this Final Judgment have been accomplished, defendants shall take all

steps necessary to comply with the Hold Separate Stipulation and Order entered by this Court. Defendants shall take no action that would jeopardize the divestitures ordered by this Court.

X. Affidavits

A. Within twenty (20) calendar days of the filing of the Complaint in this matter, and every thirty (30) calendar days thereafter until the divestiture has been completed under Section V or Section VI, defendants shall deliver to the United States an affidavit as to the fact and manner of their compliance with Section V or Section VI of this Final Judgment. Each such affidavit shall include the name, address, and telephone number of each person who, during the preceding thirty (30) calendar days, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in any of the Divestiture Radio Stations, and shall describe in detail each contact with any such person during that period. Each such affidavit shall also include a description of the efforts defendants have taken to solicit buyers for and complete the sale of each of the Divestiture Radio Stations, including efforts to secure FCC or other regulatory approvals, and to provide required information to prospective acquirers, including the limitations, if any, on such information. Assuming the information set forth in the affidavit is true and complete, any objection by the United States to information provided by defendants, including any limitations on information, shall be made within fourteen (14) calendar days of receipt of such affidavit.

B. Within twenty (20) calendar days of the filing of the Complaint in this matter, defendants shall deliver to the United States an affidavit that describes in reasonable detail all actions defendants have taken and all steps defendants have implemented on an ongoing basis to comply with Section IX of this Final Judgment. Each such affidavit shall also include a description of the efforts defendants have taken to complete the sale of each of the Divestiture Radio Stations, including efforts to secure FCC or other regulatory approvals. Defendants shall deliver to the United States an affidavit describing any changes to the efforts and actions outlined in defendants' earlier affidavits filed pursuant to this section within fifteen (15) calendar days after the change is implemented.

C. Defendants shall keep all records of all efforts made to preserve and divest the Divestiture Assets until one year after such divestiture has been completed.

XI. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment, or of any related orders such as the Hold Separate Stipulation and Order, or of determining whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, from time to time authorized representatives of the United States Department of Justice, including consultants and other persons retained by the United States, shall, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to defendants, be permitted:

(1) access during defendants' office hours to inspect and copy, or at the option of the United States, to require defendants to provide hard copy or electronic copies of, all books, ledgers, accounts, records, data and documents in the possession, custody or control of defendants, relating to any matters contained in this Final Judgment; and

(2) to interview, either informally or on the record, defendants' officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, defendants shall submit written reports or responses to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested.

C. No information or documents obtained by the means provided in this section shall be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. If at the time information or documents are furnished by defendants to the United States, defendants represent and identify in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and defendants mark each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(g) of the Federal Rules of Civil Procedure,'' then the United States shall give defendants ten (10) calendar days' notice prior to divulging such material in any legal proceeding (other than a grand jury proceeding).

XII. No Reacquisition and Other Prohibited Activities

After the Divestiture Assets have been divested to Acquirers acceptable to the United States in its sole discretion, and during the term of the Final Judgment: defendants may not (1) reacquire any part of the Divestiture Assets, (2) acquire any option to reacquire any part of the Divestiture Assets or to assign the Divestiture Assets to any other person, (3) enter into any time brokerage agreement, local marketing agreement, joint sales agreement, or other cooperative selling arrangement with respect to the Divestiture Assets, or (4) provide financing or guarantees of financing with respect to the Divestiture Assets. Entercom may not enter into any shared services agreement or conduct other business negotiations jointly with the Acquirer(s) with respect to the Divestiture Assets.

The shared services prohibition does not preclude defendants from continuing or entering into any non-sales-related shared services agreement that is approved in advance by the United States in its sole discretion.

If defendants reach an agreement to divest the Divestiture Assets to the Acquirers, defendants may also enter into an agreement, approved in advance by the United States in its sole discretion, under which a defendant cedes to the Acquirer the sole right and ability to program one or more of the Divestiture Assets after the Court's approval of the Hold Separate Stipulation and Order in this matter, provided that any such time brokerage agreement must expire upon the termination of a final agreement to divest the Divestiture Assets to the Acquirer or upon the consummation of a final agreement to divest the Divestiture Assets to the Acquirer.

XIII. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XIV. Enforcement of Final Judgment

The United States retains and reserves all rights available to it under applicable law to enforce the provisions of this Final Judgment, including its right to seek an order of contempt from this Court. Any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of this order shall be evaluated under a preponderance of the evidence standard.

XV. Expiration of Final Judgment

Unless this Court grants an extension, this Final Judgment shall expire ten (10) years from the date of its entry, except that after five years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and the Parties that the divestitures have been completed and that the continuation of the decree no longer is necessary or in the public interest.

XVI. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C § 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon, and the United States' response to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and responses to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date:

Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. § 16.

United States District Judge

[FR Doc. 2017–24548 Filed 11–9–17; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—National Spectrum Consortium

Notice is hereby given that, on October 13, 2017, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), National Spectrum Consortium (''NSC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, WaveLink, Inc., Huntsville, AL; Spectrum Bullpen, LLC, Orlando, FL; The Catholic University of America, Washington, DC; IERUS Technologies, Inc., Huntsville, AL; Expedition Technology, Inc., Dulles, VA; Stryke Industries, LLC, Fort Wayne, IN; Domo Tactical Communications, Pinellas Park, FL; and Telspan Data, LLC, Concord, CA, have been added as parties to this venture.

Boeing Company, Arlington, VA; JRC Integrated Systems, Inc., Washington, DC; Signautics Engineering Services, LLC, Dunedin, FL; Colorado School of Mines, Golden, CO; Black River Systems Company, Inc., Utica, NY; Darkblade Systems Corporation, Stafford, VA; and ANRA Technologies, LLC, Stone Ridge, VA, have withdrawn from this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and NSC intends to file additional written notifications disclosing all changes in membership.

On Septmember 24, 2014, NSC filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 4, 2014 (79 FR 65424).

The last notification was filed with the Department on July 12, 2017. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 15, 2017 (82 FR 38710).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2017–24547 Filed 11–9–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Vehicle Safety Communications 8 Consortium

Notice is hereby given that, on October 13, 2017, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Vehicle Safety Communications 8 Consortium (''VSC8 Consortium'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties to the venture are: General Motors Holdings LLC, Warren, MI; Ford Motor Company, Dearborn, MI; Hyundai-Kia America Technical Center Inc., Superior Township, MI; and Nissan Technical Center North America, Farmington Hills, MI.

The general area of VSC8 Consortium's planned activity is collaboration to conduct or facilitate cooperative research, development, testing, and evaluation procedures to gain further knowledge and understanding of connected vehicle interactions and/or applications for vehicles that are intended to transform surface transportation safety, mobility, and environmental performance through a connected vehicle environment. VSC8 Consortium's objectives are to promote the interests of the automotive sector while maintaining impartiality, the independence of its members, and vendor neutrality.

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2017–24549 Filed 11–9–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—PDES, Inc.

Notice is hereby given that, on October 10, 2017, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), PDES, Inc. (''PDES''), filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Capvidia, Leuven, BELGIUM; Engesis, Rome, ITALY;

Honeywell, Phoenix, AZ; LKSoftWare GmbH, Kuenzell, GERMANY; and NARA, Rocket Center, WV, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and PDES intends to file additional written notifications disclosing all changes in membership.

On September 20, 1988, PDES filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on October 14, 1988 (53 FR 40282).

The last notification was filed with the Department on April 20, 2016. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on May 24, 2016 (81 FR 32776).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2017–24546 Filed 11–9–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—UHD Alliance, Inc.

Notice is hereby given that, on September 28, 2017, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), UHD Alliance, Inc. (''UHD Alliance'') filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ASUSTeK Computer Inc., Taipei, TAIWAN, and THX Ltd., San Francisco, CA, have been added as parties to this venture.

Also, European Broadcasting Union (EBU), Geneva, SWITZERLAND; Eutelsat SA, Paris, FRANCE; Ittiam Systems Inc., Plano, TX; Orange Labs, Sevigne, FRANCE; and Sharp Corporation, Tochigi, JAPAN, have been dropped as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and UHD Alliance intends to file additional written notifications disclosing all changes in membership.

On June 17, 2015, UHD Alliance filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 17, 2015 (80 FR 42537).

The last notification was filed with the Department on June 6, 2017. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 5, 2017 (82 FR 31069).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2017–24550 Filed 11–9–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Notice of Lodging Proposed Consent Decree

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *United States* v. *Black Tea Oil, LLC, et al.,* Case No. 2:17–cv–02030, was lodged with the United States District Court for the District of Kansas on November 6, 2017.

This proposed Consent Decree concerns a complaint filed by the United States against Black Tea Oil, LLC and Christopher C. Leiker, pursuant to 33 U.S.C. 1319(b) and (d), to obtain injunctive relief from and impose civil penalties against the Defendants for violating the Clean Water Act by discharging pollutants without a permit into waters of the United States. The proposed Consent Decree resolves these allegations by requiring the Defendants to restore the impacted areas and to pay a civil penalty.

The Department of Justice will accept written comments relating to this proposed Consent Decree for thirty (30) days from the date of publication of this Notice. Please address comments to Phillip R. Dupré, Trial Attorney, United States Department of Justice, Environment and Natural Resources Division, Environmental Defense Section, Post Office Box 7611, Washington, DC 20044, and refer to *United States* v. *Black Tea Oil, LLC, et al.,* DJ #90–5–1–1–20653.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the District of Kansas, 500 State Avenue, Kansas City, KS 66101. In addition, the proposed Consent Decree may be examined electronically at *http://www.justice.gov/enrd/consent-decrees.*

Cherie L. Rogers,

Assistant Section Chief, Environmental Defense Section, Environment and Natural Resources Division.

[FR Doc. 2017–24461 Filed 11–9–17; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Contribution Operations, ETA–581

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (DOL), Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Contribution Operations, ETA–581.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by January 12, 2018.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of responses, and estimated total burden may be obtained free by contacting Patrick Holmes by telephone at (202) 693–3203 (this is not a toll-free number) or by email at *Holmes.Patrick.G@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance, 200 Constitution Ave. NW., Room S–4520, Washington, DC 20210; by email: *Holmes.Patrick.G@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Patrick Holmes by telephone at (202) 693–3203 (this is not a toll-free number) or by email *Holmes.Patrick.G@dol.gov.*

SUPPLEMENTARY INFORMATION: The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to

comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

State UI agencies report data on the ETA 581 report in order to measure performance, accuracy and promptness in employer registrations, timeliness of filing contribution and wage reports by employers, collections (accounts receivable), and field audits of employers. Data on the report also measures state efforts to detect employer tax avoidance schemes, which is known as State Unemployment Tax Act (SUTA) Dumping. Section 303(k) of the Social Security Act requires states to detect SUTA Dumping. ETA uses the information reported on the report to monitor and measure program performance and make projections and forecasts in conjunction with the budgetary process. Sections 303(a)(6) and (k) of the Social Security Act authorizes this information collection.

This information collection is subject to the 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 it is approved by the OMB under the PRA 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 collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0178.

Submitted comments will also be a matter of public record for this ICR and posted on the Internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The DOL is particularly interested in comments that:

- 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;
- 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;
- Enhance the quality, utility, and clarity of the information to be collected; and
- 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.

Agency: DOL–ETA.

Type of Review: Extension without changes.

Title of Collection: Contribution Operations, ETA–581.

Form: ETA 581, Contribution Operations.

OMB Control Number: 1205–0178.

Affected Public: State governments.

Estimated Number of Respondents: 53.

Frequency: Quarterly.

Total Estimated Annual Responses: 212.

Estimated Average Time per Response: 7.5 hours.

Estimated Total Annual Burden Hours: 1,590 hours.

Total Estimated Annual Other Cost Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

Nancy M. Rooney,

Deputy Assistant Secretary, Employment and Training Administration.

[FR Doc. 2017–24512 Filed 11–9–17; 8:45 am]

BILLING CODE 4510–FW–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Biological Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Biological Sciences (#1110).

Date and Time: December 19, 2017; 1:00 p.m.–3:00 p.m.

Place: National Science Foundation, 2415 Eisenhower Avenue, Room E 3410, Alexandria, VA 22314.

Please contact Rachel Evans at *rlevans@nsf.gov* to obtain a visitor badge. All visitors to the NSF will be required to show photo ID to obtain a badge.

Type of Meeting: Open.

Contact Person: Brent Miller, National Science Foundation, 2415 Eisenhower Avenue, Room C 12016, Alexandria, VA 22314; Tel No.: (703) 292–8400.

Purpose of Meeting: The Advisory Committee for the Directorate for Biological Sciences (BIO) provides advice, recommendations, and oversight concerning major program emphases, directions, and goals for the research-related activities of the divisions that make up BIO.

Agenda: This meeting will be held telephonically among the Advisory Committee members; public visitors will be able to attend the meeting in person at NSF headquarters. Agenda items will include welcoming new Advisory Committee (AC) members, review of the AC's function, discussion of potential future AC activities, and other matters relevant to the Directorate for Biological Sciences.

Dated: November 6, 2017.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2017–24543 Filed 11–9–17; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits issued.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued Under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–8224; email: *ACApermits@nsf.gov*.

SUPPLEMENTARY INFORMATION: On September 14, 2017, the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on October 16, 2017 to:

1. Jay J. Rotella, Permit No. 2018–012

2. Linnea Pearson, Permit No. 2018–013

3. David J. Smith, Permit No. 2018–010

Nadene G. Kennedy,

Polar Coordination Specialist, Office of Polar Programs.

[FR Doc. 2017–24173 Filed 11–9–17; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0249]

Information Collection: Safeguards on Nuclear Material—Implementation of United States/International Atomic Energy Agency Agreement

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) recently submitted a renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, Information Collection: Safeguards on Nuclear Material—Implementation of United States/International Atomic Energy Agency Agreement.''

DATES: Submit comments by December 13, 2017.

ADDRESSES: Submit comments directly to the OMB reviewer at: Brandon DeBruhl, Desk Officer, Office of Information and Regulatory Affairs (3150–0055), NEOB–10202, Office of Management and Budget, Washington, DC 20503; telephone: 202–395–0710, email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0249 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0249.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search*.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The supporting statement is available in ADAMS under Accession No. ML17173A062.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *http://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for revision of an existing collection of information to OMB for review entitled, ''Information Collection: Safeguards on Nuclear Material—Implementation of United States/International Atomic Energy Agency Agreement.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on April 6, 2017 (82 FR 16862).

1. *The title of the information collection:* 10 CFR part 75, ''Information Collection: Safeguards on Nuclear Material—Implementation of United States/International Atomic Energy Agency Agreement.''
2. *OMB approval number:* 3150–0055.
3. *Type of submission:* Extension.
4. *The form number if applicable:* Not applicable.
5. *How often the collection is required or requested:* Selected licensees are required to provide reports of nuclear material inventory and flow for selected facilities under the US/IAEA Safeguards Agreement, permit inspections by International Atomic Energy Agency Agreement (IAEA) inspectors, complementary access of IAEA inspectors under the Additional Protocol, give immediate notice to the NRC in specified situations involving the possibility of loss of nuclear material, and give notice for imports and exports of specified amounts of nuclear material. Reporting is done when specified events occur. Recordkeeping for nuclear material accounting and control information is done in accordance with specific instructions.
6. *Who will be required or asked to respond:* Licensees of facilities on the US eligible list who have been selected by the IAEA for reporting or recordkeeping activities.
7. *The estimated number of annual responses:* 32 (2 reporting responses + 30 recordkeepers).
8. *The estimated number of annual respondents:* 30.
9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 4,227.1 hours (0.4 reporting hours + 4226.7 hours recordkeeping).
10. *Abstract:* Part 75 of title 10 of the *Code of Federal Regulations* (10 CFR), requires selected licensees to provide reports of nuclear material inventory and flow for selected facilities under the US/IAEA Safeguards Agreement, permit inspections by IAEA inspectors, complementary access of IAEA inspectors under the Additional Protocol, give immediate notice to the NRC in specified situations involving the possibility of loss of nuclear material, and give notice for imports and exports of specified amounts of

nuclear material. This collection is being updated to include approximately 25 entities subject to the U.S.-IAEA Caribbean Territories Safeguards Agreement (INFCIRC/366). These licensees will also follow written material accounting and control procedures, although actual reporting of transfer and material balance records to the IAEA will be done through the U.S. State system (Nuclear Materials Management and Safeguards System, collected under OMB clearance numbers 3150–0003, 3150–0004, 3150–0057, and 3150–0058.) The NRC needs this information to implement its international obligations under the *U.S.-IAEA Caribbean Territories Safeguards Agreement (INFCIRC/366).*

Dated at Rockville, Maryland, this 6th of November, 2017.

For the Nuclear Regulatory Commission.

David Cullison,

Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2017–24481 Filed 11–9–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on APR1400; Notice of Meeting

The ACRS Subcommittee on APR1400 will hold a meeting on November 14, 2017, at 11545 Rockville Pike, Room T–2B1, Rockville, Maryland 20852.

The meeting will be open to public attendance with the exception of portions that may be closed to protect information that is proprietary pursuant to 5 U.S.C. 552b(c)(4). The agenda for the subject meeting shall be as follows:

Tuesday, November 14, 2017, 8:30 a.m. Until 5:00 p.m.

The Subcommittee will review APR1400 design control document Chapter 2, ''Site Characteristics,'' Chapter 5, ''Reactor Coolant System and Connecting Systems,'' Chapter 11, ''Radioactive Waste Management,'' and Chapter 12, ''Radiation Protection.'' The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Christopher Brown (Telephone 301–415–7111 or Email: *Christopher.Brown@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 4, 2017 (82 FR 46312).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, Maryland 20852. After registering with Security, please contact Mr. Theron Brown (Telephone 301–415–6207) to be escorted to the meeting room.

Dated: November 6, 2017.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2017–24434 Filed 11–8–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0174]

Information Collection: DOE/NRC Form 740M, Concise Note; DOE/NRC Form 741, Nuclear Material Transaction Report; DOE/NRC Form 742, Material Balance Report; and DOE/NRC Form 742C, Physical Inventory Listing

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collections are entitled, ''DOE/NRC Form 740M, Concise Note; DOE/NRC Form 741, Nuclear Material Transaction Report; DOE/NRC Form 742, Material Balance Report; and DOE/NRC Form 742C, Physical Inventory Listing.''

DATES: Submit comments by December 13, 2017.

ADDRESSES: Submit comments directly to the OMB reviewer at: Brandon DeBruhl, Desk Officer, Office of Information and Regulatory Affairs (3150–0003, 3150–0004, 3150–0057, and 3150–0058), NEOB–10202, Office of Management and Budget, Washington, DC 20503; telephone: 202–395–0710, email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0174 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0174. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2016–0174.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-

available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* A copy of the collection of information and related instructions may be obtained without charge by accessing the following ADAMS Accession No. ML16252A183. Guidance documents are available for the Forms as follows: NUREG/BR–0006, Revision 7 (ADAMS Accession No. ML111740924), and NUREG/BR–0007 (ADAMS Accession No. ML090120288). The supporting statements for each DOE/NRC Form and the Forms themselves are available as follows: DOE/NRC Form 740M, ''Concise Note'' (ADAMS Accession Nos. ML17009A233 and ML16252A189); DOE/NRC Form 741, ''Nuclear Material Transaction Report'' (ADAMS Accession Nos. ML17009A234 and ML16252A191); DOE/NRC Form 742, ''Material Balance Report'' (ADAMS Accession Nos. ML17009A235 and ML16252A192); and DOE/NRC Form 742C, ''Physical Inventory Listing'' (ADAMS Accession Nos. ML17009A236 and ML16252A193).

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *http://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a revision of a collection of information to OMB for review entitled, ''DOE/NRC Form 740M, Concise Note; DOE/NRC Form 741, Nuclear Material Transaction Report; DOE/NRC Form 742, Material Balance Report; and DOE/NRC Form 742C, Physical Inventory Listing.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on October 28, 2016, (81 FR 75167).

1. *The title of the information collection:* DOE/NRC Form 740M, Concise Note; DOE/NRC Form 741, Nuclear Material Transaction Report; DOE/NRC Form 742, Material Balance Report; and DOE/NRC Form 742C, Physical Inventory Listing.

2. *OMB approval numbers:*
DOE/NRC Form 740M: 3150–0057.
DOE/NRC Form 741: 3150–0003.
DOE/NRC Form 742: 3150–0004.
DOE/NRC Form 742C: 3150–0058.

3. *Type of submission:* Revision.

4. *The form number if applicable:* DOE/NRC Forms 740M, 741, 742, and 742C.

5. *How often the collection is required or requested:* DOE/NRC Form 741, Nuclear Material Transaction Reports will be collected whenever nuclear material is shipped or received into the Material Balance Area; DOE/NRC Form 742, Material Balance Report will be collected on an annual basis; DOE/NRC Form 742C, Physical Inventory Listing will be collected on an annual basis; DOE/NRC Form 740M, Concise Note Forms are used when needed.

6. *Who will be required or asked to respond:* Persons licensed to possess specified quantities of nuclear material and entities subject to the U.S.-IAEA Caribbean Territories Safeguards Agreement (INFCIRC/366) are required to respond as follows:

Any licensee who ships, receives, or otherwise undergoes an inventory change of nuclear material is required to submit a DOE/NRC Form 741 to document the change. Additional information regarding these transactions shall be submitted through Form 740M, with Safeguards Information identified and handled in accordance with section 73.21 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Requirements for the Protection of Safeguards Information.''

Any licensee who had possessed in the previous reporting period, at any one time and location, nuclear material in a quantity totaling one gram or more shall complete DOE/NRC Form 742. In addition, each licensee, Federal or State, who is authorized to possess, at any one time or location, one kilogram of foreign obligated source material, is required to file with the NRC an annual statement of source material inventory which is foreign obligated.

Any licensee, who had possessed in the previous reporting period, at any one time and location, special nuclear material in a quantity totaling one gram or more shall complete DOE/NRC Form 742C.

7. *The estimated number of annual responses:*
DOE/NRC Form 740M: 175.
DOE/NRC Form 741: 10,000.
DOE/NRC Form 742: 385.
DOE/NRC Form 742C: 385.

8. *The estimated number of annual respondents:*
DOE/NRC Form 740M: 40.
DOE/NRC Form 741: 350.
DOE/NRC Form 742: 385.
DOE/NRC Form 742C: 385.

9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:*
DOE/NRC Form 740M: 131.
DOE/NRC Form 741: 12,500.
DOE/NRC Form 742: 1,310.
DOE/NRC Form 742C: 1,490.

10. *Abstract:* Persons licensed to possess specified quantities of nuclear material currently report inventory and transaction of material to the Nuclear Materials Management and Safeguards System via the DOE/NRC Forms: DOE/NRC Form 740M, Concise Note; DOE/NRC Form 741, Nuclear Material Transaction Report; DOE/NRC Form 742, Material Balance Report; and DOE/NRC Form 742C, Physical Inventory Listing. This collection is being revised to include approximately 25 entities subject to the U.S.-IAEA Caribbean Territories Safeguards Agreement (INFCIRC/366). Part 75 requires licensees to provide reports of nuclear material inventory and flow for entities under the U.S.-IAEA Caribbean Territories Safeguards Agreement (INFCIRC/366), permit inspections by

IAEA inspectors, give immediate notice to the NRC in specified situations involving the possibility of loss of nuclear material, and give notice for imports and exports of specified amounts of nuclear material. These licensees will also follow written material accounting and control procedures. Reporting of transfer and material balance records to the IAEA will be done through the U.S. State system (Nuclear Materials Management and Safeguards System, collected under OMB clearance numbers 3150–0003, 3150–0004, 3150–0057, and 3150–0058.) The NRC needs this information to implement its international obligations under the *U.S.-IAEA Caribbean Territories Safeguards Agreement (INFCIRC/366).*

Dated at Rockville, Maryland, this 6th day of November, 2017.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2017–24480 Filed 11–9–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0216]

Vital Area Access Controls, Protection of Physical Security Equipment, and Key and Lock Controls

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; withdrawal.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is withdrawing Regulatory Guide (RG) 5.65, ''Vital Area Access Controls, Protection of Physical Security Equipment, and Key and Lock Controls,'' dated September 1986. This document is being withdrawn because it is outdated and has been superseded by other NRC guidance, and therefore, no longer provides methods that the NRC staff finds acceptable in future requests or applications for NRC's licensing actions.

DATES: The applicable date of the withdrawal of RG 5.65 is November 13, 2017.

ADDRESSES: Please refer to Docket ID NRC–2017–0216 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Web site*: Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0216. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it available in ADAMS) is provided the first time that a document is referenced. The basis for withdrawal of RG 5.65 is available in ADAMS under Accession No. ML17262A504.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Angela Wu, Office of Nuclear Reactor Regulation, telephone: 301–287–3645, email: *Angela.Wu@nrc.gov,* or Mekonen Bayssie, Office of Nuclear Regulatory Research, telephone: 301–415–1699, email: *Mekonen.Bayssie@nrc.gov.* Both are staff members of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION: The NRC is withdrawing RG 5.65, ''Vital Area Access Controls, Protection of Physical Security Equipment, and Key and Lock Controls,'' because of the following regulatory and technical issues:

• On March 27, 2009 (74 FR 13926), the Commission amended part 73 of title 10 of the *Code of Federal Regulations* (10 CFR), for nuclear power plants to incorporate security requirements that were issued through Commission security orders as a result of the September 11, 2001 terrorist attacks. In addition, the rulemaking added several new requirements to incorporate insights gained from implementation of the security orders, review of site security plans, implementation of the NRC's enhanced baseline inspection program, and the NRC's evaluation of force-on-force exercises. As a result, the guidance in RG 5.65 became outdated.

In addition, more recent regulatory guidance has been issued that supersedes the guidance in RG 5.65.

• The RG 5.66, ''Access Authorization Program for Nuclear Power Plants,'' Rev. 2 (October 2011) supersedes RG 5.65. The RG 5.65 does not address the current requirements of 10 CFR 73.56 with regard to access authorization at nuclear power plants. Instead, RG 5.66 provides an acceptable approach by which licensees can establish and implement an access authorization program for granting unescorted access to protected and vital areas of a nuclear power plant.

• The RG 5.76, ''Physical Protection at Nuclear Power Reactors'' (July 2009), which was issued to facilitate implementation of the new 10 CFR part 73 rule in 2009, supersedes RG 5.65. Specifically, RG 5.65 contains duplicative or outdated discussions regarding protection of security equipment, vital and protected area transients, delays, barriers, underground pathways, power, escort, ingress and egress, record keeping, and review/audit requirements.

• The RG 5.12, ''General Use of Locks in the Protection and Control of: Facilities, Radioactive Materials, Classified Information, Classified Matter, and Safeguards Information,'' Rev. 1 (October 2016), supersedes RG 5.65. Regarding keys and locks, the guidance offered in RG 5.65 is brief and limited to two paragraphs, discussing the requirement and frequency to change and rotate keys, locks, and combinations. The same information is discussed in much greater detail in RG 5.12.

• The RG 5.74, ''Managing the Safety/Security Interface,'' Rev. 1 (April 2015), supersedes RG 5.65. With regard to managing the safety and security interface, RG 5.65 provides only brief guidance (one paragraph) on the cross training of roles, responsibilities, and general practices of the safety and security organizations as a mechanism to reduce interface problems. The RG 5.74 provides more detailed guidance for training to aid the interface between safety and security organizations.

II. Further Information

The withdrawal of RG 5.65 does not alter any prior or existing NRC licensing approval or the acceptability of licensee commitments made regarding the withdrawn guidance. Although RG 5.65 is withdrawn, current licensees referencing this RG may continue to do so, and withdrawal does not affect any existing licenses or agreements. However, by withdrawing RG 5.65, the NRC no longer approves use of the

guidance in future requests or applications for NRC's licensing actions.

Dated at Rockville, Maryland, this 6th day of November, 2017.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2017–24484 Filed 11–9–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Regulatory Policies & Practices; Notice of Meeting

The ACRS Subcommittee on Regulatory Policies and Practices will hold a meeting on November 15, 2017, at 11545 Rockville Pike, Room T–2B1, Rockville, Maryland 20852.

This meeting will be open to public attendance. The agenda for the subject meeting shall be as follows:

Wednesday, November 15, 2017—8:30 a.m. Until 12:00 p.m.

The Subcommittee will review the Early Site Permit for Clinch River and will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Quynh Nguyen (Telephone 301–415–5844 or Email *Quynh.Nguyen@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 4, 2017 (82 FR 46312).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, Maryland 20852. After registering with Security, please contact Mr. Theron Brown (Telephone 301–415–6207) to be escorted to the meeting room.

Dated: October 31, 2017.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2017–24433 Filed 11–9–17; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Form N–54C; SEC File No. 270–184, OMB Control No. 3235–0236

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Certain investment companies can elect to be regulated as business development companies, as defined in section 2(a)(48) of the Investment Company Act of 1940 (''Investment Company Act''), under sections 55 through 65 of the Investment Company Act. Under section 54(a) of the Investment Company Act,[1] any company defined in section 2(a)(48)(A) and (B) of the Investment Company Act may, if it meets certain enumerated eligibility requirements, elect to be subject to the provisions of Sections 55 through 65 of the Investment Company Act by filing with the Commission a notification of election. Under section 54(c) of the Investment Company Act,[2] any business development company may voluntarily withdraw its election under section 54(a) of the Investment Company Act by filing a notice of withdrawal of election with the Commission. The Commission has adopted Form N–54C as the form for the notification of withdrawal of election to be subject to Sections 55 through 65 of the Investment Company Act. The purpose of Form N–54C is to notify the Commission that the business development company withdraws its election to be subject to Sections 55 through 65 of the Investment Company Act.

The Commission estimates that on average approximately four business development companies file notifications on Form N–54C each year. Each of those business development companies need only make a single filing of Form N–54C. The Commission further estimates that this information collection imposes a burden of one hour, resulting in a total annual burden of four hours. Based on the estimated wage rate, the total cost to the business development company industry of the hour burden for complying with Form N–54C would be approximately $1,380.[3]

The collection of information under Form N–54C is mandatory. The information provided by the form is not kept confidential. 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 control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the

[1] 15 U.S.C. 80a–53(a).

[2] 15 U.S.C. 80a–53(c).

[3] The industry burden is calculated by multiplying the total annual hour burden to prepare Form N–54C (four) by the estimated hourly wage rate of $345 for a compliance attorney or other business development company employee with similar duties and responsibilities. The estimated wage figure is based on published rates for compliance attorneys from the Securities Industry and Financial Markets Association's Report on Management & Professional Earnings in the Securities Industry 2013, modified by Commission staff to account for an 1800 hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead, yielding an effective hourly rate of $1,380.

Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: November 7, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24486 Filed 11–9–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32896; 812–14801]

CBOE Vest Financial, LLC, et al.

November 7, 2017.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested order would permit (a) actively-managed series of certain open-end management investment companies (''Funds'') to issue shares redeemable in large aggregations only (''Creation Units''); (b) secondary market transactions in Fund shares to occur at negotiated market prices rather than at net asset value (''NAV''); (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of shares for redemption; (d) certain affiliated persons of a Fund to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the Funds (''Funds of Funds'') to acquire shares of the Funds; and (f) certain Funds (''Feeder Funds'') to create and redeem Creation Units in-kind in a master-feeder structure.

APPLICANTS: CBOE Vest Financial, LLC (the ''Initial Adviser''), a Delaware limited liability company registered as an investment adviser under the Investment Advisers Act of 1940, ETF Series Solutions (the ''Trust''), a Delaware statutory trust registered under the Act as an open-end management investment company with multiple series.

FILING DATES: The application was filed on July 18, 2017 and amended on October 19, 2017.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 1, 2017, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: W. John McGuire, Esq., Morgan, Lewis & Bockius LLP, 1111 Pennsylvania Avenue NW., Washington, DC 20004–2541 and Michael D. Barolsky, Esq., U.S. Bancorp Fund Services, LLC, 615 E. Michigan Street, Milwaukee, WI 53202.

FOR FURTHER INFORMATION CONTACT: Brad Gude, Senior Counsel, at (202) 551–5590, or Robert H. Shapiro, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. Applicants request an order that would allow Funds to operate as actively-managed exchange traded funds (''ETFs'').[1] Fund shares will be purchased and redeemed at their NAV in Creation Units only. All orders to purchase Creation Units and all redemption requests will be placed by or through an ''Authorized Participant'' which will have signed a participant agreement with the Distributor. Shares will be listed and traded individually on a national securities exchange, where share prices will be based on the current bid/offer market. Certain Funds may operate as Feeder Funds in a master-feeder structure. Any order granting the requested relief would be subject to the terms and conditions stated in the application.

2. Each Fund will consist of a portfolio of securities and other assets and investment positions (''Portfolio Instruments''). Each Fund will disclose on its Web site the identities and quantities of the Portfolio Instruments that will form the basis for the Fund's calculation of NAV at the end of the day.

3. Shares will be purchased and redeemed in Creation Units only and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified in the application, purchasers will be required to purchase Creation Units by depositing specified instruments (''Deposit Instruments''), and shareholders redeeming their shares will receive specified instruments (''Redemption Instruments''). The Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund's portfolio (including cash positions) except as specified in the application.

4. Because shares will not be individually redeemable, applicants request an exemption from section 5(a)(1) and section 2(a)(32) of the Act that would permit the Funds to register as open-end management investment companies and issue shares that are redeemable in Creation Units only.

[1] Applicants request that the order apply to the new series of the Trust as well as to additional series of the Trust and any other open-end management investment company or series thereof that currently exist or that may be created in the future (each, included in the term ''Fund''), each of which will operate as an actively-managed ETF. Any Fund will (a) be advised by the Initial Adviser or an entity controlling, controlled by, or under common control with the Initial Adviser (each such entity and any successor thereto is included in the term ''Adviser'') and (b) comply with the terms and conditions of the application. For purposes of the requested Order, the term ''successor'' is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

5. Applicants also request an exemption from section 22(d) of the Act and rule 22c–1 under the Act as secondary market trading in shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. Applicants state that (a) secondary market trading in shares does not involve a Fund as a party and will not result in dilution of an investment in shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants represent that share market prices will be disciplined by arbitrage opportunities, which should prevent shares from trading at a material discount or premium from NAV.

6. With respect to Funds that hold non-U.S. Portfolio Instruments and that effect creations and redemptions of Creation Units in kind, applicants request relief from the requirement imposed by section 22(e) in order to allow such Funds to pay redemption proceeds within fifteen calendar days following the tender of Creation Units for redemption. Applicants assert that the requested relief would not be inconsistent with the spirit and intent of section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds.

7. Applicants request an exemption to permit Funds of Funds to acquire Fund shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter for the Funds, and/or any broker or dealer registered under the Exchange Act, to sell shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act. The application's terms and conditions are designed to, among other things, help prevent any potential (i) undue influence over a Fund through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A) and (B) of the Act.

8. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act to permit persons that are affiliated persons, or second-tier affiliates, of the Funds, solely by virtue of certain ownership interests, to effectuate purchases and redemptions in-kind. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions of Creation Units will be the same for all purchases and redemptions and Deposit Instruments and Redemption Instruments will be valued in the same manner as those Portfolio Instruments currently held by the Funds. Applicants also seek relief from the prohibitions on affiliated transactions in section 17(a) to permit a Fund to sell its shares to and redeem its shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.[2] The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the policies of the Fund of Funds and will be based on the NAVs of the Funds.

9. Applicants also request relief to permit a Feeder Fund to acquire shares of another registered investment company managed by the Adviser having substantially the same investment objectives as the Feeder Fund (''Master Fund'') beyond the limitations in section 12(d)(1)(A) and permit the Master Fund, and any principal underwriter for the Master Fund, to sell shares of the Master Fund to the Feeder Fund beyond the limitations in section 12(d)(1)(B).

10. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24487 Filed 11–9–17; 8:45 am]

BILLING CODE 8011–01–P

[2] The requested relief would apply to direct sales of shares in Creation Units by a Fund to a Fund of Funds and redemptions of those shares. Applicants, moreover, are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an Affiliated Person, or a Second-Tier Affiliate, of a Fund of Funds because an Adviser or an entity controlling, controlled by or under common control with an Adviser provides investment advisory services to that Fund of Funds.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82019; File No. SR–Phlx–2017–91]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Pricing Schedule Section II, Entitled Multiply Listed Options Fees

November 6, 2017.

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 November 1, 2017, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, 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 amend the Pricing Schedule, Section II, entitled ''Multiply Listed Options Fees,'' [3] as further discussed below.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] This includes options overlying equities, ETFs, ETNs and indexes which are multiply listed.

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 purpose of the proposed rule change is to amend Section II of the Exchange's Pricing Schedule to increase the assessment for select Firm [4] electronic simple orders.

As set forth in Section II of the Pricing Schedule, the Exchange currently charges a Penny Pilot Options Transaction Charge for electronic simple orders that is $0.48 per contract for Professional,[5] Broker-Dealer [6] and Firm orders, $0.22 per contract for Specialist [7] and Market Maker [8] orders, and $0.00 for Customer [9] orders. In addition, the Exchange charges a reduced Penny Pilot Options Transaction Charge for Firm electronic simple orders in AAPL, BAC, EEM, FB, FXI, IWM, QQQ, TWTR, VXX and XLF (hereinafter, ''Select Symbols'') that is $0.37 per contract (reduced from $0.48 per contract).[10] The reduced fee for Firm electronic simple orders in Select Symbols (such reduced fee, the ''Select Firm Fee'') is to incentivize Firms to transact more volume in Select Symbols, thereby attracting more order flow to the Exchange.

The Exchange now proposes to increase the $0.37 per contract Select Firm Fee to raise revenue for the Exchange and help defray costs. As proposed, note 1 in Section II of the Pricing Schedule will read, ''Firm electronic simple orders in AAPL, BAC, EEM, FB, FXI, IWM, QQQ, TWTR, VXX and XLF will be assessed $0.45 per contract.''

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[12] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes its proposal to increase the Select Firm Fee from $0.37 to $0.45 per contract is reasonable because the proposed increase will help defray costs, and remains lower than the $0.48 per contract Penny Pilot Options Transaction Charge assessed to all other Firm electronic simple orders.[13] Furthermore, the Exchange notes that the proposed fee remains competitive with the fees of another options market.[14] Accordingly, the Exchange believes that the proposed $0.45 per contract fee for Firm electronic simple orders in Select Symbols, which represent high volume Penny Pilot options listed on the Exchange, will continue to be competitive and attract order flow to the Exchange, to the benefit of all market participants.

In addition, the Exchange believes the proposed $0.45 per contract Select Firm Fee is equitable and not unfairly discriminatory because the Exchange will apply the same fee to all similarly situated members. For the reasons discussed above, the proposed fee provides an incentive for Firms to transact order flow on the Exchange, which order flow brings increased liquidity to the Exchange for the benefit of all Exchange participants. To the extent the purpose of the proposed Select Firm Fee is achieved, all market participants should benefit from the improved market liquidity.

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 not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, the Exchange believes that the proposed Select Firm Fee remains competitive and will continue to attract order flow to the Exchange. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed fee changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or 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 Act.[15]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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

[4] The term ''Firm'' applies to any transaction that is identified by a member or member organization for clearing in the Firm range at OCC.

[5] The term ''Professional'' applies to transactions for the accounts of Professionals, as defined in Exchange Rule 1000(b)(14) means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Pricing Schedule, Preface.

[6] The term ''Broker-Dealer'' applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category. *See* Pricing Schedule, Preface.

[7] The term ''Specialist'' applies to transactions for the account of a Specialist (as defined in Exchange Rule 1020(a)). A Specialist is an Exchange member who is registered as an options specialist pursuant to Rule 1020(a). An options Specialist includes a Remote Specialist which is defined as an options specialist in one or more classes that does not have a physical presence on an Exchange floor and is approved by the Exchange pursuant to Rule 501. *See* Pricing Schedule, Preface.

[8] For purposes of the Pricing Schedule, the term ''Market Maker'' will be utilized to describe the fees and rebates applicable to Registered Options Traders (as defined in Exchange Rule 1014(b)), Streaming Quote Traders (as defined in Exchange Rule 1014(b)(ii)(A)) and Remote Streaming Quote Traders (as defined in Exchange Rule 1014(b)(ii)(B)). *See* Pricing Schedule, Preface.

[9] The term ''Customer'' applies to any transaction that is identified by a member or member organization for clearing in the Customer range at The Options Clearing Corporation (''OCC'') which is not for the account of a broker or dealer or for the account of a ''Professional'' (as that term is defined in Rule 1000(b)(14)). *See* Pricing Schedule, Preface.

[10] *See* note 1 in Section II of the Pricing Schedule. Select symbols represent high volume Penny Pilot options listed on the Exchange.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4) and (5).

[13] *See* Pricing Schedule, Section II.

[14] *See, e.g.,* MIAX Options Fee Schedule at: *https://www.miaxoptions.com/sites/default/files/fee_schedule-files/MIAX_Options_Fee_Schedule_10112017.pdf.*

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2017–91 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2017–91. 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 Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2017–91 and should be submitted on or before December 4, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24439 Filed 11–9–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82017; File No. SR–PEARL–2017–36]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX PEARL Fee Schedule

November 6, 2017.

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 November 2, 2017, MIAX PEARL, LLC (''MIAX PEARL'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III 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 is filing a proposal to amend the MIAX PEARL Fee Schedule (the ''Fee Schedule'').

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX PEARL's principal office, and at the Commission's Public Reference Room.

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 make a number of non-substantive, technical corrections to its routing fee table set forth in Section 1(b) of the Fee Schedule to reflect recent corporate name changes to some of the options exchanges listed in the table.

As a result of recent exchange consolidation and corporate re-branding, some options exchanges have changed their names. The names of all options exchanges are set forth in the Exchange's routing fee table set forth in Section 1(b) of the Fee Schedule, which sets forth the fees for customer orders that are routed to those options exchanges for execution. Accordingly, the Exchange proposes to update its routing fee table set forth in Section 1(b) of the Fee Schedule to reflect those recent exchange name changes. No other changes are proposed to the routing fee table. Accordingly, as amended, the routing fee table shall be as follows:

(b) Fees and Rebates for Customer Orders Routed to Another Options Exchange MIAX PEARL will assess a Routing Fee to market participants on all orders routed to and executed on an away market as set forth in the table below.

Description	Fees
Routed, Priority Customer, Penny Pilot, to: NYSE American, BOX, Cboe, Cboe EDGX Options , Nasdaq MRX, MIAX OPTIONS, Nasdaq PHLX (except SPY), Nasdaq BX Options	$0.15
Routed, Priority Customer, Penny Pilot, to: NYSE Arca Options, Cboe BZX Options, Cboe C2, Nasdaq GEMX, Nasdaq ISE, NOM, Nasdaq PHLX (SPY only)	0.65
Routed, Priority Customer, Non-Penny Pilot, to: NYSE American, BOX, Cboe, Cboe EDGX Options, Nasdaq ISE, Nasdaq MRX, MIAX OPTIONS, Nasdaq PHLX, Nasdaq BX Options	0.15
Routed, Priority Customer, Non-Penny Pilot, to: NYSE Arca Options, Cboe BZX Options, Cboe C2, Nasdaq GEMX, NOM	0.97
Routed, Public Customer that is not a Priority Customer, Penny Pilot, to: NYSE American, NYSE Arca Options, Cboe BZX Options, BOX, Cboe, Cboe C2, Cboe EDGX Options, Nasdaq GEMX, Nasdaq ISE, Nasdaq MRX, MIAX OPTIONS, NOM, Nasdaq PHLX, Nasdaq BX Options	0.65

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Description	Fees
Routed, Public Customer that is not a Priority Customer, Non-Penny Pilot, to: NYSE American	0.65
Routed, Public Customer that is not a Priority Customer, Non-Penny Pilot, to: NYSE Arca Options, Cboe BZX Options, Cboe C2, Nasdaq GEMX, Nasdaq MRX, Nasdaq BX Options	1.20
Routed (Public Customer that is not a Priority Customer), Non-Penny Pilot, to: BOX, Cboe, Cboe EDGX Options, Nasdaq ISE, MIAX OPTIONS, NOM, Nasdaq PHLX	0.97

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [3] in general, and furthers the objectives of Section 6(b)(4) of the Act,[4] in that it is an equitable allocation of reasonable fees and other charges among Exchange members and other persons using its facilities, and 6(b)(5) of the Act,[5] 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 mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes the proposed changes to update its routing fee table set forth in Section 1(b) of the Fee Schedule to reflect recent exchange name changes promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule change makes non-substantive technical corrections and updates the Exchange's Fee Schedule. None of the name changes alter the application of any fees or rebates on the Fee Schedule. As such, the proposed amendments would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national exchange system. In particular, the Exchange believes that the proposed changes will provide greater clarity to Members and the public regarding the Exchange's Rules. It is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

MIAX PEARL does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes to update its routing fee table set forth in Section 1(b) of the Fee Schedule to reflect recent exchange name changes will have no impact on competition as they are not designed to address any competitive issues but rather are designed to make non-substantive technical corrections and update the Exchange's Fee Schedule.

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 Act,[6] and Rule 19b–4(f)(2) [7] 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 shall institute proceedings to determine whether the proposed rule 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–PEARL–2017–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–PEARL–2017–36. 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 Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PEARL–2017–36 and should be submitted on or before December 4, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24437 Filed 11–9–17; 8:45 am]

BILLING CODE 8011–01–P

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(4).

[5] 15 U.S.C. 78f(b)(1) and (b)(5).

[6] 15 U.S.C. 78s(b)(3)(A)(ii).

[7] 17 CFR 240.19b–4(f)(2).

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82018; File No. SR–NYSE–2017–55]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List Relating to Co-Location Services To Reflect the Name Change of a Third Party Data Feed

November 6, 2017.

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 25, 2017, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III 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 amend its Price List relating to co-location services to reflect the name change of a third party data feed. The Exchange proposes to implement the proposed change on November 1, 2017. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

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.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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 its Price List relating to co-location [4] services to reflect the name change of a third party data feed. The Exchange proposes to implement the proposed change on November 1, 2017.

The co-location services that the Exchange offers Users [5] include connectivity to third party data feeds from third party markets and other content service providers (''Third Party Data Feeds'').[6] The list of Third Party Data Feeds is set forth in the Price List, and includes the NYSE Global Index.[7]

The name of NYSE Global Index is changing to ''ICE Data Global Index.'' The Exchange accordingly proposes to amend the Price List to reflect the change. The Exchange does not propose to change the applicable monthly recurring connectivity fee. The Exchange proposes the following changes:

- In the third sentence under ''Connectivity to Third Party Data Feeds,'' the reference to ''NYSE Global Index'' would be changed to ''ICE Data Global Index.''
- In the table under ''Connectivity to Third Party Data Feeds,'' the line listing ''NYSE Global Index'' and the related $100 monthly recurring connectivity fee would be deleted, and a new line added, as follows (additions italicized):

Third Party Data Feed	Monthly recurring connectivity fee per Third Party Data Feed
Global OTC	$100
ICE Data Global Index	*100*
ICE Data Services Consolidated Feed ≤ 100 Mb	200

General

As is the case with all Exchange co-location arrangements, (i) neither a User nor any of the User's customers would be permitted to submit orders directly to the Exchange unless such User or customer is a member organization, a Sponsored Participant or an agent thereof (*e.g.,* a service bureau providing order entry services); (ii) use of the co-location services proposed herein would be completely voluntary and available to all Users on a non-discriminatory basis; [8] and (iii) a User would only incur one charge for the particular co-location service described herein, regardless of whether the User connects only to the Exchange or to the Exchange and one or both the Affiliate SROs.[9]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[11] 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 regulating, clearing, settling, processing information with respect to,

[4] The Exchange initially filed rule changes relating to its co-location services with the Commission in 2010. *See* Securities Exchange Act Release No. 62960 (September 21, 2010), 75 FR 59310 (September 27, 2010) (SR–NYSE–2010–56). The Exchange operates a data center in Mahwah, New Jersey (the ''data center'') from which it provides co-location services to Users.

[5] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR–NYSE–2015–40). As specified in the Price List, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates NYSE American LLC (''NYSE American'') and NYSE Arca, Inc. (''NYSE Arca'' and, together with NYSE American, the ''Affiliate SROs''). *See* Securities Exchange Act Release No. 70206 (August 15, 2013), 78 FR 51765 (August 21, 2013) (SR–NYSE–2013–59).

[6] *See* Securities Exchange Act Release No. 80311 (March 24, 2017), 82 FR 15741 (March 30, 2017) (SR–NYSE–2016–45).

[7] The NYSE Global Index feed includes index and exchange traded product valuations data, with data drawn from the Exchange, the Affiliate SROS, and third party exchanges. Because it includes third party data, the NYSE Global Index feed is considered a Third Party Data Feed. *See id.,* at 15749.

[8] As is currently the case, Users that receive co-location services from the Exchange will not receive any means of access to the Exchange's trading and execution systems that is separate from, or superior to, that of other Users. In this regard, all orders sent to the Exchange enter the Exchange's trading and execution systems through the same order gateway, regardless of whether the sender is co-located in the data center or not. In addition, co-located Users do not receive any market data or data service product that is not available to all Users, although Users that receive co-location services normally would expect reduced latencies in sending orders to, and receiving market data from, the Exchange.

[9] *See* SR–NYSE–2013–59, *supra* note 5 at 51766. The Affiliate SROs have also submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSEAmer–2017–28 and SR–NYSEArca–2017–124.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The non-substantive change proposed is intended solely to reflect the name change of ''NYSE Global Index'' to ''ICE Data Global Index.'' The proposed rule change, therefore would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because it would update the Price List to reflect the name change, increasing the clarity and transparency of the Exchange's rules.

For the reasons above, the proposed changes would not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[12] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because it is solely intended to reflect the name change of ''NYSE Global Index'' to ''ICE Data Global Index.'' No other change is proposed.

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 foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[13] of the Act and subparagraph (f)(2) of Rule 19b–4[14] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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)[15] 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2017–55 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–NYSE–2017–55. 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 Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2017–55 and should be submitted on or before December 4, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24438 Filed 11–9–17; 8:45 am]

BILLING CODE 8011–01–P

[12] 15 U.S.C. 78f(b)(8).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82020; File No. SR–NYSE–2017–56]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Certain of Its Listing Fees

November 6, 2017.

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 30, 2017, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III 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 amend certain of its listing fees. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 Chapter Nine of the Manual to amend certain of its listing fee provisions. The amended fees will take effect in the 2018 calendar year. The following are the proposed fee increases:

- For certain listed securities, the per share fee would increase from $0.00105 per share to $0.00108.[3]
- The minimum annual fee applicable to the primary class of common shares (including Equity Investment Tracking Stock) or the primary class of preferred stock (if no class of common shares is listed) listed under Section 703.05 [sic] would increase from $59,500 to $65,000.
- The minimum annual fee applicable to structured products listed under Section 703.19 [sic] would increase from $20,000 to $25,000.
- The initial and annual listing fees for debt listed under Section 102.03 and 103.05 of NYSE equity issuers and affiliated companies would each increase from $20,000 to $25,000.
- The initial and annual listing fees for debt listed under Section 102.03 and 103.05 of companies other than NYSE equity issuers and affiliated companies would increase from $40,000 to $45,000.[4]
- The initial and annual listing fees for securities (including short-term securities) that list under the debt standard in Section 703.19 and trade on NYSE Bonds would increase from $20,000 to $25,000.

As described below, the Exchange proposes to make the aforementioned fee increases to better reflect the Exchange's costs related to listing the above-referenced types of securities and the corresponding value of such listing to issuers.

The Exchange also proposes to remove a number of references throughout Chapter Nine to (i) fees that are no longer applicable as they were superseded by new fee rates specified in the rule text and (ii) effectiveness dates of revised fee levels with respect to which the effective date has now passed.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(4)[6] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(5) of the Act,[7] in that it is 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 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 and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that it is reasonable to amend Chapter Nine of the Manual to increase the various listing fees as set forth above. In that regard, the Exchange notes that it continues to improve and increase the services it provides to listed companies. These improvements include the continued development and enhancement of an interactive web-based platform designed to improve communication between the Exchange and listed companies, the availability to listed companies of the Exchange's new state-of-the-art conference facilities at 11 Wall Street, and continued development and content in an investor relations tool available to all listed companies which provides companies with information enabling them to better understand the trading and ownership of their securities.

The Exchange believes that the proposed fee increases are equitably allocated because the per share fee increase will be the same for all issuers on the Exchange. Therefore, the proposed fee increases will not be unfairly discriminatory towards any individual issuer. The Exchange believes it is consistent with Section 6(b)(5) of the Act to apply different fees to bonds of companies that do not have their equity securities listed on the NYSE than to companies with NYSE-listed equity securities and their affiliates, as there is a greater regulatory and administrative burden associated with listing bonds of companies with which the Exchange does not otherwise have a regulatory or listing relationship.

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 proposed rule change is designed to ensure that the fees charged by the Exchange accurately reflect the services provided and benefits realized by listed companies. The market for listing services is extremely competitive. Each listing exchange has a different fee schedule that applies to issuers seeking to list securities on its exchange. Issuers have the option to list their securities on these alternative venues based on the fees charged and the value provided by each listing. Because issuers have a choice to list their securities on a different national securities exchange, the Exchange does not believe that the proposed fee changes impose a burden on competition.

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 foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[8] of the Act and subparagraph (f)(2) of Rule 19b–4[9] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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

[3] The affected securities are as follows: Primary class of common shares (including Equity Investment Tracking Stock); each additional class of common shares (including tracking stock); primary class of preferred stock (if no class of common shares is listed); each additional class of preferred stock (whether primary class is common stock or preferred stock); each class of warrants; structured products listed under Section 703.19 [sic]; and short term securities.

[4] Domestic debt of issuers not subject to registration under the Act is exempt from all listing fees.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(2).

the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [10] 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2017–56 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2017–56. 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 Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2017–56, and should be submitted on or before December 4, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24440 Filed 11–9–17; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(2)(B).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82016; File No. SR–NYSEARCA–2017–124]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Options Fees and Charges Schedule and the NYSE Arca Equities Fees and Charges Schedule Relating to Co-Location Services To Reflect the Name Change of a Third Party Data Feed

November 6, 2017.

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 25, 2017, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III 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 amend the NYSE Arca Options Fees and Charges schedule and the NYSE Arca Equities Fees and Charges schedule (together, the ''Fee Schedules'') relating to co-location services to reflect the name change of a third party data feed. The Exchange proposes to implement the proposed change on November 1, 2017. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[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 the Fee Schedules relating to co-location [4] services to reflect the name change of a third party data feed. The Exchange proposes to implement the proposed change on November 1, 2017.

The co-location services that the Exchange offers Users [5] include connectivity to third party data feeds from third party markets and other content service providers (''Third Party Data Feeds'').[6] The list of Third Party Data Feeds is set forth in the Fee Schedules, and includes the NYSE Global Index.[7]

The name of NYSE Global Index is changing to ''ICE Data Global Index.''

[4] The Exchange initially filed rule changes relating to its co-location services with the Commission in 2010. *See* Securities Exchange Act Release No. 63275 (November 8, 2010), 75 FR 70048 (November 16, 2010) (SR–NYSEArca–2010–100). The Exchange operates a data center in Mahwah, New Jersey (the ''data center'') from which it provides co-location services to Users.

[5] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76010 (September 29, 2015), 80 FR 60197 (October 5, 2015) (SR–NYSEArca–2015–82). As specified in the Price List, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates New York Stock Exchange LLC (''NYSE LLC'') and NYSE American LLC (''NYSE American'' and, together with NYSE LLC, the ''Affiliate SROs''). *See* Securities Exchange Act Release No. 70173 (August 13, 2013), 78 FR 50459 (August 19, 2013) (SR–NYSEArca–2013–80).

[6] *See* Securities Exchange Act Release No. 80310 (March 24, 2017), 82 FR 15763 (March 30, 2017) (SR–NYSEArca–2016–89).

[7] The NYSE Global Index feed includes index and exchange traded product valuations data, with data drawn from the Exchange, the Affiliate SROS, and third party exchanges. Because it includes third party data, the NYSE Global Index feed is considered a Third Party Data Feed. *See id.,* at 15771.

The Exchange accordingly proposes to amend the Fee Schedules to reflect the change. The Exchange does not propose to change the applicable monthly recurring connectivity fee. The Exchange proposes the following changes:

• In the third sentence under ''Connectivity to Third Party Data Feeds,'' the reference to ''NYSE Global Index'' would be changed to ''ICE Data Global Index.''

• In the table under ''Connectivity to Third Party Data Feeds,'' the line listing ''NYSE Global Index'' and the related $100 monthly recurring connectivity fee would be deleted, and a new line added, as follows (additions italicized):

Third Party Data Feed	Monthly recurring connectivity fee per Third Party Data Feed
Global OTC	$100
ICE Data Global Index	*100*
ICE Data Services Consolidated Feed ≤ 100 Mb	200

General

As is the case with all Exchange co-location arrangements, (i) neither a User nor any of the User's customers would be permitted to submit orders directly to the Exchange unless such User or customer is a member organization, a Sponsored Participant or an agent thereof (*e.g.,* a service bureau providing order entry services); (ii) use of the co-location services proposed herein would be completely voluntary and available to all Users on a non-discriminatory basis; [8] and (iii) a User would only incur one charge for the particular co-location service described herein, regardless of whether the User connects only to the Exchange or to the Exchange and one or both the Affiliate SROs.[9]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[11] 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The non-substantive change proposed is intended solely to reflect the name change of ''NYSE Global Index'' to ''ICE Data Global Index.'' The proposed rule change, therefore would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because it would update the Fee Schedules to reflect the name change, increasing the clarity and transparency of the Exchange's rules.

For the reasons above, the proposed changes would not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[12] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because it is solely intended to reflect the name change of ''NYSE Global Index'' to ''ICE Data Global Index.'' No other change is proposed.

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 foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [13] of the Act and subparagraph (f)(2) of Rule 19b–4 [14] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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) [15] 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 (*http://www.sec.gov/rules/sro.shtml*); or

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2017–124 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–NYSEARCA–2017–124. 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

[8] As is currently the case, Users that receive co-location services from the Exchange will not receive any means of access to the Exchange's trading and execution systems that is separate from, or superior to, that of other Users. In this regard, all orders sent to the Exchange enter the Exchange's trading and execution systems through the same order gateway, regardless of whether the sender is co-located in the data center or not. In addition, co-located Users do not receive any market data or data service product that is not available to all Users, although Users that receive co-location services normally would expect reduced latencies in sending orders to, and receiving market data from, the Exchange.

[9] *See* 78 FR 50459, *supra* note 5, at 50459. The Affiliate SROs have also submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2017–55 and SR–NYSEAMER–2017–28.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78f(b)(8).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

[15] 15 U.S.C. 78s(b)(2)(B).

Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2017–124 and should be submitted on or before December 4, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24442 Filed 11–9–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82021; File No. SR–NYSEAMER–2017–28]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend the NYSE American Equities Price List and the NYSE American Options Fee Schedule Relating to Co-Location Services To Reflect the Name Change of a Third Party Data Feed

November 6, 2017.

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 25, 2017, NYSE American LLC (''Exchange'' or ''NYSE American'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III 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 amend the NYSE American Equities Price List (''Price List'') and the NYSE American Options Fee Schedule (''Fee Schedule'') relating to co-location services to reflect the name change of a third party data feed. The Exchange proposes to implement the proposed change on November 1, 2017. The proposed change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

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 the Price List and Fee Schedule relating to co-location[4] services to reflect the name change of a third party data feed. The Exchange proposes to implement the proposed change on November 1, 2017.

The co-location services that the Exchange offers Users[5] include connectivity to third party data feeds from third party markets and other content service providers (''Third Party Data Feeds'').[6] The list of Third Party Data Feeds is set forth in the Price List and Fee Schedule, and includes the NYSE Global Index.[7]

The name of NYSE Global Index is changing to ''ICE Data Global Index.'' The Exchange accordingly proposes to amend the Price List and Fee Schedule to reflect the change. The Exchange does not propose to change the applicable monthly recurring connectivity fee. The Exchange proposes the following changes:

- In the third sentence under ''Connectivity to Third Party Data Feeds,'' the reference to ''NYSE Global Index'' would be changed to ''ICE Data Global Index.''
- In the table under ''Connectivity to Third Party Data Feeds,'' the line listing ''NYSE Global Index'' and the related $100 monthly recurring connectivity fee would be deleted, and a new line added, as follows (additions italicized):

Third Party Data Feed	Monthly recurring connectivity fee per Third Party Data Feed
Global OTC	$100
ICE Data Global Index	*100*
ICE Data Services Consolidated Feed ≤ 100 Mb	200

General

As is the case with all Exchange co-location arrangements, (i) neither a User nor any of the User's customers would be permitted to submit orders directly to the Exchange unless such User or customer is a member organization, a Sponsored Participant or an agent thereof (*e.g.,* a service bureau providing

[16] 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] The Exchange initially filed rule changes relating to its co-location services with the Commission in 2010. *See* Securities Exchange Act Release No. 62961 (September 21, 2010), 75 FR 59299 (September 27, 2010) (SR–NYSEAmex–2010–80). The Exchange operates a data center in Mahwah, New Jersey (the ''data center'') from which it provides co-location services to Users.

[5] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76009 (September 29, 2015), 80 FR 60213 (October 5, 2015) (SR–NYSEMKT–2015–67). As specified in the Price List and Fee Schedule, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates New York Stock Exchange LLC (''NYSE LLC'') and NYSE Arca, Inc. (''NYSE Arca'' and, together with NYSE LLC, the ''Affiliate SROs''). *See* Securities Exchange Act Release No. 70176 (August 13, 2013), 78 FR 50471 (August 19, 2013) (SR–NYSEMKT–2013–67).

[6] *See* Securities Exchange Act Release No. 80309 (March 24, 2017), 82 FR 15725 (March 30, 2017) (SR–NYSEMKT–2016–63).

[7] The NYSE Global Index feed includes index and exchange traded product valuations data, with data drawn from the Exchange, the Affiliate SROS, and third party exchanges. Because it includes third party data, the NYSE Global Index feed is considered a Third Party Data Feed. *See id.,* at 15733.

order entry services); (ii) use of the co-location services proposed herein would be completely voluntary and available to all Users on a non-discriminatory basis; [8] and (iii) a User would only incur one charge for the particular co-location service described herein, regardless of whether the User connects only to the Exchange or to the Exchange and one or both the Affiliate SROs.[9]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[11] 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The non-substantive change proposed is intended solely to reflect the name change of ''NYSE Global Index'' to ''ICE Data Global Index.'' The proposed rule change, therefore would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because it would update the Price List and Fee Schedule to reflect the name change, increasing the clarity and transparency of the Exchange's rules.

For the reasons above, the proposed changes would not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[12] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because it is solely intended to reflect the name change of ''NYSE Global Index'' to ''ICE Data Global Index.'' No other change is proposed.

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 foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [13] of the Act and subparagraph (f)(2) of Rule 19b–4 [14] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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) [15] 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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2017–28 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–2017–28. 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 Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2017–28 and should be submitted on or before December 4, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24441 Filed 11–9–17; 8:45 am]

BILLING CODE 8011–01–P

[8] As is currently the case, Users that receive co-location services from the Exchange will not receive any means of access to the Exchange's trading and execution systems that is separate from, or superior to, that of other Users. In this regard, all orders sent to the Exchange enter the Exchange's trading and execution systems through the same order gateway, regardless of whether the sender is co-located in the data center or not. In addition, co-located Users do not receive any market data or data service product that is not available to all Users, although Users that receive co-location services normally would expect reduced latencies in sending orders to, and receiving market data from, the Exchange.

[9] *See* 78 FR 50471, *supra* note 5, at 50471. The Affiliate SROs have also submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2017–55 and SR–NYSEArca–2017–124.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78f(b)(8).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission Office of FOIA Services 100 F Street NE., Washington, DC 20549–2736

Extension:

Rule 17a–7, SEC File No. 270–238, OMB Control No. 3235–0214

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information described below.

Rule 17a–7 (17 CFR 270.17a–7) (the ''rule'') under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (the ''Act'') is entitled ''Exemption of certain purchase or sale transactions between an investment company and certain affiliated persons thereof.'' It provides an exemption from section 17(a) of the Act for purchases and sales of securities between registered investment companies (''funds''), that are affiliated persons (''first-tier affiliates'') or affiliated persons of affiliated persons (''second-tier affiliates''), or between a fund and a first- or second-tier affiliate other than another fund, when the affiliation arises solely because of a common investment adviser, director, or officer. Rule 17a–7 requires funds to keep various records in connection with purchase or sale transactions effected in reliance on the rule. The rule requires the fund's board of directors to establish procedures reasonably designed to ensure that the rule's conditions have been satisfied. The board is also required to determine, at least on a quarterly basis, that all affiliated transactions effected during the preceding quarter in reliance on the rule were made in compliance with these established procedures. If a fund enters into a purchase or sale transaction with an affiliated person, the rule requires the fund to compile and maintain written records of the transaction.[1] The Commission's examination staff uses these records to evaluate for compliance with the rule.

While most funds do not commonly engage in transactions covered by rule 17a–7, the Commission staff estimates that nearly all funds have adopted procedures for complying with the rule.[2] Of the approximately 3,243 currently active funds, the staff estimates that virtually all have already adopted procedures for compliance with rule 17a–7. This is a one-time burden, and the staff therefore does not estimate an ongoing burden related to the policies and procedures requirement of the rule for funds.[3] The staff estimates that there are approximately 97 new funds that register each year, and that each of these funds adopts the relevant policies and procedures. The staff estimates that it takes approximately 4 hours to develop and adopt these policies and procedures. Therefore, the total annual burden related to developing and adopting these policies and procedures would be approximately 388 hours.[4]

Of the 3,243 existing funds, the staff assumes that approximately 25%, (or 811) enter into transactions affected by rule 17a–7 each year (either by the fund directly or through one of the fund's series), and that the same percentage (25%, or 24 funds) of the estimated 97 funds that newly register each year will also enter into these transactions, for a total of 835 [5] companies that are affected by the recordkeeping requirements of rule 17a–7. These funds must keep records of each of these transactions, and the board of directors must quarterly determine that all relevant transactions were made in compliance with the company's policies and procedures. The rule generally imposes a minimal burden of collecting and storing records already generated for other purposes.[6] The staff estimates that the burden related to making these records and for the board to review all transactions would be 3 hours annually for each respondent, (2 hours spent by compliance attorneys and 1 hour spent by the board of directors) [7] or 2,505 total hours each year.[8]

Based on these estimates, the staff estimates the combined total annual burden hours associated with rule 17a–7 is 2,893 hours.[9] The staff also estimates that there are approximately 835 respondents and 6,680 total responses.[10]

The estimates of burden hours are made solely for the purposes of the Paperwork Reduction Act, and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. The collection of information required by rule 17a–7 is necessary to obtain the benefits of the rule. Responses will not be kept confidential. 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 control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: November 7, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24485 Filed 11–9–17; 8:45 am]

BILLING CODE 8011–01–P

[1] The written records are required to set forth a description of the security purchased or sold, the identity of the person on the other side of the transaction, and the information or materials upon which the board of directors' determination that the transaction was in compliance with the procedures was made.

[2] Unless stated otherwise, these estimates are based on conversations with the examination and inspections staff of the Commission and fund representatives.

[3] Based on our reviews and conversations with fund representatives, we understand that funds rarely, if ever, need to make changes to these policies and procedures once adopted, and therefore we do not estimate a paperwork burden for such updates.

[4] This estimate is based on the following calculations: (4 hours × 97 new funds = 388 hours).

[5] This estimate is based on the following calculation: (811 + 24 = 835).

[6] Commission staff believes that rule 17a–7 does not impose any costs associated with record preservation in addition to the costs that funds already incur to comply with the record preservation requirements of rule 31a–2 under the Act. Rule 31a–2 requires companies to preserve certain records for specified periods of time.

[7] The staff estimates that funds that rely on rule 17a–7 annually enter into an average of 8 rule 17a–7 transactions each year. The staff estimates that the compliance attorneys of the companies spend approximately 15 minutes per transaction on this recordkeeping, and the board of directors spends a total of 1 hour annually in determining that all transactions made that year were done in compliance with the company's policies and procedures.

[8] This estimate is based on the following calculation: (3 hours × 835 companies = 2,505 hours).

[9] This estimate is based on the following calculation: (388 hours + 2,505 hours = 2,893 total hours).

[10] This estimate is based on the following calculations: 835 funds that engage in rule 17a–7 transactions × 8 transactions per year = 6,680.

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15370; Oregon Disaster Number OR–00088 Declaration of Economic Injury]

Administrative Declaration of an Economic Injury Disaster for the State of Oregon

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the State of Oregon, dated 10/31/2017.

Incident: Eagle Creek Fire.

Incident Period: 09/02/2017 and continuing.

DATES: Issued on 10/31/2017.

Economic Injury (EIDL) Loan Application Deadline Date: 07/31/2018.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's EIDL declaration, applications for economic injury disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Hood River, Wasco

Contiguous Counties:

Oregon: Clackamas, Gilliam, Jefferson, Marion, Multnomah, Sherman, Wheeler

Washington: Klickitat, Skamania

The Interest Rates are:

	Percent
Businesses and Small Agricultural Cooperatives without Credit Available Elsewhere	3.305
Non-Profit Organizations without Credit Available Elsewhere	2.500

The number assigned to this disaster for economic injury is 153700.

The States which received an EIDL Declaration # are Oregon, Washington.

(Catalog of Federal Domestic Assistance Number 59008)

Linda E. McMahon,

Administrator.

[FR Doc. 2017–24475 Filed 11–9–17; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15374 and #15375; PUERTO RICO Disaster Number PR–00032]

Presidential Declaration of a Major Disaster for Public Assistance Only for the Commonwealth of Puerto Rico

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Puerto Rico (FEMA–4339–DR), dated 11/02/2017.

Incident: Hurricane Maria.

Incident Period: 09/17/2017 and continuing.

DATES: Issued on 11/02/2017.

Physical Loan Application Deadline Date: 01/02/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 08/02/2018.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 11/02/2017, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Municipalities: Adjuntas, Aguada, Aguadilla, Aguas Buenas, Aibonito, Anasco, Arecibo, Arroyo, Barceloneta, Barranquitas, Bayamon, Cabo Rojo, Caguas, Camuy, Canovanas, Carolina, Catano, Cayey, Ceiba, Ciales, Cidra, Coamo, Comerio, Corozal, Culebra, Dorado, Fajardo, Florida, Guanica, Guayama, Guayanilla, Guaynabo, Gurabo, Hatillo, Hormigueros, Humacao, Isabela, Jayuya, Juana Diaz, Juncos, Lajas, Lares, Las Marias, Las Piedras, Loiza, Luquillo, Manati, Maricao, Maunabo, Mayaguez, Moca, Morovis, Naguabo, Naranjito, Orocovis, Patillas, Penuelas, Ponce, Quebradillas, Rincon, Rio Grande, Sabana Grande, Salinas, San German, San Juan, San Lorenzo, San Sebastian, Santa Isabel, Toa Alta, Toa Baja, Trujillo Alto, Utuado, Vega Alta, Vega Baja, Vieques, Villalba, Yabucoa, Yauco

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	2.500
Non-Profit Organizations without Credit Available Elsewhere	2.500
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 153748 and for economic injury is 153750.

(Catalog of Federal Domestic Assistance Number 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2017–24476 Filed 11–9–17; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15322 and #15323; Puerto Rico Disaster Number PR–00031]

Presidential Declaration Amendment of a Major Disaster for the Commonwealth of Puerto Rico

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the Commonwealth of Puerto Rico (FEMA–4339–DR), dated 09/20/2017. *Incident:* Hurricane Maria.

Incident Period: 09/17/2017 and continuing.

DATES: Issued on 11/06/2017.

Physical Loan Application Deadline Date: 03/20/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 06/20/2018.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the Commonwealth of Puerto Rico, dated 09/20/2017, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 03/20/2018.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2017–24478 Filed 11–9–17; 8:45 am]

BILLING CODE 8025–01–P

TENNESSEE VALLEY AUTHORITY

Meeting of the Regional Energy Resource Council

AGENCY: Tennessee Valley Authority (TVA).

ACTION: Notice of meeting.

SUMMARY: The TVA Regional Energy Resource Council (RERC) will hold a meeting on Wednesday, November 29, 2017, to consider various matters related to energy resources in the Tennessee Valley.

The RERC was established to advise TVA on its energy resource activities and the priority to be placed among competing objectives and values. Notice of this meeting is given under the Federal Advisory Committee Act (FACA).

DATES: The public meeting will be held on Wednesday, November 29, 2017, from 8:30 a.m. to 3:30 p.m., EST.

ADDRESSES: The meeting will be held at Hilton Knoxville, 501 West Church Avenue, Knoxville, Tennessee 37902, and will be open to the public. Anyone needing special access or accommodations should let the contact below know at least a week in advance.

FOR FURTHER INFORMATION CONTACT: Barbie Perdue, 865–632–6113, *baperdue@tva.gov.*

SUPPLEMENTARY INFORMATION:

The meeting agenda includes the following:

1. Introductions
2. An overview of TVA's Mission and Scope
3. Presentations regarding TVA's Rates and Finances, TVA's Long Range Energy Planning efforts and Energy Efficiency projects for Low Income Residents
4. Public Comments
5. Council Discussion

The RERC will hear opinions and views of citizens by providing a public comment session starting at 1:15 p.m. EST, lasting up to one hour, on Wednesday, November 29, 2017. Persons wishing to speak are requested to register at the door between 11:00 a.m. and 1:00 p.m., EST, on Wednesday, November 29, 2017, and will be called on during the public comment period. TVA will set time limits for providing oral comments, once registered. Handout materials should be limited to one printed page. Written comments are also invited and may be mailed to the Regional Energy Resource Council, Tennessee Valley Authority, 400 West Summit Hill Drive, WT–9 D, Knoxville, Tennessee 37902.

Dated: November 6, 2017.

Joseph J. Hoagland,

Vice President, Enterprise Relations and Innovation, Tennessee Valley Authority.

[FR Doc. 2017–24499 Filed 11–9–17; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Bureau of the Fiscal Service; Senior Executive Service; Fiscal Service Performance Review Board

AGENCY: Bureau of the Fiscal Service, Treasury.

ACTION: Notice of Appointments to the Fiscal Service Performance Review Board.

SUMMARY: This notice announces the appointment of the members of the Fiscal Service Performance Review Board (PRB) for the Bureau of the Fiscal Service (Fiscal Service). The PRB reviews the performance appraisals of career senior executives who are below the level of Assistant Commissioner/Executive Director and who are not assigned to the Office of the Commissioner in the Fiscal Service. The PRB makes recommendations regarding proposed performance appraisals, ratings, bonuses, pay adjustments, and other appropriate personnel actions.

DATES: Applicable on November 13, 2017.

FOR FURTHER INFORMATION CONTACT: Randy L. Thornton, Chief Human Capital Officer, Bureau of the Fiscal Service, (202) 874–5147.

SUPPLEMENTARY INFORMATION: This Notice announces the appointment of the following primary and alternate members to the Fiscal Service PRB:

Primary Members:

Stephen L. Manning, Deputy Commissioner, Finance & Administration, Fiscal Service

Dara N. Seaman, Assistant Commissioner, Wholesale Securities Services, Fiscal Service

Douglas Anderson, Assistant Commissioner, Shared Services, Fiscal Service

Alternate Member:

John B. Hill, Assistant Commissioner, Financial Innovation & Transformation, Fiscal Service

Authority: 5 U.S.C. Section 4314(c)(4)

Sheryl R. Morrow,

Commissioner, Bureau of the Fiscal Service.

[FR Doc. 2017–24513 Filed 11–9–17; 8:45 am]

BILLING CODE 4810–AS–P

FEDERAL REGISTER

Vol. 82 Monday,
No. 217 November 13, 2017

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 414, 416, and 419
Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 414, 416, and 419

[CMS–1678–FC]

RIN 0938–AT03

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2018 to implement changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

DATES:

Effective date: This final rule with comment period is effective on January 1, 2018, unless otherwise noted.

Comment period: To be assured consideration, comments on the payment classifications assigned to HCPCS codes identified in Addenda B, AA, and BB with the comment indicator ''NI'' and on other areas specified throughout this final rule with comment period must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on December 31, 2017.

ADDRESSES: In commenting, please refer to file code CMS–1678–FC when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1678–FC, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1678–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: (We note that public comments must be submitted through one of the four channels outlined in the **ADDRESSES** section above. Comments may not be submitted via email.)

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov.*

Ambulatory Surgical Center (ASC) Payment System, contact Elisabeth Daniel via email *Elisabeth.Daniel1@cms.hhs.gov* or at 410–786–0237.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Blood and Blood Products, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* at 410–786–9732.

Cancer Hospital Payments, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

Care Management Services, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

CPT Codes, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email *Chuck.Braver@cms.hhs.gov* or at 410–786–6719.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

Comprehensive APCs (C–APCs), contact Lela Strong via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

Inpatient Only (IPO) Procedures List, contact Lela Strong via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

No Cost/Full Credit and Partial Credit Devices, contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

OPPS Brachytherapy, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email *Erick.Chuang@cms.hhs.gov* or at 410–786–1816 or Elisabeth Daniel via email *Elisabeth.Daniel1@cms.hhs.gov* or at 410–786–0237.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Elisabeth Daniel via email *Elisabeth.Daniel1@cms.hhs.gov* or at 410–786–0237.

OPPS New Technology Procedures/Services, contact the New Technology APC email at *NewTechAPCapplications@cms.hhs.gov*.

OPPS Exceptions to the 2 Times Rule, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

OPPS Packaged Items/Services, contact Elisabeth Daniel via email *Elisabeth.Daniel1@cms.hhs.gov* or at 410–786–0237.

OPPS Pass-Through Devices, contact the Device Pass-Through email at *DevicePTapplications@cms.hhs.gov*.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email *Marina.Kushnirova@cms.hhs.gov* or at 410–786–2682.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov*.

Revisions to the Laboratory Date of Service Policy, contact Craig Dobyski via email *Craig.Dobyski@cms.hhs.gov* or at 410–786–4584 or Rasheeda Johnson via email *Rasheeda.Johnson1@cms.hhs.gov* or at 410–786–3434 or Marjorie Baldo (for OPPS) via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

Rural Hospital Payments, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

Skin Substitutes, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Lela Strong via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov/*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

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In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS Web site. The Addenda relating to the OPPS are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The Addenda relating to the ASC payment system are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Alphabetical List of Acronyms Appearing in This Federal Register Document

AHA American Hospital Association
AMA American Medical Association
AMI Acute myocardial infarction
APC Ambulatory Payment Classification
API Application programming interface
APU Annual payment update
ASC Ambulatory surgical center
ASCQR Ambulatory Surgical Center Quality Reporting
ASP Average sales price
AUC Appropriate use criteria
AWP Average wholesale price
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS Bureau of Labor Statistics
CAH Critical access hospital
CAHPS Consumer Assessment of Healthcare Providers and Systems
CAP Competitive Acquisition Program
C–APC Comprehensive Ambulatory Payment Classification
CASPER Certification and Survey Provider Enhanced Reporting
CAUTI Catheter-associated urinary tract infection
CBSA Core-Based Statistical Area
CCM Chronic care management
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDC Centers for Disease Control and Prevention
CED Coverage with Evidence Development
CERT Comprehensive Error Rate Testing
CFR Code of Federal Regulations
CI Comment indicator
CLABSI Central Line [Catheter] Associated Blood Stream Infection
CLFS Clinical Laboratory Fee Schedule
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services
CoP Condition of participation
CPI–U Consumer Price Index for All Urban Consumers
CPT Current Procedural Terminology (copyrighted by the American Medical Association)
CR Change request
CRC Colorectal cancer
CSAC Consensus Standards Approval Committee
CT Computed tomography
CV Coefficient of variation
CY Calendar year
DFO Designated Federal Official
DME Durable medical equipment
DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
DOS Date of service
DRA Deficit Reduction Act of 2005, Public Law 109–171
DSH Disproportionate share hospital
EACH Essential access community hospital
EAM Extended assessment and management
ECD Expanded criteria donor
EBRT External beam radiotherapy
ECG Electrocardiogram
ED Emergency department
EDTC Emergency department transfer communication
EHR Electronic health record
E/M Evaluation and management
ESRD End-stage renal disease
ESRDQIP End-Stage Renal Disease Quality Improvement Program
FACA Federal Advisory Committee Act, Public Law 92–463
FDA Food and Drug Administration
FFS [Medicare] Fee-for-service
FY Fiscal year
GAO Government Accountability Office
GI Gastrointestinal
GME Graduate medical education
HAI Healthcare-associated infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCERA Health Care and Education Reconciliation Act of 2010, Public Law 111–152
HCP Health care personnel
HCPCS Healthcare Common Procedure Coding System
HCRIS Healthcare Cost Report Information System
HCUP Healthcare Cost and Utilization Project
HEU Highly enriched uranium
HHQRP Home Health Quality Reporting Program

HHS Department of Health and Human Services
HIE Health information exchange
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HOP Hospital Outpatient Payment [Panel]
HOPD Hospital outpatient department
HOPQDRP Hospital Outpatient Quality Data Reporting Program
HPMS Health Plan Management System
IBD Inflammatory bowel disease
ICC Interclass correlation coefficient
ICD Implantable cardioverter defibrillator
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10 International Classification of Diseases, Tenth Revision
ICH In-center hemodialysis
ICR Information collection requirement
IDTF Independent diagnostic testing facility
IGI IHS Global, Inc.
IHS Indian Health Service
I/OCE Integrated Outpatient Code Editor
IOL Intraocular lens
IORT Intraoperative radiation treatment
IPFQR Inpatient Psychiatric Facility Quality Reporting
IPPS [Hospital] Inpatient Prospective Payment System
IQR [Hospital] Inpatient Quality Reporting
IRF Inpatient rehabilitation facility
IRFQRP Inpatient Rehabilitation Facility Quality Reporting Program
IT Information technology
LCD Local coverage determination
LDR Low dose rate
LTCH Long-term care hospital
LTCHQR Long-Term Care Hospital Quality Reporting
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114–10
MAP Measure Application Partnership
MDH Medicare-dependent, small rural hospital
MedPAC Medicare Payment Advisory Commission
MEG Magnetoencephalography
MFP Multifactor productivity
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MLR Medical loss ratio
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MPFS Medicare Physician Fee Schedule
MR Medical review
MRA Magnetic resonance angiography
MRgFUS Magnetic Resonance Image Guided Focused Ultrasound
MRI Magnetic resonance imaging
MRSA Methicillin-Resistant Staphylococcus Aureus
MS–DRG Medicare severity diagnosis-related group
MSIS Medicaid Statistical Information System
MUC Measure under consideration
NCCI National Correct Coding Initiative
NEMA National Electrical Manufacturers Association
NHSN National Healthcare Safety Network
NOTA National Organ and Transplantation Act
NOS Not otherwise specified
NPI National Provider Identifier
NQF National Quality Forum
NQS National Quality Strategy
NTIOL New technology intraocular lens
NUBC National Uniform Billing Committee
OACT [CMS] Office of the Actuary
OBRA Omnibus Budget Reconciliation Act of 1996, Public Law 99–509
O/E Observed to expected event
OIG [HHS] Office of the Inspector General
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPD [Hospital] Outpatient Department
OPPS [Hospital] Outpatient Prospective Payment System
OPSF Outpatient Provider-Specific File
OQR [Hospital] Outpatient Quality Reporting
OT Occupational therapy
PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93
PCHQR PPS-Exempt Cancer Hospital Quality Reporting
PCR Payment-to-cost ratio
PDC Per day cost
PDE Prescription Drug Event
PE Practice expense
PHP Partial hospitalization program
PHSA Public Health Service Act, Public Law 96–88
PN Pneumonia
POS Place of service
PPI Producer Price Index
PPS Prospective payment system
PQRI Physician Quality Reporting Initiative
PQRS Physician Quality Reporting System
QDC Quality data code
QIO Quality Improvement Organization
RFA Regulatory Flexibility Act
RHQDAPU Reporting Hospital Quality Data for Annual Payment Update
RTI Research Triangle Institute, International
RVU Relative value unit
SAD Self-administered drug
SAMS Secure Access Management Services
SCH Sole community hospital
SCOD Specified covered outpatient drugs
SES Socioeconomic status
SI Status indicator
SIA Systems Improvement Agreement
SIR Standardized infection ratio
SNF Skilled nursing facility
SRS Stereotactic radiosurgery
SRTR Scientific Registry of Transplant Recipients
SSA Social Security Administration
SSI Surgical site infection
TEP Technical Expert Panel
TOPs Transitional Outpatient Payments
VBP Value-based purchasing
WAC Wholesale acquisition cost

Table of Contents

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this final rule with comment period, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments

(HOPDs) and ambulatory surgical centers (ASCs) beginning January 1, 2018. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. We describe these and various other statutory authorities in the relevant sections of this final rule with comment period. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

2. Summary of the Major Provisions

• *OPPS Update:* For CY 2018, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.35 percent. This increase factor is based on the hospital inpatient market basket percentage increase of 2.7 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment of 0.6 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2018 is approximately $70 billion, an increase of approximately $5.8 billion compared to estimated CY 2017 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

• *High Cost/Low Cost Threshold for Packaged Skin Substitutes:* As we did for CY 2017, we are assigning skin substitutes with a geometric mean unit cost (MUC) or a per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, for CY 2018, we are establishing that a skin substitute product that does not exceed either the CY 2018 MUC or PDC threshold for CY 2018, but was assigned to the high cost group for CY 2017, is assigned to the high cost group for CY 2018. The goal of our policy is to maintain similar levels of payment for skin substitute products for CY 2018 while we study our current skin substitute payment methodology to determine whether refinements to our existing methodologies may be warranted.

• *Supervision of Hospital Outpatient Therapeutic Services:* In the CY 2009 and CY 2010 OPPS/ASC proposed rules and final rules with comment period, we clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals, CAHs, and in provider-based departments (PBDs) of hospitals, as set forth in the CY 2000 OPPS final rule with comment period. For several years, there has been a moratorium on the enforcement of the direct supervision requirement for CAHs and small rural hospitals, with the latest moratorium on enforcement expiring on December 31, 2016. In this final rule with comment period, as we proposed, we are reinstating the nonenforcement policy for direct supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals having 100 or fewer beds and reinstating our enforcement instruction for CY 2018 and CY 2019.

• *340B Drug Pricing:* We are changing our current Medicare Part B drug payment methodology for 340B hospitals that we believe will better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. These changes will lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program. For CY 2018, we are exercising the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. Rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are excluded from this payment adjustment in CY 2018. In addition, in this final rule with comment period, we are establishing two modifiers to identify whether a drug billed under the OPPS was purchased under the 340B Program—one for hospitals that are subject to the payment reduction and another for hospitals not subject to the payment reduction but that acquire drugs under the 340B Program.

• *Device Pass-Through Payment Applications:* For CY 2018, we evaluated five devices for eligibility to receive pass through payments and sought public comments in the CY 2018 proposed rule on whether each of these items meet the criteria for device pass-through payment status. None of the applications were approved for device pass-through payments for CY 2018.

• *Rural Adjustment:* We are continuing the adjustment of 7.1 percent to the OPPS payments to certain rural SCHs, including essential access community hospitals (EACHs). This adjustment will apply to all services paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to cost.

• *Cancer Hospital Payment Adjustment:* For CY 2018, we are continuing to provide additional payments to cancer hospitals so that the cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, beginning CY 2018, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, a target PCR of 0.88 will be used to determine the CY 2018 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.88 for each cancer hospital.

• *Changes to the Inpatient Only List:* For CY 2018, we are finalizing our proposal to remove total knee arthroplasty (TKA) from the inpatient only list. In addition, we are precluding the Recovery Audit Contractors from reviewing TKA procedures for ''patient status'' (that is, site of service) for a period of 2 years. We note that we will monitor changes in site of service to determine whether changes may be necessary to certain CMS Innovation Center models. In addition, we are removing five other procedures from the inpatient only list and adding one procedure to the list.

• *Comprehensive APCs:* For CY 2018, we did not propose to create any new C–APCs or make any extensive changes to the already established methodology used for C–APCs. There will be a total

number of 62 C–APCs as of January 1, 2018. For CY 2018, for the C–APC for stereotactic radio surgery (SRS), specifically, C–APC 5627 (Level 7 Radiation Therapy), we are continuing to make separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 30 days of the SRS treatment. In addition, the data collection period for SRS claims with modifier ''CP'' is set to conclude on December 31, 2017. Accordingly, for CY 2018, we are deleting this modifier and discontinuing its required use.

• *Packaging Policies:* In CY 2015, we implemented a policy to conditionally package ancillary services assigned to APCs with a geometric mean cost of $100 or less prior to packaging, with some exceptions, including drug administration services. For CY 2018, we are removing the exception for certain drug administration services and conditionally packaging payment for low-cost drug administration services. We did not propose to package drug administration add-on codes for CY 2018, but solicited comments on this policy. The public comments that we received are discussed in this final rule with comment period. In addition, we solicited comments on existing packaging policies that exist under the OPPS, including those related to drugs that function as a supply in a diagnostic test or procedure or in a surgical procedure. The public comments that we received are also discussed in this final rule with comment period.

• *Payment Changes for X-rays Taken Using Computed Radiography Technology:* Section 502(b) of Division O, Title V of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1833(t)(16) of the Act by adding new subparagraph (F). New section 1833(t)(16)(F)(ii) of the Act provides for a phased-in reduction of payments for imaging services that are taken using computed radiography technology. That section provides that payments for such services furnished during CYs 2018 through 2022 shall be reduced by 7 percent, and if such services are furnished during CY 2023 or a subsequent year, payments for such services shall be reduced by 10 percent. We are establishing a new modifier that will be reported on claims to identify those HCPCS codes that describe X-rays taken using computed radiography technology. Specifically, this modifier, as allowed under the provisions of new section 1833(t)(16)(F)(ii) of the Act, will be reported with the applicable HCPCS code to describe imaging services that are taken using computed radiography technology beginning January 1, 2018.

• *ASC Payment Update:* For CY 2018, we are increasing payment rates under the ASC payment system by 1.2 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a projected CPI–U update of 1.7 percent minus a multifactor productivity adjustment required by the Affordable Care Act of 0.5 percentage point. Based on this update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2018 is approximately $4.62 billion, an increase of approximately $130 million compared to estimated CY 2017 Medicare payments. In addition, in the CY 2018 proposed rule, we solicited comment on payment reform for ASCs, including the collection of cost data which may support a rate update other than CPI–U. We discuss the public comments that we received in response to this solicitation in this final rule with comment period.

• *Comment Solicitation on ASC Payment Reform:* In the CY 2018 proposed rule, we indicated that we were broadly interested in feedback from stakeholders and other interested parties on potential reforms to the current payment system, including, but not limited to (1) the rate update factor applied to ASC payments, (2) whether and how ASCs should submit data relating to costs, (3) whether ASCs should bill on the institutional claim form rather than the professional claim form, and (4) other ideas to improve payment accuracy for ASCs. We discuss the feedback we received in this final rule with comment period.

• *Changes to the List of ASC Covered Surgical Procedures:* For CY 2018, we are adding three procedures to the ASC covered procedures list. In addition, in the CY 2018 proposed rule, we solicited comment on whether total knee arthroplasty, partial hip arthroplasty and total hip arthroplasty meet the criteria to be added to the ASC covered procedures list. We also solicited comments from stakeholders on whether there are codes that are outside the AMA–CPT surgical code range that nonetheless, should be considered to be a covered surgical procedure. We discuss the public comments we received on this solicitation in this final rule with comment period.

• *Revisions to the Laboratory Date of Service Policy:* To better understand the potential impact of the current date of service (DOS) policy on billing for molecular pathology tests and advanced diagnostic laboratory tests (ADLTs) under the new private payor rate-based Clinical Laboratory Fee Schedule (CLFS), in the CY 2018 proposed rule, we solicited public comments on billing for molecular pathology tests and certain ADLTs ordered less than 14 days of a hospital outpatient discharge and discussed potential modifications to our DOS policy to address those tests. After considering the public comments received, we are adding an additional exception to our current laboratory DOS regulations at 42 CFR 414.510. This new exception to the laboratory DOS policy generally permits laboratories to bill Medicare directly for ADLTs and molecular pathology tests excluded from OPPS packaging policy if the specimen was collected from a hospital outpatient during a hospital outpatient encounter and the test was performed following the patient's discharge from the hospital outpatient department. We discuss the public comments we received on this solicitation in this final rule with comment period.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are finalizing our proposals to remove and delay certain measures for the CY 2020 payment determination and subsequent years. Specifically, beginning with the CY 2020 payment determination, we are finalizing our proposals to remove: (1) OP–21: Median Time to Pain Management for Long Bone Fracture; and (2) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures. While we proposed to remove: OP–1: Median Time to Fibrinolysis, OP–4: Aspirin at Arrival, OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional, and OP–25: Safe Surgery Checklist for the CY 2021 payment determination and subsequent years, we are finalizing these proposals with modification, such that we are removing them for the CY 2020 payment determination and subsequent years, one year earlier than proposed. We are also finalizing our proposal to delay the OAS CAHPS Survey-based measures (OP–37a–e) beginning with the CY 2020 payment determination (CY 2018 reporting). In addition, for the CY 2020 payment determination and subsequent years we are: (1) Providing clarification on our procedures for validation of chart-abstracted measures for targeting the poorest performing outlier hospitals; (2) formalizing the validation educational review process and updating it to allow corrections of incorrect validation results for chart-abstracted measures,

and modifying the CFR accordingly; (3) aligning the first quarter for which to submit data for hospitals that did not participate in the previous year's Hospital OQR Program and make corresponding changes to the CFR; and (4) aligning the naming of the Extraordinary Circumstances Exceptions (ECE) policy with that used in our other quality reporting and value-based payment programs and making corresponding changes to the CFR. We are not finalizing our proposal to extend the Notice of Participation (NOP) deadline and make corresponding changes to the CFR. Lastly, we are finalizing with modifications, our proposal to publicly report OP–18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are finalizing measures and policies for the CY 2019 payment determination, 2021 payment determination, and CY 2022 payment determination and subsequent years. Specifically, we are finalizing our proposals to, beginning with the CY 2019 payment determination, remove three measures from the ASCQR Program measure set: (1) ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing; (2) ASC–6: Safe Surgery Checklist Use; and, (3) ASC–7: Ambulatory Surgical Center Facility Volume Data on Selected Ambulatory Surgical Center Surgical Procedures. In addition, we are also finalizing our proposal to delay the OAS CAHPS Survey measures (ASC–15a–e) beginning with the CY 2020 payment determination (CY 2018 data collection). Furthermore, starting with CY 2018, we are finalizing our proposals to: (1) Expand the CMS online tool to also allow for batch submission of measure data and make corresponding changes to the CFR; and (2) align the naming of the Extraordinary Circumstances Exceptions (ECE) policy with that used in our other quality reporting and value-based payment programs and make corresponding changes to the CFR. We are not finalizing our proposal to adopt one new measure, ASC–16: Toxic Anterior Segment Syndrome, beginning with the CY 2021 payment determination. However, we are finalizing proposals to adopt two new measures collected via claims, beginning with the CY 2022 payment determination, ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures and ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures.

Response: We appreciate the commenters' support. However, as we stated earlier in section V.B.1.c. of this final rule with comment period in response to a similar request for additional radiopharmaceutical payment, we continue to believe that a single payment is appropriate for radiopharmaceuticals with pass-through payment status in CY 2018 and that the payment rate of ASP+6 percent is appropriate to provide payment for both the radiopharmaceutical's acquisition cost and any associated nuclear medicine handling and compounding costs incurred by the hospital pharmacy. Payment for the radiopharmaceutical and radiopharmaceutical processing services is made through the single ASP-based payment. We refer readers to the CMS guidance document available via the Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Archives.html* for details on submission of ASP data for therapeutic radiopharmaceuticals.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent. We also are finalizing our proposal to continue to rely on CY 2016 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The CY 2018 final rule payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site).

4. Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States would like to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, and conversion to such production has begun. We expect that this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68321).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation is that this additional payment will be needed for the duration of the industry's conversion to alternative methods to producing Tc-99m without HEU. We also stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68316). We have reassessed this payment for CY 2018 and did not identify any new information that would cause us to modify payment. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33631), for CY 2018, we proposed to continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources.

Comment: Commenters supported CMS' proposal to provide an additional $10 payment for the marginal cost of radioisotopes produced by non-HEU sources and supported continuation of the policy. However, the commenters requested that CMS update the payment amount using the hospital market basket update or hospital cost data. The commenters also requested that CMS assess whether the collection of a beneficiary copayment could discourage hospital adoption.

Response: We appreciate the commenters' support. As discussed in the CY 2013 OPPS/ASC final rule with comment period, we did not finalize a policy to use the usual OPPS methodologies to update the non-HEU add-on payment (77 FR 68317). The purpose for the additional payment is limited to mitigating any adverse impact of transitioning to non-HEU sources and

is based on the authority set forth at section 1833(t)(2)(E) of the Act. Accordingly, because we do not have authority to waive beneficiary copayment for this incentive payment, we believe it is unnecessary to assess whether a beneficiary copayment liability would deter a hospital from reporting HCPCS code Q9969. Furthermore, reporting of HCPCS code Q9969 is optional. Hospitals that are not experiencing high volumes of significantly increased costs are not obligated to request this additional payment (77 FR 68323).

Comment: One commenter requested that CMS publish HCPCS code volume and cost data in the proposed and final rule ''Drug Blood Brachy Cost Statistics'' files yearly.

Response: We appreciate the request and will consider revising the content of the ''Drug Blood Brachy Cost statistics'' file to include data on HCPCS code Q9969 for future rulemaking. In the interim, claims data on HCPCS code Q9969 are available for purchase in the claims data sets released with publication of this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue the policy of providing an additional $10 payment for radioisotopes produced by non-HEU sources for CY 2018, which will be the sixth year in which this policy is in effect in the OPPS. We will continue to reassess this policy annually, consistent with the original policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68319).

5. Payment for Blood Clotting Factors

For CY 2017, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (81 FR 79676). That is, for CY 2017, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2017 updated furnishing fee was $0.209 per unit.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33631), for CY 2018, we proposed to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update was based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we were not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017 by an off-campus

outpatient department of a provider (as defined in subparagraph (B) of paragraph (21). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals include:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under the Maryland All-Payer Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and
- Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an external advisory panel of experts to annually review the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the PHS Act which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and at that time named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise), reviews clinical data, and advises CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel—

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 21, 2016, for a 2-year period (81 FR 94378).

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*.

3. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on August 21, 2017. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for Panel membership, to announce new members and to announce any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). Further information on the 2017 summer meeting can be found in the meeting notice titled ''Medicare Program: Announcement of the Advisory Panel on Hospital Outpatient Payment (the Panel) Meeting on August 21–22, 2017'' (82 FR 24128).

In addition, the Panel has established an operational structure that, in part, currently includes the use of three subcommittees to facilitate its required review process. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made;
- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and
- Visits and Observation Subcommittee, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS.

Each of these subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 21, 2017 meeting that the subcommittees continue. We accepted this recommendation.

In addition, discussions of the other recommendations made by the Panel at the August 21, 2017 Panel meeting are included in the sections of this final rule with comment period that are specific to each recommendation. For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS Web site mentioned earlier in this section, and the FACA database at *http://facadatabase.gov*.

We note that we received some public comments on the CY 2018 OPPS/ASC proposed rule related to the HOP Panel meeting presentations, which we address below.

Comment: One commenter supported CMS' extension of the HOP Panel meeting presentation submission deadline when there is a truncated submittal timeframe due to delayed publication of the OPPS/ASC proposed rule. However, to avoid the need to modify the submission deadline in the future, the commenter suggested that CMS revise the submission deadline in the **Federal Register** notice from a firm date to a fluid 21 days from the proposed rule display date to avoid this deadline issue in the future.

Response: We appreciate the commenter's request to modify the HOP Panel meeting submission deadline format. However, frequency, timing, and presentation deadlines are outside the scope of the proposed rule and are generally announced through either a separate **Federal Register** notice or subregulatory channel such as the CMS Web site, or both.

Comment: One commenter requested that CMS reinstate the winter Panel meetings as part of a multifaceted process that would allow for multiple proposal refinements with Panel input prior to finalization of a policy. The commenter also suggested that CMS use this winter meeting as a vehicle to allow stakeholders to review and discuss updated cost data for HCPCS codes and APCs prior to the release of the data in the proposed rule.

Response: We appreciate the commenter's request to modify the Panel meeting processes. However, the frequency of Panel meetings is outside the scope of the proposed rule; meetings are generally announced through either a separate **Federal Register** notice or a subregulatory channel such as the CMS Web site, or both.

F. Public Comments Received on the CY 2017 OPPS/ASC Final Rule With Comment Period

We received 39 timely pieces of correspondence on the CY 2017 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 14, 2016 (81 FR 79562), some of which contained comments on the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes (identified with comment indicator ''NI'' in OPPS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule), the potential limitation on clinical service line expansion or volume of service increases by nonexcepted off-campus provider-based departments, and the Medicare Physician Fee Schedule (MPFS) payment rates for nonexcepted items and services furnished and billed by nonexcepted off-campus provider-based departments of hospitals. Summaries of the public comments are set forth in the CY 2018 proposed rule and this final rule with comment period under the appropriate subject matter headings. Summaries of public comments on the MPFS payment rates for nonexcepted items and services are set forth in the CY 2018 MPFS final rule with comment period.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33568), for CY 2018, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2018, and before January 1, 2019 (CY 2018), using the same basic methodology that we described in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79574 through 79595). For this final rule with comment period, for CY 2018, we recalibrated the APC relative payment weights for services furnished on or after January 1, 2018, and before January 1, 2019 (CY 2018), using the same basic methodology that we described in the CY 2017 OPPS/ASC final rule with comment period, using updated CY 2016 claims data. That is, we recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights.

For the purpose of recalibrating the APC relative payment weights for CY 2018, we began with approximately 163 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2016, and before January 1, 2017, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 86 million final action claims to develop the CY 2018 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this CY 2018 OPPS/ASC final rule with comment period on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Addendum N to this final rule with comment period (which is available via the Internet on the CMS Web site) includes the list of bypass codes for CY 2018. The list of bypass codes contains codes that were reported on claims for services in CY 2016 and, therefore, includes codes that were in effect in CY 2016 and used for billing, but were deleted for CY 2017. We retained these deleted bypass codes on the CY 2018 bypass list because these codes existed in CY 2016 and were covered OPD services in that period, and CY 2016 claims data are used to calculate CY 2018 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this final rule with comment period. HCPCS codes that we are adding for CY 2018 are identified by asterisks (*) in the fourth column of Addendum N.

Table 1 below contains the list of codes that we are removing from the CY 2018 bypass list.

TABLE 1—HCPCS CODES REMOVED FROM THE CY 2018 BYPASS LIST

HCPCS code	HCPCS short descriptor
77305	Teletx isodose plan simple.
77310	Teletx isodose plan intermed.
77315	Teletx isodose plan complex.
77327	Brachytx isodose calc intern.

TABLE 1—HCPCS CODES REMOVED FROM THE CY 2018 BYPASS LIST—Continued

HCPCS code	HCPCS short descriptor
90801	Psy dx interview.
90802	Intac psy dx interview.
90804	Psytx office 20–30 min.
90805	Psytx off 20–30 min w/e&m.
90806	Psytx off 45–50 min.
90807	Psytx off 45–50 min w/e&m.
90808	Psytx office 75–80 min.
90809	Psytx off 75–80 w/e&m.
90810	Intac psytx off 20–30 min.
90811	Intac psytx 20–40 w/e&m.
90812	Intac psytx off 45–50 min.
90857	Intac group psytx.
90862	Medication management.
95115	Immunotherapy one injection.
95117	Immunotherapy injections.
95144	Antigen therapy services.
95147	Antigen therapy services.
95165	Antigen therapy services.
96402	Chemo hormon antineopl sq/im.
99201	Office/outpatient visit new.
99202	Office/outpatient visit new.
99203	Office/outpatient visit new.
99204	Office/outpatient visit new.
99205	Office/outpatient visit new.
99212	Office/outpatient visit est.
99213	Office/outpatient visit est.
99214	Office/outpatient visit est.
C1300	Hyperbaric oxygen.
G0340	Robt lin-radsurg fractx 2–5.
G9141	Influenza A H1N1, admin w cou.
M0064	Visit for drug monitoring.

b. Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2018, in this CY 2018 OPPS/ASC final rule with comment period, as we proposed, we are continuing to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the CY 2018 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2016 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2015. For the final CY 2018 OPPS payment rates, we used the set of claims processed during CY 2016. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. That crosswalk is available for review and continuous comment on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2016 (the year of claims data we used to calculate the CY 2018 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2016 Data Specifications Manual.

In accordance with our longstanding policy, we calculate CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of this final rule with comment period.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74840 through 74847), we finalized our policy of creating new cost centers and distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. However, in response to the CY 2014 OPPS/ASC proposed rule, commenters reported that some hospitals currently use an imprecise ''square feet'' allocation methodology for the costs of large moveable equipment like CT scan and MRI machines. They indicated that while CMS recommended using two alternative allocation methods, ''direct assignment'' or ''dollar value,'' as a more accurate methodology for directly assigning equipment costs, industry analysis suggested that approximately only half of the reported cost centers for CT scans and MRIs rely on these preferred methodologies. In response to concerns from commenters, we finalized a policy for the CY 2014 OPPS to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs associated with the CT and MRI APCs (78 FR 74847). Further, we finalized a transitional policy to estimate imaging APC relative payment weights using only CT and MRI cost data from providers that do not use ''square feet'' as the cost allocation statistic. We provided that this finalized policy would sunset in 4 years to provide a sufficient time for hospitals to transition to a more accurate cost allocation method and for the related data to be available for ratesetting purposes (78 FR 74847). Therefore, beginning CY 2018, with the sunset of the transition policy, we will estimate the imaging APC relative payment weight using cost data from all providers, regardless of the cost allocation statistic employed.

As we discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33570), some stakeholders have raised concerns regarding using claims from all providers to calculate CT and MRI CCRs, regardless of the cost allocations statistic employed (78 FR 74840 through 74847). Stakeholders noted that providers continue to use the ''square feet'' cost allocation method and that including claims from such providers would cause significant reductions in imaging APC payment rates.

Table 2 below demonstrates the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using ''square feet'' as the cost allocation method by extracting HCRIS data on Worksheet B–1. Table 3 below provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods.

TABLE 2—PERCENTAGE CHANGE IN ESTIMATE COST FOR CT AND MRI APCS WHEN EXCLUDING CLAIMS FROM PROVIDER USING ''SQUARE FEET'' AS THE COST ALLOCATION METHOD

APC	APC descriptor	Percentage change
5521	Level 1 Imaging without Contrast	−3.8
5522	Level 2 Imaging without Contrast	5.3
5523	Level 3 Imaging without Contrast	6.3
5524	Level 4 Imaging without Contrast	5.0

TABLE 2—PERCENTAGE CHANGE IN ESTIMATE COST FOR CT AND MRI APCS WHEN EXCLUDING CLAIMS FROM PROVIDER USING ''SQUARE FEET'' AS THE COST ALLOCATION METHOD—Continued

APC	APC descriptor	Percentage change
5571	Level 1 Imaging with Contrast	9.0
5572	Level 2 Imaging with Contrast	7.0
5573	Level 3 Imaging with Contrast	2.1
8005	CT and CTA without Contrast Composite	14.4
8006	CT and CTA with Contrast Composite	11.9
8007	MRI and MRA without Contrast Composite	7.2
8008	MRI and MRA with Contrast Composite	7.5

TABLE 3—CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost allocation method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0387	0.0538	0.0795	0.1059
Square Feet Only	0.0317	0.0488	0.0717	0.0968
Direct Assign	0.0557	0.0650	0.1032	0.1222
Dollar Value	0.0457	0.0603	0.0890	0.1178
Direct Assign and Dollar Value	0.0457	0.0603	0.0893	0.1175

Our analysis showed that since the CY 2014 OPPS in which we established the transition policy, the number of valid MRI CCRs has increased by 17.5 percent to 2,177 providers and the number of valid CT CCRs has increased by 15.1 percent to 2,251 providers. However, in the proposed rule, we noted that, as shown in Table 2 above, nearly all imaging APCs would see an increase in payment rates for CY 2018 if claims from providers that report ''square feet'' cost allocation method were removed. This can be attributed to the generally lower CCR values from providers that use a cost allocation method of ''square feet'' as shown in Table 3 above. We stated in the proposed rule that we believe that the imaging CCRs that we have are appropriate for ratesetting. However, in response to provider concerns and to provide added flexibility for hospitals to improve their cost allocation methods, we proposed to extend the transition policy an additional year, for the CY 2018 OPPS.

For the CY 2018 OPPS, we proposed to continue to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs with the CT and MRI APCs identified in Table 2 above. Beginning in CY 2019, we would estimate the imaging APC relative payment weights using cost data from all providers, regardless of the cost allocation statistic employed.

Comment: Commenters supported CMS' proposal to extend the transition policy an additional year, for the CY 2018 OPPS. Several commenters recommended that CMS continue to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CT and MRI CCRs in subsequent calendar years.

Response: We thank the commenters for their support. As we discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33570), our analysis shows that the number of valid MRI and CT CCRs has increased since we established the transition policy. We believe extending our transition policy for 1 additional year will provide hospitals adequate time to implement a more accurate cost allocation method for the costs of large moveable equipment like CT scan and MRI machines.

Comment: Some commenters recommended that CMS discontinue the use of CT and MRI cost centers for developing CT and MRI CCRs. One commenter believed that creating separate CT and MRI cost centers has resulted in a decline in geometric means for imaging APCs which can be attributed to costs being dropped out and changes in hospital charging practices.

Response: We are not convinced that the change in CT and MRI CCRs over the previous years is a result of costs not being reported accurately. The standard cost centers for CT scans and MRIs have been in effect since cost reporting periods beginning on or after May 1, 2010, on the revised Medicare cost report Form CMS–2552–10. Therefore, the cost reports that we used to develop the CY 2018 OPPS relative payment weights were the fifth or sixth opportunity for hospitals to submit cost reports with the CT and MRI cost centers. However, we will continue to monitor cost reporting practices with respect to CT scan and MRI cost centers as well as trends in CT and MRI CCRs.

After consideration of the public comments we received, we are finalizing our proposal to extend our transition policy for 1 additional year and continue to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CT and MRI CCRs for the CY 2018 OPPS.

2. Data Development Process and Calculation of Costs Used for Ratesetting

In this section of this final rule with comment period, we discuss the use of claims to calculate the OPPS payment rates for CY 2018. The Hospital OPPS page on the CMS Web site on which this final rule with comment period is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS Web site, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, includes information about obtaining the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–10–CM diagnosis codes and revenue code payment amounts.

This file is derived from the CY 2016 claims that were used to calculate the payment rates for the CY 2018 OPPS.

In the history of the OPPS, we have traditionally established the scaled relative weights on which payments are based using APC median costs, which is a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. For CY 2018, in this CY 2018 OPPS/ASC final rule with comment period, as we proposed, we are continuing to use geometric mean costs to calculate the relative weights on which the CY 2018 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this final rule with comment period to calculate the costs we used to establish the relative payment weights used in calculating the OPPS payment rates for CY 2018 shown in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this final rule with comment period for a discussion of the conversion of APC costs to scaled payment weights.

For details of the claims process used in this final rule with comment period, we refer readers to the claims accounting narrative under supporting documentation for this CY 2018 OPPS/ASC final rule with comment period on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

(a) Methodology

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33571), we proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, in order to address the differences in CCRs and to better reflect hospitals' costs, we proposed to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We also proposed to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We proposed to calculate the costs upon which the proposed CY 2018 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated blood-specific CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that this methodology in CY 2018 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that, as discussed in section II.A.2.e. of the CYs 2014 through 2017 OPPS/ASC final rules with comment period (78 FR 74861 through 74910, 79 FR 66798 through 66810, 80 FR 70325 through 70339, and 81 FR 79580 through 79585, respectively), we defined a comprehensive APC (C–APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C–APCs. In the CY 2018 OPPS/ASC proposed rule (82 FR 33571), we proposed to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C–APCs. Because the costs of blood and blood products would be reflected in the overall costs of the C–APCs (and, as a result, in the proposed payment rates of the C–APCs), we proposed to not make separate payments for blood and blood products when they appear on the same claims as services assigned to the C–APCs (we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66796)).

We also referred readers to Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2018 payment rates for blood and blood products (which are identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

We invited public comments on our proposals.

Comment: Several commenters continued to support using the blood-specific CCR methodology to establish payment rates for blood and blood products, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. The commenters also supported using a blood-specific APC with a separate APC for each blood and blood product service code. The commenters viewed the blood-specific

CCR methodology as the best current methodology to report the costs of blood and blood products.

Response: We appreciate the commenters' support.

Comment: Several commenters expressed concerns about reduced payment for several blood and blood products HCPCS codes, including HCPCS codes P9010 (Blood (whole), for transfusion, per unit), P9011 (Blood, split unit), P9012 (Cryoprecipitate, each unit), P9016 (Red blood cells, leukocytes reduced, each unit), P9023 (Plasma, pooled multiple donor, solvent/detergent treated, frozen, each unit), P9035 (Platelets, pheresis, leukocytes reduced, each unit), P9043 (Infusion, plasma protein fraction (human), 5%, 50 ml), P9048 (Infusion, plasma protein fraction (human), 5%, 250 ml), P9055 (Platelets, leukocytes reduced, cmv-negative, apheresis/pheresis, each unit), and P9060 (Fresh frozen plasma, donor retested, each unit). Commenters supported the higher payment rates for several HCPCS codes, including HCPCS codes P9019 (Platelets, each unit) and P9034 (Platelets, pheresis, each unit).

Response: We used claims data from CY 2016 and the same blood-specific CCR methodology we used in previous years to calculate these proposed payment rates and believe the changes in costs for the services mentioned by these commenters are a result of normal variations in the claims data.

Comment: Two commenters expressed concern that the proposed payment rate for HCPCS code P9070 (Plasma, pooled multiple donor, pathogen reduced, frozen, each unit) does not accurately reflect the cost of the blood product.

Response: HCPCS code P9070 was established on January 1, 2016, and for CY 2016 and CY 2017, we linked the payment of HCPCS code P9070 to a blood product, HCPCS code P9059 (Fresh frozen plasma between 8–24 hours of collection, each unit), that we believed would have a comparable cost to HCPCS code P9070. CY 2018 is the first year for which we have claims data that will allow us to directly determine the cost of HCPCS code P9070. In this case, the payment rate for HCPCS code P9070 in CY 2018 is lower than the CY 2017 payment rate. However, we believe the CY 2018 payment rate is appropriate because it is based on actual claims data for HCPCS code P9070 rather than for HCPCS code P9059.

Comment: Commenters requested that CMS immediately include the cost of newly implemented FDA blood safety measures for blood and blood products prior to receiving claims data that would contain the costs for the new safety measures.

Response: As stated earlier in this section, the OPPS covers hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products. The cost of blood and blood products is determined using claims data and blood-specific CCRs from hospitals. To the extent that compliance with blood safety measures is included in hospital reporting of the cost of collecting, processing and storing blood and blood products, these costs would be reflected in the hospital rates. It is not possible to estimate the potential costs of new safety measures outside of claims data.

Comment: Several commenters resubmitted the comments they made in response to a solicitation for public comments in the CY 2017 OPPS/ASC proposed rule (81 FR 45617 through 45618) and summarized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79577) on the current set of active HCPCS P-codes that describe blood products regarding how the code descriptors could be revised and updated (if necessary) to reflect the current blood products provided to hospital outpatients.

The commenters supported a thorough examination of the current set of HCPCS P-codes for blood products as a necessary undertaking because the HCPCS P-codes were created several years ago. Several commenters recommended that CMS convene a stakeholder group that includes representatives of hospitals, blood banks, the American Red Cross, and others to discuss a framework to systematically review and revise the HCPCS P-codes for blood products. Commenters also suggested that CMS establish a ''not otherwise classified (NOC)'' code for blood products, which would allow hospitals to begin immediately billing for a new blood product that is not described by a specific HCPCS P-code. One commenter supported the use of broader descriptions for HCPCS P-codes when more granular language is no longer meaningful for differentiating between different types of blood and blood products, and where the costs and volume of the HCPCS P-codes are similar. Other commenters suggested specific modifications to the order, classification, and code descriptors of the blood and blood product HCPCS P-codes.

Response: We appreciate the commenters' detailed responses. The safety of the nation's blood supply continues to be among the highest priorities, and we will work with the commenters and other stakeholders to ensure that any future updates to the HCPCS P-codes will support our goal of maintaining the safety of the blood supply.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to establish payment rates for blood and blood products using our blood-specific CCR methodology. Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site) contains the final CY 2018 payment rates for blood and blood products (which are identified with status indicator ''R'').

(b) Pathogen-Reduced Platelets and Rapid Bacterial Testing for Platelets

In March 2016, the Food and Drug Administration (FDA) issued draft guidance for blood collection establishments and transfusion services entitled ''Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion'' (available at: *https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM425952.pdf*). This draft guidance recommended, among other things, the use of rapid bacterial testing devices secondary to testing using a culture-based bacterial detection device or the implementation of pathogen-reduction technology for platelets to adequately control the risk of bacterial contamination of platelets.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70322), we established HCPCS code P9072 (Platelets, pheresis, pathogen reduced, each unit). The CMS HCPCS Workgroup later revised HCPCS code P9072 to include the use of pathogen-reduction technology or rapid bacterial testing. Specifically, the descriptor for this code was revised, effective January 1, 2017, to read as follows: HCPCS code P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit). The payment rate for HCPCS code P9072 is based on a crosswalk to HCPCS code P9037 (Platelets, pheresis, leukocyte reduced, irradiated, each unit). We refer readers to the CY 2016 OPPS/ASC final rule with comment period for a further discussion of crosswalks for pathogen-reduced blood products (80 FR 70323).

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33571 and 33572), after the release of the CY 2017 OPPS/ASC final rule with comment

period, several blood and blood product stakeholders expressed concerns about the revised code descriptor for HCPCS code P9072. The stakeholders believed that the revision to HCPCS code P9072 to describe both pathogen reduction and rapid bacterial testing was an inappropriate code descriptor. They stated that separate coding is needed to describe each service because each service is distinct. The stakeholders also noted that the code descriptor for HCPCS code P9072 results in hospitals receiving the same payment rate for platelets undergoing rapid bacterial testing that the hospitals receive for platelets treated with pathogen reduction technology, despite the fact that pathogen reduction is significantly more expensive than rapid bacterial testing.

After review of the concerns expressed by the blood and blood product stakeholders, the CMS HCPCS Workgroup deactivated HCPCS code P9072 for Medicare reporting and replaced the code with two new HCPCS codes effective July 1, 2017. Specifically, effective July 1, 2017, HCPCS code Q9988 (Platelets, pheresis, pathogen reduced, each unit) is used to report the use of pathogen-reduction technology and HCPCS code Q9987 (Pathogen(s) test for platelets) is used to report rapid bacterial testing or other pathogen tests for platelets, instead of HCPCS code P9072. We note that HCPCS code Q9987 should be reported to describe the test used for the detection of bacterial contamination in platelets as well as any other test that may be used to detect pathogen contamination. HCPCS code Q9987 should not be used for reporting donation testing for infectious agents such as viruses. The coding changes associated with these codes were published on the CMS HCPCS Quarterly Update Web site, effective July 2017, at: *https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.html*. In addition, for OPPS, we announced the new HCPCS codes that were effective July 1, 2017 through the July 2017 OPPS quarterly update Change Request (Transmittal 3783, Change Request 10122, dated May 26, 2017). We note that, effective July 1, 2017, HCPCS code Q9988 is assigned to APC 9536 (Pathogen Reduced Platelets), with a payment rate of $647.12, and HCPCS code Q9987 is assigned to New Technology APC 1493, with a payment rate of $25.50.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70322 through 70323), we reiterated that we calculate payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. Because HCPCS code P9072 was new for CY 2016, there were no claims data available on the charges and costs for this blood product upon which to apply our blood-specific CCR methodology. Therefore, we established an interim payment rates for this HCPCS code based on a crosswalk to existing blood product HCPCS code P9037, which we believed provided the best proxy for the costs of the new blood product. In addition, we stated that once we had claims data for HCPCS code P9072, we would calculate its payment rate using the claims data that should be available for the code beginning in CY 2018, which is our practice for other blood product HCPCS codes for which claims data have been available for 2 years.

We stated in the proposed rule that, although our standard practice for new codes involves using claims data to set payment rates once claims data become available, we are concerned that there may have been confusion among the provider community about the services that HCPCS code P9072 described. That is, as early as 2016, there were discussions about changing the descriptor for HCPCS code P9072 to include the phrase ''or rapid bacterial tested'', which is a much less costly technology than pathogen reduction. In addition, as noted above, effective January 2017, the code descriptor for HCPCS code P9072 was, in fact, changed to also describe rapid bacterial testing of platelets and, effective July 1, 2017, the descriptor for the temporary successor code for HCPCS code P9072 (that is, HCPCS code Q9988) was changed again back to the original descriptor for HCPCS code P9072 that was in place for 2016.

Based on the ongoing discussions involving changes to the original HCPCS code P9072 established in CY 2016, we believe that claims for pathogen reduced platelets may potentially reflect certain claims for rapid bacterial testing of platelets. The geometric mean costs based on submitted claims for HCPCS code P9072 based on available claims data from CY 2016 is $491.53, which is a 24-percent reduction from the CY 2017 payment rate of $647.12. Because we believe that there may have been confusion related to ongoing discussions about changes to the original code descriptor for HCPCS code P9072, we believe it is appropriate to continue to crosswalk the payment amount for at least 1 additional year. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33571 and 33572), we proposed for CY 2018 to determine the payment rate for HCPCS code Q9988 (the successor code to HCPCS code P9072) by continuing to use the payment rate that has been crosswalked from HCPCS code P9037 of $647.12.

In the CY 2018 OPPS/ASC proposed rule, we solicited public comments on the proposed APC and status indicator assignments for HCPCS codes Q9987 and Q9988 for the CY 2018 OPPS update. The proposed payment rates for HCPCS codes Q9987 and Q9988 were included in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site).

Comment: Commenters expressed their appreciation to CMS for working collaboratively with the American Red Cross and other stakeholders in the blood banking community to respond to their concerns about HCPCS code P9072. The commenters supported the actions of CMS to deactivate HCPCS code P9072 and replace it with HCPCS codes Q9987 and Q9988 to have coding options that more accurately reflect available technologies. The commenters also appreciated that separate payment for each code was established in the OPPS and is proposed to continue in CY 2018.

Response: We appreciate the support for our actions in CY 2017 and our proposal for CY 2018.

Comment: One commenter requested that the description of HCPCS code Q9987 (Pathogen(s) test for platelets) be modified by adding the word ''secondary'' to clarify in the procedure code descriptor that HCPCS code Q9987 is intended to be used for secondary bacterial testing of platelets.

Response: We believe the guidance we have provided through the CY 2018 proposed rule (82 FR 33571 and 33572) and associated subregulatory guidance (Pub. 100–04 Medicare Claims Processing, Transmittal 3783, Change Request 10122) are sufficient for providers to understand how to appropriately report HCPCS code Q9987. We do not agree with the suggestion to modify the descriptor of HCPCS code Q9987, as we want the code to have the flexibility to be used to report new tests that may be developed in the future that are designed to identify pathogen contamination of platelets.

After consideration of the public comments we received, we are finalizing our CY 2018 proposal for reporting pathogen-reduced platelets and rapid bacterial testing for platelets. The only changes are to replace HCPCS code Q9987 (Pathogen(s) test for platelets) with HCPCS code P9100

(Pathogen(s) test for platelets) and to replace HCPCS code Q9988 (Platelets, pheresis, pathogen-reduced, each unit) with HCPCS code P9073 (Platelets, pheresis, pathogen-reduced, each unit). Details of the replacement of HCPCS codes Q9987 and Q9988 with HCPCS codes P9100 and P9073, respectively, are found in Table 4 below. The final payment rates for HCPCS codes P9100 and P9073 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 4—REPLACEMENT CODES FOR HCPCS CODES Q9987 AND Q9988 AS OF JANUARY 1, 2018

CY 2017 HCPCS code	CY 2018 HCPCS code	CY 2018 long descriptor	Final CY 2018 SI	Final CY 2018 APC
Q9987	P9100	Pathogen(s) test for platelets	S	1493
Q9988	P9073	Platelets, pheresis, pathogen-reduced, each unit	R	9536

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33572), for CY 2018, we proposed to use the costs derived from CY 2016 claims data to set the proposed CY 2018 payment rates for brachytherapy sources because CY 2016 is the same year of data we proposed to use to set the proposed payment rates for most other items and services that would be paid under the CY 2018 OPPS. We proposed to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we proposed for other items and services paid under the OPPS, as discussed in section II.A.2. of the proposed rule. We also proposed to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We proposed to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per source basis (as opposed to, for example, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also proposed to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010 by section 142 of Pub. L. 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

The proposed CY 2018 payment rates for brachytherapy sources were included in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) and were identified with status indicator ''U''. For CY 2018, we proposed to assign status indicator ''E2'' (Items and Services for Which Pricing Information and Claims Data Are Not Available) to HCPCS code C2645 (Brachytherapy planar, palladium-103, per square millimeter) because this code was not reported on CY 2016 claims. Therefore, we are unable to calculate a proposed payment rate based on the general OPPS ratesetting methodology described earlier. Although HCPCS code C2645 became effective January 1, 2016, and although we would expect that if a hospital furnished a brachytherapy source described by this code in CY 2016, HCPCS code C2645 should appear on the CY 2016 claims, there were no CY 2016 claims reporting this code available for the proposed rule. In addition, unlike our policy for new brachytherapy sources HCPCS codes, we did not consider external data to determine a proposed payment rate for HCPCS code C2645 for CY 2018. Therefore, we proposed to assign status indicator ''E2'' to HCPCS code C2645.

In addition, we assigned status indicator ''E2'' to HCPCS code C2644 (Brachytherapy, cesium-131 chloride, per square millimeter) because this code was not reported on any CY 2015 claims (that is, there were no Medicare claims submitted by any hospitals in 2015 that reported this HCPCS code). In our review of CY 2016 claims (which are used to set rates for CY 2018), we found that one hospital submitted one claim reporting HCPCS code C2644. Therefore, we proposed to assign status indicator ''U'' to HCPCS code C2644.

We invited public comments on our proposals.

Comment: One commenter suggested that CMS set the CY 2018 APC payment rate for HCPCS code C2636 (Brachytherapy linear, non-stranded, palladium-103, per 1mm) at $26.99 per millimeter.

Response: As noted in past rulemaking cycles and in the CY 2018 OPPS/ASC proposed rule (82 FR 33572), we believe that adopting the general OPPS prospective payment

methodology for brachytherapy sources is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. Further, while we assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals, HCPCS code C2636 is neither new nor lacks claim information. HCPCS code C2636 became effective July 1, 2007. The final CY 2018 APC payment rate for HCPCS code C2636 is $27.08 based on data for the 8 claims we received for the CY 2018 OPPS standard ratesetting process and can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

Comment: Some commenters suggested that HCPCS code C2645 (Brachytherapy, planar, palladium-103) had been incorrectly assigned status indicator ''E2'' (Items and Services for Which Pricing Information and Claims Data Are Not Available). These commenters stated that CMS has considered external data and other relevant information where no claims data exist for new HCPCS codes for new brachytherapy sources. For example, commenters included the following excerpt from the CY 2008 OPPS/ASC final rule with comment period regarding CMS' policy with respect to establishing a payment rate for HCPCS code C2637 (Brachytherapy non-stranded, ytterbium-169, per source) for which CMS lacked claims data: ''if in public comments to the proposed rule or later in CYs 2007 or 2008, we would receive relevant and reliable information on the hospital cost for ytterbium-169 and information that this source is being marketed, we could establish a prospective payment rate for the source in the CY 2008 final rule with comment period or in a quarterly OPPS update, respectively'' (72 FR 66786).

In addition, commenters noted that, for CY 2016 and CY 2017, HCPCS code C2645 was assigned an OPPS status indicator of ''U'' (Brachytherapy Sources, Paid under OPPS; separate APC payment) and a payment rate of $4.69 per mm^2 and that the payment rate was based upon external pricing data previously supplied by the developer of the brachytherapy source described by HCPCS code C2645. The developer of the brachytherapy source noted that there were no outpatient claims from CY 2016 for HCPCS code C2645 because all of the cases in CY 2016 that used the brachytherapy source were inpatient cases. However, the commenter noted its expectation that such source would begin to be used in the hospital outpatient department setting beginning approximately in mid-2018. This commenter noted that the ''E2'' status indicator would effectively render the outpatient payment rate as $0 for CY 2018. The commenter supplied external invoices to support maintaining the current payment rate of $4.69 per mm^2.

Response: We note that the CY 2008 final rule with comment period preamble language that the commenters referenced to support their argument that external data have been used in the past was in reference to a brachytherapy source for which there appeared to have been erroneous claims submitted since the claims were from 2006, but the brachytherapy source did not come to market until 2007. This is distinguishable from the situation with HCPCS code C2645 which has been on the market since August 29, 2014 and had a code effective date of January 1, 2016. Nonetheless, as the commenters noted, there are no Medicare claims data available at this time. While this brachytherapy source is no longer ''new,'' the absence of even a single Medicare claim in the outpatient hospital data leads us to agree with the commenter that using an external source of data would be appropriate at this time. Accordingly, for CY 2018, we are assigning status indicator ''U'' to HCPCS code C2645 and are using external data (invoice prices) and other relevant information to establish the APC payment rate for HCPCS code C2645. Specifically, we are setting the payment rate at $4.69 per mm^2, the same rate that was in effect for CYs 2016 and 2017.

After consideration of the public comments we received, we are finalizing our proposal to assign status indicator ''U'' to HCPCS code C2636 (Brachytherapy linear, non-stranded, palladium-103, per 1mm) and assigning an APC payment rate for HCPCS code C2636 at $27.08 based on the 8 claims we received for the CY 2018 OPPS standard ratesetting process. We also are finalizing our proposal to assign status indicator ''U'' to HCPCS code C2644 (Brachytherapy, cesium-131 chloride, per millicurie) and are modifying our proposal to assign status indicator ''E2'' to HCPCS code C2645 (Brachytherapy planar, palladium-103, per square millimeter) and instead adopting a status indicator of ''U'' for CY 2018. The final CY 2018 payment rates for brachytherapy sources can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site) and are identified with status indicator ''U''.

We continue to invite hospitals and other parties to submit recommendations to us for new codes to describe new brachytherapy sources. Such recommendations should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C–APCs) for CY 2018

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66810). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70332), we finalized 10 additional C–APCs to be paid under the existing C–APC payment policy and added one additional level to both the Orthopedic Surgery and Vascular Procedures clinical families. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584 through 79585), we finalized another 25 C–APCs.

Under this policy, we designate a service described by a HCPCS code assigned to a C–APC as the primary service when the service is identified by OPPS status indicator ''J1''. When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment

for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C–APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C–APC policy is included in Addendum J to this final rule with comment period (which is available via the Internet on the CMS Web site).

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period for the C–APCs and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C–APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1'', excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator ''J1'' are assigned to C–APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C–APC payment methodology to qualifying extended assessment and management encounters through the ''Comprehensive Observation Services'' C–APC (C–APC 8011). Services within this APC are assigned status indicator ''J2''. Specifically, we make a payment through C–APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service on the same day or 1 day earlier than the date of service associated with services described by HCPCS code G0378;
- Contains 8 or more units of services described by HCPCS code G0378 (Observation services, per hour);
- Contains services provided on the same date of service or 1 day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and
- Does not contain services described by a HCPCS code to which we have assigned status indicator ''J1''.

The assignment of status indicator ''J2'' to a specific combination of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. Therefore, the requirement for functional reporting under the regulations at 42 CFR 410.59(a)(4) and

42 CFR 410.60(a)(4) does not apply. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C–APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator ''J1'' as a single ''J1'' unit procedure claim (78 FR 74871 and 79 FR 66801). Line item charges for services included on the C–APC claim are converted to line item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator ''J1'' and later used to develop the geometric mean costs for the C–APC relative payment weights. (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a C–APC, inclusive of all of the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator ''J1'' according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof, we identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported ''J1'' services on a claim map to different C–APCs, we designate the ''J1'' service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator ''J1'' to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and certain add-on codes (as described further below) from the originating C–APC (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule in the originating C–APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C–APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary ''J1'' service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2018, in the CY 2018 OPPS/ASC proposed rule (82 FR 33575), we proposed to apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code for the primary J1 service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a

complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C–APC within the same clinical family of C–APCs. As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C–APC. We listed the complexity adjustments proposed for ''J1'' and add-on code combinations for CY 2018, along with all of the other proposed complexity adjustments, in Addendum J to the proposed rule (which is available via the Internet on the CMS Web site).

Addendum J to the proposed rule included the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to the proposed rule also contained summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and were proposed to be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations were represented by an alphanumeric code with the first 4 digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C–APC 5224 (Level 4 Pacemaker and Similar Procedures), included all paired code combinations that were proposed to be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to the proposed rule allowed stakeholders the opportunity to better assess the impact associated with the proposed reassignment of claims with each of the paired code combinations eligible for a complexity adjustment.

Comment: Several commenters requested exceptions to the current complexity adjustment criteria of 25 or more claims reporting the code combination (frequency) and a violation of the 2 times rule in the originating C–APC (cost) to allow claims with code combinations that do not currently meet these criteria to be paid at the next higher paying C–APC. The C–APC complexity adjustments requested by the commenters are listed in Table 5 below. We did not propose for claims with these code combinations to receive complexity adjustments because they failed to meet either the cost or frequency criteria.

TABLE 5—C–APC COMPLEXITY ADJUSTMENTS REQUESTED BY THE COMMENTERS

Primary ''J1'' HCPCS code	Secondary ''J1'' HCPCS code	Primary APC assignment	Requested complexity adjusted APC assignment
20983 (Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radio frequency).	22513 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic).	5114	5115
20983 (Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radio frequency)).	22514 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar).	5114	5115
28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint with arthrodesis, any method).	28285 (Correction, hammertoe (eg, interphalangeal fusion, partial or total phalangectomy)).	5114	5115
28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint with arthrodesis, any method).	28292 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with resection of proximal phalanx base, when performed, any method).	5114	5115
28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint).	28285 (Correction, hammertoe (eg, interphalangeal fusion, partial or total phalangectomy)).	5114	5115
61885 (Insertion or replacement of cranial nuerostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array).	61885 (Insertion or replacement of cranial nuerostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array).	5463	5464
28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint).	28292 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with resection of proximal phalanx base, when performed, any method).	5114	5115
52234 (Cystourethroscopy, with biopsy(s))	C9738 * (Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure)).	5374	5375
52235 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands).	C9738 * (Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure)).	5374	5375

TABLE 5—C–APC COMPLEXITY ADJUSTMENTS REQUESTED BY THE COMMENTERS—Continued

Primary "J1" HCPCS code	Secondary "J1" HCPCS code	Primary APC assignment	Requested complexity adjusted APC assignment
52240 (Cystourethroscopy with fulgration (including cryosurgery or laser surgery) or treatment of MINOR (less than 0.5 cm) lesion(s) with or without biopsy).	C9738 * (Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure)).	5375	5376

* HCPCS code C9738 was identified in the proposed rule as HCPCS code C97XX.

Other commenters requested various changes to the complexity adjustment criteria. One commenter requested that CMS amend the current cost criterion for a complexity adjustment to allow for code combinations that have qualified for a complexity adjustment in the previous year to qualify for a complexity adjustment for the subsequent year if the code combination is within 5 percent of the cost criterion for the subsequent year. Another commenter requested that CMS eliminate the criterion that the code combination must create a violation of the 2 times rule in the originating C–APC in order to qualify for a complexity adjustment.

Some commenters recommended that CMS create a complexity adjustment for endoscopic sinus surgery claims that include a drug or device code (C-code or a J-code), or more than two ''J1'' procedures. Other commenters requested that CMS revise its complexity adjustment methodology to account for the higher costs that essential hospitals incur when performing complex procedures and treating sicker patients.

Response: We appreciate these comments. However, at this time, we do not believe changes to the C–APC complexity adjustment criteria are necessary or that we should make exceptions to the criteria to allow claims with the code combinations suggested by the commenters to receive complexity adjustments. As stated previously (81 FR 79582), we continue to believe that the complexity adjustment criteria, which require a frequency of 25 or more claims reporting a code combination and a violation of the 2 times rule in the originating C–APC in order to receive payment in the next higher cost C–APC within the clinical family, are adequate to determine if a combination of procedures represents a complex, costly subset of the primary service. If a code combination meets these criteria, the combination receives payment at the next higher cost C–APC. Code combinations that do not meet these criteria receive the C–APC payment rate associated with the primary ''J1'' service.

A minimum of 25 claims is already very low for a national payment system. Lowering the minimum of 25 claims further could lead to unnecessary complexity adjustments for service combinations that are rarely performed. The complexity adjustment cost threshold compares the code combinations to the lowest cost significant procedure assigned to the APC. If the cost of the code combination does not exceed twice the cost of the lowest cost significant procedure within the APC, no complexity adjustment is made. Lowering or eliminating this threshold could remove so many claims from the accounting for the primary ''J1'' service that the geometric mean costs attributed to the primary procedure could be skewed.

Regarding the request for a code combination that qualified previously for a complexity adjustment to qualify for the subsequent year if the code combination is within 5 percent of the cost criterion for the subsequent year, we evaluate code combinations each year against our complexity adjustment criteria using the latest available data. We do not believe it is necessary to expand the ability for code combinations to meet the cost criterion in this manner.

We also do not believe that it is necessary to adjust the complexity adjustment criteria to allow claims that include a drug or device code, more than two ''J1'' procedures, or procedures performed at certain hospitals to qualify for a complexity adjustment. As mentioned earlier, we believe the current criteria are adequate to determine if a combination of procedures represents a complex, costly subset of the primary service.

Comment: Some commenters noted that there were certain code combinations that met the complexity adjustment criteria that were not included in Addendum J of the CY 2018 OPPS/ASC proposed rule. Specifically, commenters noted that the combinations of procedures described by the following codes were not included in Addendum J:

- CPT code 22510 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic) and CPT code 22512 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body) for multi-level vertebroplasty in the cervicothoracic region);
- CPT code 22511 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral) and CPT code 22512 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body); and
- CPT code 22511 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral) and CPT code 20982 (Ablation therapy for reduction or eradication of 1 or more bone tumors (*e.g.,* metastasis), including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency).

Response: These code combinations were inadvertently excluded from Addendum J to the CY 2018 OPPS/ASC proposed rule. These code combinations and all other code combinations that qualify for complexity adjustments are included in Addendum J to this final rule with comment period.

Comment: One commenter stated that CMS should have included the following add-on CPT codes in the complexity adjustment evaluation:

- CPT code 92978 (Endoluminal imaging of coronary vessel or graft using

intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (List separately in addition to code for primary procedure);

- CPT code 92979 (Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (List separately in addition to code for primary procedure));
- CPT code 93571 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (List separately in addition to code for primary procedure)); and
- CPT code 93572 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel (List separately in addition to code for primary procedure)) in the complexity adjustment evaluation.

Response: We note that CPT codes 92978 and 93571 were both included in the complexity adjustment evaluation in Addendum J to the CY 2018 OPPS/ASC proposed rule. However, CPT codes 92979 and 93572 are not add-on codes to primary ''J1'' services. As stated in the CY 2018 OPPS/ASC proposed rule, to determine the code combinations that qualify for complexity adjustments, we apply the established frequency and cost criteria thresholds and tests claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code *for the primary ''J1'' service* (82 FR 33575). Accordingly, because CPT codes 92979 and 93572 are not add-on codes for any primary ''J1'' services, it would not have been appropriate to include them in our complexity adjustment evaluation.

After consideration of the public comments we received, we are applying the complexity adjustment criteria as proposed. The finalized complexity adjustments for CY 2018 can be found in Addendum J to this final rule with comment period (which is available via the Internet on the CMS Web site).

(2) C–APCs for CY 2018

For CY 2018 and subsequent years, in the CY 2018 OPPS/ASC proposed rule (82 FR 33576), we proposed to continue to apply the C–APC payment policy methodology made effective in CY 2015 and updated with the implementation of status indicator ''J2'' in CY 2016. A discussion of the C–APC payment policy methodology can be found at 81 FR 79583.

As a result of our annual review of the services and APC assignments under the OPPS, we did not propose any additional C–APCs to be paid under the existing C–APC payment policy beginning in CY 2018. Table 4 of the proposed rule listed the proposed C–APCs for CY 2018, all of which were established in past rules. All C–APCs were displayed in Addendum J to the proposed rule (which is available via the Internet on the CMS Web site). Addendum J to the proposed rule also contained all of the data related to the C–APC payment policy methodology, including the list of proposed complexity adjustments and other information.

Comment: Several commenters supported the proposed C–APCs for CY 2018.

Response: We appreciate the commenters' support.

Comment: Several commenters noted that CPT code 67027 (Implantation of intravitreal drug delivery system (*e.g.,* ganciclovir implant), includes concomitant removal of vitreous) is assigned to a single-procedure C–APC (C–APC 5494 (Level 4 Intraocular Procedures)) with status indicator ''J1''. The commenters stated that the C–APC policy packages payment for adjunctive services into the payment for the primary ''J1'' procedure at the claim level, and that when the drug Retisert (described by HCPCS code J7311) is included on the claim with CPT code 62707, payment for the drug is packaged into the C–APC payment. The commenters noted that the costs of claims for the procedure, including the drug (approximately $18,433), were more than twice the proposed CY 2018 geometric mean cost for C–APC 5494 (approximately $9,134) and that, as such, this represents a violation of the 2 times rule. The commenters suggested that CMS address this issue by either separately paying for Retisert (described by HCPCS code J7311) or creating a unique APC for procedures with which HCPCS code J7311 may be billed.

Response: As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79612), section 1833(t)(2) of the Act provides that items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the APC group is more than 2 times greater than the lowest cost for an item or service within the same APC group (the 2 times rule). In accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine if there are any APC violations of the 2 times rule and whether there are any appropriate revisions to APC assignments that may be necessary or exceptions to be made. In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims.

It is the cost of the primary item or service that drives assignment to an APC group. In this case, the primary service is described by CPT code 67027, which is the only CPT code assigned to C–APC 5494 (Level 4 Intraocular Procedures). The costs of drugs or other packaged ancillary items or services that may be used with a primary service are packaged into the costs of the primary service and are not separately paid. In this case, because CPT code 67027 is assigned to a C–APC, the costs of drugs, such as Retisert, and any other items or services that are billed with the ''J1'' service are packaged into the geometric mean cost for HCPCS code 67027 and are bundled into the C–APC payment. The geometric mean cost is based on reported costs for all hospitals paid under the OPPS; to the extent that Retisert or other items are billed with the primary service, those costs are also reflected in the cost of the primary service. Therefore, because the cost of the Retisert drug is packaged into the cost of CPT code 67027, assignment of HCPCS code 67027 to C–APC 5494 does not create a 2 times rule violation.

In addition, with regard to the packaging of the drug Retisert based on the C–APC policy, as stated in previous rules (78 FR 74868 through 74869 and 74909 and 79 FR 66800), items included in the packaged payment provided with the primary ''J1'' service include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies. Therefore, we believe that HCPCS code J3711 is appropriately packaged, and we are not providing separate payment for the drug.

Comment: One commenter suggested that APC 5491 (Level 1 Intraocular Procedures) no longer be labeled a C–APC and instead be considered a traditional APC. The commenter noted that there was little cost difference for APC 5491 if it is considered a C–APC or a traditional APC and that no specific

justification was given for making APC 5491 a C–APC. The commenter suggested that only higher level Intraocular Procedure APCs have enough complexity to suggest that they should be classified as C–APCs.

Response: We continue to believe that the procedures assigned to C–APC 5491 are appropriately paid through a comprehensive APC. As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584), procedures assigned to C–APCs are primary services (mostly major surgical procedures) that are typically the focus of the hospital outpatient stay. Therefore, we believe that these procedures are appropriately assigned to a C–APC.

Comment: One commenter expressed concern that the proposal to continue to assign status indicator ''J2'' to CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) and to assign it to C–APC 8011 (Comprehensive Observation Services) when certain criteria are met would have negative effects on critical care (CPT codes 99291 and 99292 (Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes) provided in the intensive care unit ICU). Specifically, the commenter was concerned that the proposal would impact payment for tests that were ordered and furnished in the emergency room when they are appropriately repeated in the ICU and urged CMS to move with caution, and provide transparency and impact tables for hospitals, in continuing C–APC 8011.

Response: We appreciate this comment and will continue to monitor the impact of this C–APC on critical care services. We note that in situations where a patient receives critical care services in the hospital outpatient setting and is subsequently transferred to the ICU as part of an appropriate hospital inpatient admission, payment for the services furnished in the hospital outpatient setting, including critical care services, may be bundled into the Part A hospital inpatient claim via the ''Payment Window for Outpatient Services Treated as Inpatient Services (also known as the 3-day payment rule), when certain criteria are met. In addition, when a patient receiving critical care services in the hospital outpatient setting is transferred to the ICU but is not admitted to the hospital as an inpatient, payment for all eligible services is made through C–APC 8011, when certain criteria are met. We also note that CPT code 99292 is an add-on code which is packaged under the OPPS and is not one of the codes eligible to trigger payment through C–APC 8011.

After consideration of the public comments we received, we are finalizing the proposed C–APCs for CY 2018. Table 6 below lists the final C–APCs for CY 2018, all of which were established in past rules. All C–APCs are displayed in Addendum J to this final rule with comment period (which is available via the Internet on the CMS Web site). Addendum J to this final rule with comment period also contains all of the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information for CY 2018.

TABLE 6—CY 2018 C–APCS

C–APC	CY 2018 APC title	Clinical family
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS
5093	Level 3 Breast/Lymphatic Surgery & Related Procedures	BREAS
5094	Level 4 Breast/Lymphatic Surgery & Related Procedures	BREAS
5112	Level 2 Musculoskeletal Procedures	ORTHO
5113	Level 3 Musculoskeletal Procedures	ORTHO
5114	Level 4 Musculoskeletal Procedures	ORTHO
5115	Level 5 Musculoskeletal Procedures	ORTHO
5116	Level 6 Musculoskeletal Procedures	ORTHO
5153	Level 3 Airway Endoscopy	AENDO
5154	Level 4 Airway Endoscopy	AENDO
5155	Level 5 Airway Endoscopy	AENDO
5164	Level 4 ENT Procedures	ENTXX
5165	Level 5 ENT Procedures	ENTXX
5166	Cochlear Implant Procedure	COCHL
5191	Level 1 Endovascular Procedures	VASCX
5192	Level 2 Endovascular Procedures	VASCX
5193	Level 3 Endovascular Procedures	VASCX
5194	Level 4 Endovascular Procedures	VASCX
5200	Implantation Wireless PA Pressure Monitor	WPMXX
5211	Level 1 Electrophysiologic Procedures	EPHYS
5212	Level 2 Electrophysiologic Procedures	EPHYS
5213	Level 3 Electrophysiologic Procedures	EPHYS
5222	Level 2 Pacemaker and Similar Procedures	AICDP
5223	Level 3 Pacemaker and Similar Procedures	AICDP
5224	Level 4 Pacemaker and Similar Procedures	AICDP
5231	Level 1 ICD and Similar Procedures	AICDP
5232	Level 2 ICD and Similar Procedures	AICDP
5244	Level 4 Blood Product Exchange and Related Services	SCTXX
5302	Level 2 Upper GI Procedures	GIXXX
5303	Level 3 Upper GI Procedures	GIXXX
5313	Level 3 Lower GI Procedures	GIXXX
5331	Complex GI Procedures	GIXXX
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX
5361	Level 1 Laparoscopy & Related Services	LAPXX
5362	Level 2 Laparoscopy & Related Services	LAPXX

TABLE 6—CY 2018 C–APCS—Continued

C–APC	CY 2018 APC title	Clinical family
5373	Level 3 Urology & Related Services	UROXX
5374	Level 4 Urology & Related Services	UROXX
5375	Level 5 Urology & Related Services	UROXX
5376	Level 6 Urology & Related Services	UROXX
5377	Level 7 Urology & Related Services	UROXX
5414	Level 4 Gynecologic Procedures	GYNXX
5415	Level 5 Gynecologic Procedures	GYNXX
5416	Level 6 Gynecologic Procedures	GYNXX
5431	Level 1 Nerve Procedures	NERVE
5432	Level 2 Nerve Procedures	NERVE
5462	Level 2 Neurostimulator & Related Procedures	NSTIM
5463	Level 3 Neurostimulator & Related Procedures	NSTIM
5464	Level 4 Neurostimulator & Related Procedures	NSTIM
5471	Implantation of Drug Infusion Device	PUMPS
5491	Level 1 Intraocular Procedures	INEYE
5492	Level 2 Intraocular Procedures	INEYE
5493	Level 3 Intraocular Procedures	INEYE
5494	Level 4 Intraocular Procedures	INEYE
5495	Level 5 Intraocular Procedures	INEYE
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE
5627	Level 7 Radiation Therapy	RADTX
5881	Ancillary Outpatient Services When Patient Dies	N/A
8011	Comprehensive Observation Services	N/A

C–APC Clinical Family Descriptor Key: AENDO = Airway Endoscopy; AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices; BREAS = Breast Surgery; COCHL = Cochlear Implant; EBIDX = Excision/Biopsy/Incision and Drainage; ENTXX = ENT Procedures; EPHYS = Cardiac Electrophysiology; EXEYE = Extraocular Ophthalmic Surgery; GIXXX = Gastrointestinal Procedures; GYNXX = Gynecologic Procedures; INEYE = Intraocular Surgery; LAPXX = Laparoscopic Procedures; NERVE = Nerve Procedures; NSTIM = Neurostimulators; ORTHO = Orthopedic Surgery; PUMPS = Implantable Drug Delivery Systems; RADTX = Radiation Oncology; SCTXX = Stem Cell Transplant; UROXX = Urologic Procedures; VASCX = Vascular Procedures; WPMXX = Wireless PA Pressure Monitor.

(3) Brachytherapy Insertion Procedures

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584), we finalized 25 new C–APCs. Some of the HCPCS codes assigned to the C–APCs established for CY 2017 described surgical procedures for inserting brachytherapy catheters/needles and other related brachytherapy procedures such as the insertion of tandem and/or ovoids and the insertion of Heyman capsules. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583), we stated that we received public comments which noted that claims that included several insertion codes for brachytherapy devices often did not also contain a brachytherapy treatment delivery code (CPT codes 77750 through 77799). The brachytherapy insertion codes that commenters asserted were not often billed with a brachytherapy treatment code included the following:

- CPT code 57155 (Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy);
- CPT code 20555 (Placement of needles or catheters into muscle and/or soft tissue for subsequent interstitial radioelement application (at the time of or subsequent to the procedure));
- CPT code 31643 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application);
- CPT code 41019 (Placement of needles, catheters, or other device(s) into the head and/or neck region (percutaneous, transoral, or transnasal) for subsequent interstitial radioelement application);
- CPT code 43241 (Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube catheter);
- CPT code 55920 (Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application); and
- CPT code 58346 (Insertion of Heyman capsules for clinical brachytherapy).

The commenters concluded that brachytherapy delivery charges are being underrepresented in ratesetting under the C–APC methodology because a correctly coded claim should typically include an insertion and treatment delivery code combination. The commenters stated that the insertion procedure and brachytherapy treatment delivery generally occur on the same day or within the same week and therefore the services should appear on a claim together. In the CY 2017 OPPS/ASC final rule with comment period, we indicated that we would not exclude claims from the CY 2017 ratesetting calculation because we generally do not remove claims from the claims accounting when stakeholders believe that hospitals included incorrect information on some claims (81 FR 79583). However, we stated that we would examine the claims for the brachytherapy insertion codes in question and determine if any future adjustment to the methodology (or possibly code edits) would be appropriate.

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33577 through 33578), we analyzed the claims that include brachytherapy insertion codes assigned to status indicator ''J1'' and that received payment through a C–APC, and we determined that several of these codes are frequently billed without an associated brachytherapy treatment code. As mentioned above, stakeholders have expressed concerns that using claims for ratesetting for brachytherapy insertion procedures that do not also include a brachytherapy treatment code may not capture all of the costs associated with the insertion procedure. To address this issue and base payment on claims for the most common clinical scenario, for CY 2018 and subsequent years, we indicated in the CY 2018 OPPS/ASC proposed rule

(82 FR 33578) that we were establishing a code edit that requires a brachytherapy treatment code when a brachytherapy insertion code is billed.

As noted in section II.A.2.c. of the proposed rule and this final rule with comment period, we also proposed to delete composite APC 8001 (LDR Prostate Brachytherapy Composite) and assign HCPCS code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to status indicator ''J1'' and to provide payment for this procedure through the C–APC payment methodology, similar to the payment methodology for other surgical insertion procedures related to brachytherapy. Specifically, when HCPCS code 55875 is the primary service reported on a hospital outpatient claim, we proposed to package payments for all adjunctive services reported on the claim into the payment for HCPCS code 55875. We proposed to assign HCPCS code 55875 to C–APC 5375 (Level 5 Urology and Related Services). The code edit for claims with brachytherapy services described above that will be effective January 1, 2018, will require the brachytherapy application HCPCS code 77778 (Interstitial radiation source application; complex) to be included on the claim with the brachytherapy insertion procedure (HCPCS code 55875).

Comment: Several commenters opposed the implementation of a code edit that requires a brachytherapy treatment code when a brachytherapy insertion code is billed. These commenters noted that, in some cases, the insertion procedure and the brachytherapy treatment are performed on different days and reported on separate claims. The commenters also noted that the brachytherapy insertion procedure and radiation treatment delivery are not always performed in the same facility, in which case they would be on different claims. The commenters stated that this practice pattern is especially common in the treatment of breast cancer and related breast brachytherapy catheter codes.

Response: We appreciate the commenters' views. We intended to address the concerns raised by commenters in CY 2017 rulemaking regarding ratesetting for C–APCs for brachytherapy insertion procedures by establishing a code edit to require a brachytherapy treatment code when a brachytherapy insertion code is billed. This was largely based on information received from commenters last year, in which commenters had suggested that brachytherapy insertion procedures and brachytherapy radiation treatment are often performed on the same day or within the same week and are often billed on the same claim. However, based on comments received in response to the code edit, it appears that there may be some clinical scenarios where that is not the case. Accordingly, in light of the numerous comments opposing this code edit and the information provided by commenters that suggests that brachytherapy insertion and treatment services may be appropriately furnished on different dates and different claims, we have decided not to implement an edit which would require a brachytherapy treatment code when a brachytherapy insertion code is billed. As we have previously stated, we rely on hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report charges on claims and charges and costs on their Medicare hospital cost reports appropriately (77 FR 68324). We will continue to examine the issues involving ratesetting for brachytherapy insertion procedures assigned to C–APCs and welcome the public's input regarding alternative payment policies that could appropriately address the issue while maintaining the C–APC policy.

Comment: Some commenters requested that CMS discontinue the C–APC payment policy for all brachytherapy insertion codes identified in the CY 2018 OPPS/ASC proposed rule. These commenters expressed concerns that hospital billing practices for radiation oncology services are variable and inconsistent with the C–APC policy which packages services at the claim level. The commenters stated that, in some cases, needles or catheters are surgically placed prior to the brachytherapy treatment delivery, which consists of multiple fractions over several days or weeks and may be delivered at a different site of service. The commenters also requested that CMS continue the composite APC for Low Dose Rate Brachytherapy instead of assigning CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to a C–APC (Level 5 Urology and Related Services). The commenters stated that CPT codes 55920 and 19298 should be assigned to a different C–APC if CMS maintained the C–APC payment policy for brachytherapy insertion procedures in CY 2018.

Response: We continue to believe that the C–APC payment policy is appropriately applied to brachytherapy insertion procedures, including the procedure described by CPT code 55875. These procedures, like other procedures assigned to C–APCs, are primary services (mostly major surgical procedures) that are typically the focus of the hospital outpatient stay. As mentioned previously, we welcome input on alternative payment policies to address concerns surrounding the variation in hospital billing practices for radiation oncology while maintaining the C–APC policy, and we will continue to monitor this issue. The APC assignments for CPT codes 55920 and 19298 are discussed in greater detail in section XII.D.2. of this final rule with comment period.

Comment: Some commenters requested that CMS continue to provide payment for the brachytherapy insertion procedures through the C–APC policy, but exclude all radiation oncology codes on the claim (defined as CPT codes 77261 through 77799) and make separate payment for the brachytherapy treatment delivery and related planning and preparation services in addition to the C–APC payment for the brachytherapy insertion procedures. These commenters stated that this was similar to the C–APC policy for stereotactic radiosurgery (SRS) treatment.

Response: The policy intent of C–APCs is to bundle payment for all services related and adjunctive to the primary ''J1'' procedure. We do not believe that providing separate payment for radiation oncology codes that are included on a claim with a brachytherapy insertion procedure assigned to status indicator ''J1'' is in accordance with the C–APC policy. With regard to the SRS treatment policy to pay separately for the planning and preparation procedures, as stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583), this policy is a temporary special exception to the C–APC packaging policy that packages all adjunctive services (with a few exceptions listed in Addendum J to this final rule with comment period).

After consideration of the public comments we received, we are not establishing a code edit that requires a brachytherapy treatment code when a brachytherapy insertion code is billed. We are finalizing our proposal to delete composite APC 8001 (LDR Prostate Brachytherapy Composite) and assign HCPCS code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to status indicator ''J1'' and to provide payment for this procedure through the

C–APC payment methodology, similar to the payment methodology for other surgical insertion procedures related to brachytherapy.

(4) C–APC 5627 (Level 7 Radiation Therapy) Stereotactic Radiosurgery (SRS)

Stereotactic radiosurgery (SRS) is a type of radiation therapy that targets multiple beams of radiation to precisely deliver radiation to a brain tumor while sparing the surrounding normal tissue. SRS treatment can be delivered by Cobalt-60-based (also referred to as gamma knife) technology or robotic linear accelerator-based (LINAC)-based technology. As stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70336), section 634 of the American Taxpayer Relief Act (ATRA) of 2012 (Pub. L. 112–240) amended section 1833(t)(16) of the Act by adding a new subparagraph (D) to require that OPPS payments for Cobalt-60-based SRS be reduced to equal that of payments for LINAC-based SRS for covered OPD services furnished on or after April 1, 2013. Because section 1833(t)(16)(D) of the Act requires equal payment for SRS treatment delivered by Cobalt-60-based or LINAC-based technology, the two types of services involving SRS delivery instruments (which are described by HCPCS code 77371 (Radiation treatment delivery, stereotactic radiosurgery [SRS], complete course of treatment cranial lesion(s) consisting of 1 session; multi-source Cobalt 60-based) and HCPCS code 77372 (Linear accelerator-based)) are assigned to the same C–APC (C–APC 5627 Level 7 Radiation Therapy).

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70336), we stated that we had identified differences in the billing patterns for SRS procedures delivered using Cobalt-60-based and LINAC-based technologies. In particular, our claims data analysis revealed that services involving SRS delivered by Cobalt-60-based technologies (as described by HCPCS code 77371) typically included SRS treatment planning services (for example, imaging studies, radiation treatment aids, and treatment planning) and the actual deliveries of SRS treatment on the same date of service and reported on the same claim. In contrast, claims data analysis results revealed that services involving SRS delivered by LINAC-based technologies (as described by HCPCS code 77372) frequently included services related to SRS treatment (for example, imaging studies, radiation treatment aids, and treatment planning) that were provided on different dates of service and reported on claims separate from the actual delivery of SRS treatment.

We stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70336) that the intent of the C–APC policy is to package payment for all services adjunctive to the primary ''J1'' procedure and that we believed that all essential planning and preparation services related to the SRS treatment are adjunctive to the SRS treatment delivery procedure. Therefore, payment for these adjunctive services should be packaged into the C–APC payment for the SRS treatment instead of reported on a different claim and paid separately. To identify services that are adjunctive to the primary SRS treatment described by HCPCS codes 77371 and 77372, but reported on a different claim, we established modifier ''CP'' which became effective in CY 2016 and required the use of the modifier for CY 2016 and CY 2017.

To ensure appropriate ratesetting for the SRS C–APC, we believed it was necessary to unbundle payment for the adjunctive services for CY 2016 and CY 2017. Therefore, we finalized a policy to change the payment for SRS treatment for the 10 SRS planning and preparation services identified in our claims data (HCPCS codes 70551, 70552, 70553, 77011, 77014, 77280, 77285, 77290, 77295, and 77336) that were reported differentially using HCPCS codes 77371 and 77372 both on the same claim as the SRS services and on claims 1 month prior to the delivery of SRS services. These codes were removed from the geometric mean cost calculations for C–APC 5627. In addition, for CY 2016 and CY 2017, we provided separate payment for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology, even when the planning service was included on the same claim as the primary ''J1'' SRS treatment service. The use of the modifier ''CP'' was not required to identify these 10 planning and preparation codes.

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33564 and 33465), the data collection period for SRS claims with modifier ''CP'' began on January 1, 2016 and concludes on December 31, 2017. Based on our analysis of preliminary data collected with modifier ''CP'', we have identified some additional services that are adjunctive to the primary SRS treatment and reported on a different claim outside of the 10 SRS planning and preparation codes that were removed from the SRS C–APC costs calculations and paid separately.

However, the ''CP'' modifier has been used by a small number of providers since its establishment. In addition, our analysis showed that several of the HCPCS codes that were billed with modifier ''CP'' belonged to the group of 10 SRS planning and preparation codes that we pay separately and do not require the use of modifier ''CP''. Also, some providers erroneously included the modifier when reporting the HCPCS code for the delivery of the LINAC-based SRS treatment. As stated above, the data collection period for SRS claims with modifier ''CP'' was set to conclude on December 31, 2017. Accordingly, for CY 2018, we are deleting this modifier and discontinuing its required use.

For CY 2018, we also proposed to continue to make separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 1 month of the SRS treatment. The continued separate payment of these services will allow us to complete our analysis of the claims data including modifier ''CP'' from both CY 2016 and CY 2017 claims. As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583), we will consider in the future whether repackaging all adjunctive services (planning, preparation, and imaging, among others) back into cranial single session SRS is appropriate.

We invited public comments on these proposals.

Comment: Commenters generally supported the proposal to continue to make separate payments for the planning and preparation services adjunctive to the delivery of the SRS treatment and requested that CMS continue to pay separately for these services in the future. Commenters also supported the deletion of modifier ''CP''.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to make separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 1 month of the SRS treatment.

(5) Complexity Adjustment for Blue Light Cystoscopy Procedures

As discussed in prior OPPS/ASC final rules with comment period, and most recently in the CY 2017 OPPS/ASC final

rule with comment period (81 FR 79668), we continue to believe that Cysview® (hexaminolevulinate HCl) (described by HCPCS code C9275) is a drug that functions as a supply in a diagnostic test or procedure and is therefore packaged with payment for the primary procedure. In addition, as discussed in section II.A.2.b.(1) of the CY 2018 OPPS/ASC proposed rule and this final rule with comment period, drugs that are not eligible for pass-through payment are always packaged when billed with a comprehensive service. To maintain the integrity of the OPPS, we believe it is generally not appropriate to allow exceptions to our drug packaging policy or comprehensive APC policy that would result in separate payment for the drug based on the product's ASP+6 percent payment rate. While we did not propose in the CY 2018 proposed rule to pay separately for Cysview®, we have heard concerns from stakeholders that the payment for blue light cystoscopy procedures involving Cysview® may be creating a barrier to beneficiaries receiving access to reasonable and necessary care for which there may not be a clinically comparable alternative. Therefore, as we stated in the proposed rule, we revisited our payment policy for blue light cystoscopy procedures. As described in more detail below, we believe certain code combinations for blue light cystoscopy procedures should be eligible to qualify for a complexity adjustment, given the unique properties of the procedure and resource costs.

Traditionally, white light (or standard) cystoscopy, typically performed by urologists, has been the gold standard for diagnosing bladder cancer. Enhanced bladder cancer diagnostics, such as narrow band imaging or blue light cystoscopy, increase tumor detection in nonmuscle invasive bladder cancer over white light cystoscopy alone, thus enabling more precise tumor removal by the urologist. Blue light cystoscopy can only be performed after performance of white light cystoscopy. Because blue light cystoscopy requires specialized imaging equipment to view cellular uptake of the dye that is not otherwise used in white light cystoscopy procedures, some practitioners consider blue light cystoscopy to be a distinct and adjunctive procedure to white light cystoscopy. However, the current CPT coding structure for cystoscopy procedures does not identify blue light cystoscopy in the coding descriptions separate from white light cystoscopy. Therefore, the existing cystoscopy CPT codes do not distinguish cystoscopy procedures involving only white light cystoscopy from those involving both white and blue light cystoscopy, which require additional resources compared to white light cystoscopy alone.

As discussed in the CY 2018 OPPS/ASC proposed rule, after discussion with our clinical advisors (including a urologist), we believe that blue light cystoscopy represents an additional elective but distinguishable service as compared to white light cystoscopy that, in some cases, may allow greater detection of bladder tumors in beneficiaries relative to white light cystoscopy alone. Given the additional equipment, supplies, operating room time, and other resources required to perform blue light cystoscopy in addition to white light cystoscopy, for CY 2018, in the proposed rule, we proposed to create a new HCPCS C-code to describe blue light cystoscopy and to allow for a complexity adjustment to APC 5374 (Level 4 Urology and Related Services) for certain code combinations in APC 5373 (Level 3 Urology and Related Services). (In the proposed rule, we cited HCPCS code ''C97XX'' as a placeholder for the new code. However, for ease of reading, hereafter in this section, we refer to the replacement code HCPCS code C9738 (Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure)) instead of the placeholder code.) Specifically, to determine which code pair combinations of a procedure described by proposed new HCPCS code C9738 and a cystoscopy procedure would qualify for a complexity adjustment, we first crosswalked the costs of the procedure described by HCPCS code C9275 (Hexaminolevulinate hcl) to the procedure described by proposed new HCPCS code C9738 assigned status indicator ''N''. Next, we identified the procedure codes used to describe white light cystoscopy of the bladder which include the following CPT codes and APC assignments:

- APC 5372 (Level 2 Urology and Related Services)
  - ☐ CPT code 52000
- APC 5373 (Level 3 Urology and Related Services)
  - ☐ CPT code 52204
  - ☐ CPT code 52214
  - ☐ CPT code 52224
- APC 5374 (Level 4 Urology and Related Services)
  - ☐ CPT code 52234
  - ☐ CPT code 52235
- APC 5375 (Level 5 Urology and Related Services)
  - ☐ CPT code 52240

Because APC 5372 is not a C–APC, cystoscopy procedures assigned to Level 2 Urology are not eligible for a complexity adjustment, and therefore, we did not analyze these codes to determine whether they met the criteria for this adjustment. We modeled the data to determine which code pair combinations exceed the claim frequency and cost threshold in APC 5373, APC 5374, and APC 5375, which are all C–APCs. In the proposed rule, we stated that the results of our analysis indicate that the code pair combination of procedures described by proposed new HCPCS code C9738 and cystoscopy procedures assigned to APC 5373 would be eligible for a complexity adjustment based on current criteria and cost data because they meet the frequency and cost criteria thresholds. Likewise, our results indicated that the combination of procedures described by proposed new HCPCS code C9738 and cystoscopy procedures assigned to APC 5374 and APC 5375 would not qualify for a complexity adjustment because they do not meet the frequency and cost criteria thresholds.

We indicated in the proposed rule that, under the C–APC policy, blue light cystoscopy would be packaged, but when performed with a cystoscopy procedure in APC 5373 and reported with proposed new HCPCS code C9738 in addition to the cystoscopy CPT code, there would be a complexity adjustment to the next higher level APC in the series, resulting in a higher payment than for the white light cystoscopy procedure alone. That is, if the code pair combination of proposed new HCPCS code C9738 with CPT code 52204, 52214, or 52224 is reported on a claim, the claim will qualify for payment reassignment from APC 5373 to APC 5374. We stated that we plan to track the utilization and the costs associated with white light/blue light cystoscopy procedure combinations that will receive a complexity adjustment.

We invited public comments on our CY 2018 proposal to allow for a complexity adjustment when a white light cystoscopy procedure followed by a blue light cystoscopy procedure is performed. In addition, we sought public comments on whether alternative procedures, such as narrow band imaging, may be disadvantaged by this proposed policy.

Comment: One commenter agreed that there are differences in resource utilization between cystoscopy procedures involving white light only and cystoscopy procedures involving both white light and blue light. However, the commenter recommended that a proposal to expand the

cystoscopy CPT codes be submitted to the American Medical Association (AMA) to capture the resource distinction. The commenter stated that the use of CPT codes and HCPCS C-codes (for example, the proposed HCPCS code C9738) to capture cystoscopy procedures is duplicative, administratively burdensome, and can affect the quality of claims data.

Response: We appreciate the commenter's concerns. However, we proposed to establish this code based on programmatic need under the OPPS to accurately describe blue light cystoscopy procedures. Given that a CPT code that describes blue light cystoscopy with an optical imaging agent does not exist in the CY 2018 CPT code set published by the AMA, it is unclear to us why the commenter believes HCPCS code C9738 would be duplicative, administratively burdensome, or affect the quality of claims data. Moreover, it is the combination of two different procedures that trigger a complexity adjustment; therefore, two distinct CPT or HCPCS codes are necessary to effectuate a complexity adjustment. If the AMA establishes a CPT code that describes blue light cystoscopy with an optical imaging agent, we would consider recognizing that CPT code under the OPPS as a replacement for HCPCS code C9738.

Comment: A few commenters generally supported the proposal to allow for a complexity adjustment for blue light cystoscopy with Cysview procedures. Many commenters, including several commenters with experience utilizing blue light cystoscopy with Cysview, shared their views on how this procedure has positively affected patient care management. These commenters recommended that CMS apply a complexity adjustment to all blue light cystoscopy with Cysview procedures performed in HOPDs to improve utilization and beneficiary access to care. Alternatively, the commenters recommended that CMS pay separately for Cysview to allow access in both white light and blue light cystoscopies in HOPD and ASC settings or establish a payment methodology conceptually similar to the device-intensive payment procedure for ASCs. The commenters suggested that a ''device-intensive like'' payment for a cystoscopy procedure performed in the ASC would be set based on the service cost and the drug cost (as determined by the manufacturer-reported average sales price).

Response: We appreciate the commenters' support. In developing the blue light cystoscopy procedure complexity adjustment payment proposal, we considered the unique properties and resources required to perform blue light cystoscopy with Cysview. As described in the proposal, we approximated the costs for the additional resources required to perform blue light cystoscopy by crosswalking the costs associated with HCPCS code C9275 to HCPCS code C9738. We then applied the established complexity adjustment criteria to determine which cystoscopy procedures, when performed with blue light cystoscopy, would qualify for a complexity adjustment. For this final rule with comment period, we repeated the analysis to determine which code pair combinations of HCPCS code C9738 with a cystoscopy procedure CPT code satisfied the complexity adjustment criteria. Consistent with the proposed rule results, based on the updated final rule with comment period claims data, the code pair combination of HCPCS code C9738 with CPT code 52204, 52214, or 52224 each will qualify for a complexity adjusted payment from APC 5373 to APC 5374. Because APC 5372 is not a C–APC, cystoscopy procedures assigned to Level 2 Urology are not eligible for a complexity adjustment. Therefore, we did not analyze these codes to determine whether they were eligible for a complexity adjustment. Likewise, our analysis of the final rule claims data indicated that the combination of proposed HCPCS code C9738 and cystoscopy procedures assigned to APC 5374 and APC 5375 would not qualify for a complexity adjustment because they do not meet the frequency and cost criteria thresholds.

We did not propose and the commenters did not provide evidence to support waiving application of the complexity adjustment criteria and allowing for a complexity adjustment whenever a blue light cystoscopy procedure is performed with any white light cystoscopy procedure. To allow for a complexity adjustment under any circumstance would require a change to the complexity adjustment criteria, which we did not propose. Therefore, we are finalizing the blue light cystoscopy complexity adjustment proposal, without modification. In addition we are establishing HCPCS code C9738 (Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure)), which replaces proposed HCPCS code C97XX. For CY 2018, the code pair combination of HCPCS code C9738 with CPT code 52204, 52214, or 52224 will qualify for a complexity adjusted payment from APC 5373 to APC 5374.

With respect to the public comments on unpackaging Cysview to allow for separate payment in both the HOPD and ASC settings, as we stated in the background section for the proposal, we continue to believe that Cysview is a drug that functions as a supply in a diagnostic test or procedure and therefore is packaged with payment for the primary procedure. In the CY 2018 OPPS/ASC proposed rule, we did not propose to make any changes to the ''drugs that function as a supply'' packaging policy or make any corresponding proposals to pay separately for Cysview in the HOPD and ASC settings. Therefore, Cysview will remain packaged.

With respect to the recommendation that we establish a payment methodology for blue light cystoscopy with Cysview procedures conceptually similar to the ASC device intensive payment policy, we did not propose revisions to the ASC device-intensive procedure policy. In addition, it is unclear to us exactly how such a policy would work and to what precise procedures in addition to blue light cystoscopy it might apply. Further, we believe that the C–APC payment adequately reflects the average resources expended by hospitals as reflected in hospital claims data. In addition, for especially costly cases, we believe our proposed policy appropriately recognizes the additional costs of blue light cystoscopy with white light cystoscopy through the complexity adjustment. We will continue to analyze the data and evaluate whether refinements to the C–APC policy, including the complexity adjustment criteria, should be considered in future rulemaking.

Comment: A few commenters responded to the solicitation for public comments on whether an alternative procedure, such as narrow band imaging, would be disadvantaged by the blue light cystoscopy with Cysview complexity adjustment proposal. One commenter, the manufacturer of Cysview, requested that CMS not establish a complexity adjustment for narrow band imaging because this imaging does not require a drug, additional technology, or additional resource. The commenter stated that the equipment used in narrow band imaging cystoscopy procedures is not different than the equipment for white light cystoscopy and does not require more resource time, expense, or cost to the hospital because narrow band imaging technology is part of the standard equipment available for cystoscopic

procedures. Another commenter, the developer of narrow band imaging, contended that the procedure shares many clinical and procedural similarities with blue light cystoscopy with Cysview procedures, and therefore narrow band imaging should be eligible for a complexity adjustment. In addition, the commenter expressed concern that a complexity adjustment for blue light cystoscopy with Cysview and not narrow band imaging would provide a financial incentive for providers to choose one technology over the other. However, the commenter did not provide cost information for narrow band imaging.

Response: We appreciate the commenters' responses. We do not believe that the information presented supports a complexity adjustment for narrow band imaging. The lack of cost information for narrow band imaging and the fact that narrow band imaging does not require use of a contrast agent (and, therefore, avoids the cost of contrast and the time associated with the administration of contrast) lead us to question whether the resource costs of narrow band imaging are the same as those of blue light cystoscopy with Cysview. For these reasons, we do not believe it is appropriate to modify the proposal to allow for a complexity adjustment when narrow band imaging is performed with white light cystoscopy.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to allow for a complexity adjustment when HCPCS code C9738 is reported on the same claim as CPT code 52204, 52214, or 52224. The result of billing any one of these three code pair combinations is a payment reassignment from APC 5373 to APC 5374.

(6) Analysis of C–APC Packaging Under the OPPS

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584), we accepted a recommendation made at the August 22, 2016 HOP Panel meeting to analyze the effects of C–APCs. The HOP panel recommendation did not elucidate specific concerns with the C–APC policy or provide detailed recommendations on particular aspects of the policy to analyze. Therefore, we took a broad approach in studying HCPCS codes and APCs subject to the C–APC policy to determine whether aberrant trends in the data existed. Overall, we observed no such aberrancies and believe that the C–APC policy is working as intended.

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33580), specifically, using OPPS claims data for the CY 2016 final rule with comment period, the CY 2017 final rule with comment period, and the CY 2018 proposed rule, which reflect an observation period of CY 2014 to CY 2016, we examined the effects of C–APCs and their impact on OPPS payments. We started with all hospital outpatient claims billed on the 13X claim-type and, from that, separately identified HCPCS codes and APCs that were subject to the comprehensive methodology in CYs 2015 and 2016 (that is, HCPCS codes or APCs assigned status indicator ''J1'' or ''J2''). Next, we analyzed the claims to create a subset of claims that contain the HCPCS codes and APCs that were subject to the comprehensive methodology. Using the claims noted above, we analyzed claim frequency, line frequency, number of billing units, and the total OPPS payment between CYs 2014 and 2016 for each HCPCS code and APC that had been previously identified. In reviewing the cost statistics for HCPCS codes for procedures with status indicator ''S'', ''T'', or ''V'' in CY 2014 that were assigned to a C–APC in either CY 2015 or CY 2016, overall, we observed an increase in claim line frequency, units billed, and Medicare payment, which suggest that the C–APC payment policy did not adversely affect access to care or reduce payments to hospitals. Decreases in these cost statistics would suggest our comprehensive packaging logic is not working as intended and/or the C–APC payment rates were inadequate, resulting in lower volume due to migration of services to other settings or the cessation of providing these services. Likewise, because the cost statistics of major separately payable codes (that is, HCPCS codes with status indicator ''S'', ''T'', or ''V'') that were packaged into a C–APC prospectively were consistent with the cost statistics of the codes packaged on the claim, in actuality, indicate that costs were appropriately redistributed, we believe the C–APC payment methodology is working as intended.

Comment: A few commenters appreciated CMS' analysis of C–APC packaging under the OPPS and urged CMS to continue to monitor the data and report on any changes in billing patterns or utilization for particular items or services.

Response: We appreciate the commenters' support. We will continue to monitor the impact of our C–APC policy on OPPS rate setting and evaluate if future adjustments are needed.

c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for low dose rate (LDR) prostate brachytherapy, mental health services, and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for a full discussion of the development of the composite APC methodology (72 FR 66611 through 66614 and 66650 through 66652) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) for more recent background.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33580), for CY 2018 and subsequent years, we proposed to continue our composite APC payment policies for mental health services and multiple imaging services, as discussed below. As discussed in section II.A.2.b. of the proposed rule and this final rule with comment period, we proposed to assign CPT code 55875 (Transperineal placement of needs or catheters into prostate for interstitial radioelement application, with or without cystoscopy) a status indicator of ''J1'' and assign it to a C–APC. In conjunction with this proposal, we also proposed to delete the low dose rate (LDR) prostate brachytherapy composite APC for CY 2018 and subsequent years. We refer readers to section II.A.2.b. of the CY 2018 OPPS/ASC proposed rule and this final rule with comment period for our discussion on our low dose rate (LDR) prostate brachytherapy APC proposal for CY 2018 and subsequent years.

(1) Mental Health Services Composite APC

In the CY 2018 OPPS/ASC proposed rule (82 FR 33580), we proposed to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79588 through 79589), we finalized a policy to combine the existing Level 1 and Level 2 hospital-based PHP APCs into a single hospital-based PHP APC and, thereby, discontinue APCs 5861 (Level 1 Partial Hospitalization (3 services) for Hospital-Based PHPs) and 5862 (Level 2 Partial Hospitalization (4 or more services) for Hospital-Based PHPs) and replace them with APC 5863 (Partial Hospitalization (3 or more services per day)). For CY 2018, and subsequent years, we proposed that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 (Mental Health Services Composite) for CY 2018. In addition, we proposed to set the payment rate for composite APC 8010 for CY 2018 at the same payment rate that we proposed for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the payment rate for composite APC 8010. Under this policy, the I/OCE would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5863 for all of the specified mental health services furnished by the hospital on that single date of service. We stated that we continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource intensive of all outpatient mental health services. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

We did not receive any public comments on these proposals. Therefore, we are finalizing our CY 2018 proposal, without modification, that when aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a date of service, based on the payment rates with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 for CY 2018. In addition, we are finalizing our CY 2018 proposal, without modification, to set the payment rate for composite APC 8010 for CY 2018 at the same payment rate that we established for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the payment rate for composite APC 8010.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, in order to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 12 of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74920 through 74924).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

In the CY 2018 OPPS/ASC proposed rule (82 FR 33581), we proposed, for CY 2018 and subsequent years, to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We stated that we continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

The proposed CY 2018 payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from a partial year of CY 2016 claims available for the CY 2018 OPPS/ASC proposed rule that qualified for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we used to calculate the final geometric

mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), were identified by asterisks in Addendum N to the CY 2018 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site) and were discussed in more detail in section II.A.1.b. of the CY 2018 OPPS/ASC proposed rule.

For the CY 2018 OPPS/ASC proposed rule, we were able to identify approximately 634,918 ''single session'' claims out of an estimated 1.7 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 36 percent of all eligible claims, to calculate the proposed CY 2018 geometric mean costs for the multiple imaging composite APCs. Table 6 of the CY 2018 OPPS/ASC proposed rule listed the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2018.

Comment: One commenter supported the composite APC policy for imaging services and recommended that CMS pay composite imaging APCs separately when billed on a claim with a service that has been assigned a ''J1'' status indicator, that is, as a C–APC.

Response: We appreciate the commenter's support. Regarding the recommendation about paying for composite APCs separately when billed on a claim with a service that has been assigned a ''J1'' status indicator, procedures assigned to C–APCs are primary services that are typically the focus of the hospital outpatient stay. As discussed in section II.A.2.b. of this final rule with comment period, our C–APC policy packages payment for adjunctive and secondary items, services, and procedures, including diagnostic procedures, into the most costly procedure under the OPPS at the claim level. We believe that paying for composite APCs separately when billed with a service that has been assigned a ''J1'' status indicator would be in conflict with the intent of our C–APC policy and would not be appropriate.

After consideration of the public comments we received, we are finalizing our proposal to continue the use of multiple imaging composite APCs to pay for services providing more than one imaging procedure from the same family on the same date, without modification. Table 7 below lists the HCPCS codes that will be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2018.

TABLE 7—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

CY 2018 APC 8004 (ultrasound composite)	CY 2018 approximate APC geometric mean cost = $300
Family 1—Ultrasound	
76700	Us exam, abdom, complete.
76705	Echo exam of abdomen.
76770	Us exam abdo back wall, comp.
76776	Us exam k transpl w/Doppler.
76831	Echo exam, uterus.
76856	Us exam, pelvic, complete.
76857	Us exam, pelvic, limited.
CY 2018 APC 8005 (CT and CTA without contrast composite) *	CY 2018 approximate APC geometric mean cost = $275
Family 2—CT and CTA with and without Contrast	
70450	Ct head/brain w/o dye.
70480	Ct orbit/ear/fossa w/o dye.
70486	Ct maxillofacial w/o dye.
70490	Ct soft tissue neck w/o dye.
71250	Ct thorax w/o dye.
72125	Ct neck spine w/o dye.
72128	Ct chest spine w/o dye.
72131	Ct lumbar spine w/o dye.
72192	Ct pelvis w/o dye.
73200	Ct upper extremity w/o dye.
73700	Ct lower extremity w/o dye.
74150	Ct abdomen w/o dye.
74261	Ct colonography, w/o dye.
74176	Ct angio abd & pelvis.
CY 2018 APC 8006 (CT and CTA with contrast composite)	CY 2018 approximate APC geometric mean cost = $501
70487	Ct maxillofacial w/dye.
70460	Ct head/brain w/dye.
70470	Ct head/brain w/o & w/dye.
70481	Ct orbit/ear/fossa w/dye.
70482	Ct orbit/ear/fossa w/o & w/dye.
70488	Ct maxillofacial w/o & w/dye.
70491	Ct soft tissue neck w/dye.
70492	Ct sft tsue nck w/o & w/dye.
70496	Ct angiography, head.
70498	Ct angiography, neck.
71260	Ct thorax w/dye.

TABLE 7—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

71270	Ct thorax w/o & w/dye.
71275	Ct angiography, chest.
72126	Ct neck spine w/dye.
72127	Ct neck spine w/o & w/dye.
72129	Ct chest spine w/dye.
72130	Ct chest spine w/o & w/dye.
72132	Ct lumbar spine w/dye.
72133	Ct lumbar spine w/o & w/dye.
72191	Ct angiograph pelv w/o & w/dye.
72193	Ct pelvis w/dye.
72194	Ct pelvis w/o & w/dye.
73201	Ct upper extremity w/dye.
73202	Ct uppr extremity w/o & w/dye.
73206	Ct angio upr extrm w/o & w/dye.
73701	Ct lower extremity w/dye.
73702	Ct lwr extremity w/o & w/dye.
73706	Ct angio lwr extr w/o & w/dye.
74160	Ct abdomen w/dye.
74170	Ct abdomen w/o & w/dye.
74175	Ct angio abdom w/o & w/dye.
74262	Ct colonography, w/dye.
75635	Ct angio abdominal arteries.
74177	Ct angio abd & pelv w/contrast.
74178	Ct angio abd & pelv 1+ regns.

* If a ''without contrast'' CT or CTA procedure is performed during the same session as a ''with contrast'' CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.

CY 2018 APC 8007 (MRI and MRA without contrast composite) *	CY 2018 approximate APC geometric mean cost = $556
Family 3—MRI and MRA with and without Contrast	
70336	Magnetic image, jaw joint.
70540	Mri orbit/face/neck w/o dye.
70544	Mr angiography head w/o dye.
70547	Mr angiography neck w/o dye.
70551	Mri brain w/o dye.
70554	Fmri brain by tech.
71550	Mri chest w/o dye.
72141	Mri neck spine w/o dye.
72146	Mri chest spine w/o dye.
72148	Mri lumbar spine w/o dye.
72195	Mri pelvis w/o dye.
73218	Mri upper extremity w/o dye.
73221	Mri joint upr extrem w/o dye.
73718	Mri lower extremity w/o dye.
73721	Mri jnt of lwr extre w/o dye.
74181	Mri abdomen w/o dye.
75557	Cardiac mri for morph.
75559	Cardiac mri w/stress img.
C8901	MRA w/o cont, abd.
C8904	MRI w/o cont, breast, uni.
C8907	MRI w/o cont, breast, bi.
C8910	MRA w/o cont, chest.
C8913	MRA w/o cont, lwr ext.
C8919	MRA w/o cont, pelvis.
C8932	MRA, w/o dye, spinal canal.
C8935	MRA, w/o dye, upper extr
CY 2018 APC 8008 (MRI and MRA with contrast composite)	CY 2018 approximate APC geometric mean cost = $871
70549	Mr angiograph neck w/o & w/dye.
70542	Mri orbit/face/neck w/dye.
70543	Mri orbt/fac/nck w/o & w/dye.
70545	Mr angiography head w/dye.
70546	Mr angiograph head w/o & w/dye.
70547	Mr angiography neck w/o dye.
70548	Mr angiography neck w/dye.
70552	Mri brain w/dye.
70553	Mri brain w/o & w/dye.
71551	Mri chest w/dye.
71552	Mri chest w/o & w/dye.
72142	Mri neck spine w/dye.
72147	Mri chest spine w/dye.
72149	Mri lumbar spine w/dye.

TABLE 7—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

72156	Mri neck spine w/o & w/dye.
72157	Mri chest spine w/o & w/dye.
72158	Mri lumbar spine w/o & w/dye.
72196	Mri pelvis w/dye.
72197	Mri pelvis w/o & w/dye.
73219	Mri upper extremity w/dye.
73220	Mri uppr extremity w/o & w/dye.
73222	Mri joint upr extrem w/dye.
73223	Mri joint upr extr w/o & w/dye.
73719	Mri lower extremity w/dye.
73720	Mri lwr extremity w/o & w/dye.
73722	Mri joint of lwr extr w/dye.
73723	Mri joint lwr extr w/o & w/dye.
74182	Mri abdomen w/dye.
74183	Mri abdomen w/o & w/dye.
75561	Cardiac mri for morph w/dye.
75563	Card mri w/stress img & dye.
C8900	MRA w/cont, abd.
C8902	MRA w/o fol w/cont, abd.
C8903	MRI w/cont, breast, uni.
C8905	MRI w/o fol w/cont, brst, un.
C8906	MRI w/cont, breast, bi.
C8908	MRI w/o fol w/cont, breast.
C8909	MRA w/cont, chest.
C8911	MRA w/o fol w/cont, chest.
C8912	MRA w/cont, lwr ext.
C8914	MRA w/o fol w/cont, lwr ext.
C8918	MRA w/cont, pelvis.
C8920	MRA w/o fol w/cont, pelvis.
C8931	MRA, w/dye, spinal canal.
C8933	MRA, w/o&w/dye, spinal canal.
C8934	MRA, w/dye, upper extremity.
C8936	MRA, w/o&w/dye, upper extr.

* If a ''without contrast'' MRI or MRA procedure is performed during the same session as a ''with contrast'' MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.

3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular patient. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which often occurs if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2000 OPPS final rule (65 FR 18434), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70343), and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592). As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the

OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

For CY 2018, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment of the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and outpatient hospital billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies. In the CY 2018 OPPS/ASC proposed rule (82 FR 33584 through 33585), for CY 2018, we proposed to conditionally package the costs of selected newly identified ancillary services into payment with a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code. Below we discuss the items and services that we proposed to package beginning in CY 2018.

b. Drug Administration Packaging Policy

(1) Background of Drug Administration Packaging Policy

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74942 through 74945), we finalized a policy to unconditionally package procedures described by add-on codes. Procedures described by add-on codes represent an extension or continuation of a primary procedure, which means that they are typically supportive, dependent, or adjunctive to a primary service. The primary code defines the purpose and typical scope of the patient encounter and the add-on code describes incremental work, when the extent of the procedure encompasses a range rather than a single defined endpoint applicable to all patients. Given the dependent nature and adjunctive characteristics of procedures described by add-on codes and in light of longstanding OPPS packaging principles, we finalized a policy to unconditionally package add-on codes with the primary procedure. However, in response to stakeholder comments on the appropriateness of packaging drug administration add-on codes, we did not finalize our proposal to package drug administration add-on codes (78 FR 74945).

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66819 through 66822), we conditionally packaged payment for ancillary services assigned to APCs with a geometric mean cost of less than or equal to $100 (prior to application of the conditional packaging status indicator). The ancillary services that we identified are primarily minor diagnostic tests and procedures that are often performed with a primary service, although there are instances where hospitals provide such services alone and without another primary service during the same encounter. Under this policy, we assigned the conditionally packaged services to status indicator ''Q1'', which indicates that the service is separately payable when not billed on the same claim as a HCPCS code assigned status indicator ''S'', ''T'', or ''V''. Exclusions to this ancillary service packaging policy include preventive services, certain psychiatric and counseling-related services, and certain low-cost drug administration services. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66819), we indicated that we did not propose to package certain low-cost drug administration services because we were examining various alternative payment policies for drug administration, including the associated drug administration add-on codes.

(2) Packaging of Level 1 and Level 2 Drug Administration Services

As stated earlier, our overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule. To achieve this goal, it is important that we are consistent in our approach to packaging items and services under the established packaging categories. Although we excluded packaging of low-cost drug administration services from the ancillary services packaging policy in the CY 2015 rulemaking, separate payment for drug administration services is an example of inconsistent application of our packaging policy where we are continuing to pay separately for a service, regardless of cost and performance with another service. Given the frequency of drug administration in hospital outpatient care, in the CY 2018 OPPS/ASC proposed rule, we stated that we believe it is appropriate for us to reconsider whether payment for drug administration services with a geometric mean cost of less than or equal to $100 (prior to application of the conditional packaging status indicator) should continue to be excluded from the ancillary services packaging policy.

As part of our review of CY 2016 claims data used for ratesetting in the CY 2018 OPPS/ASC proposed rule, we examined drug administration billing patterns and payment for drug administration services under the OPPS. Based on our analysis of CY 2016 claims data used for the CY 2018 proposed rule ratesetting, we found that the geometric mean cost for APC 5691 (Level 1 Drug Administration) is approximately $37 and the geometric mean cost for APC 5692 (Level 2 Drug Administration) is approximately $59. In addition, we observed that drug administration services in APC 5692 are frequently reported on the same claim with other separately payable services, such as an emergency department or clinic visit, while drug administration services in APC 5691 are sometimes reported with other separately payable services. Accordingly, Medicare data show that these drug administration services are currently being provided as part of another separately payable service for which two separate payments are made, and support that packaging these services, when they are reported with another separately payable service, is appropriate. Further, packaging for Levels 1 and 2 Drug Administration services is consistent with the ancillary packaging policy that was adopted in CY 2015, as noted earlier in this section. Therefore, given the low geometric mean costs of drug administration services in APC 5691 and APC 5692 as well as their associated billing patterns, we stated in the CY 2018 OPPS/ASC proposed rule that we believe that when these services are performed with another separately payable service, they should be packaged, but that they should be separately paid when performed alone. That is, we stated that we believe it is no longer necessary to exclude low-cost drug administration services from packaging under the ancillary services packaging policy adopted in CY 2015.

In addition, as we examine payment differences between the hospital outpatient department and the physician office for similar services, under the OPPS, hospitals may receive separate payments for a clinic (office) visit and a drug administration service. In contrast, physicians are not eligible to receive payment for an office visit when a drug administration service is also provided. As a result, for furnishing the same drug administration service, hospitals receive an additional payment

for which physician offices are not eligible. We stated in the proposed rule that we believe that conditional packaging of drug administration services would promote equitable payment between the physician office and the hospital outpatient hospital department. Accordingly, for CY 2018, we proposed to conditionally package payment for HCPCS codes describing drug administration services in APC 5691 and APC 5692, except for add-on codes and preventive services, when these services are performed with another service.

Because preventive services are excluded from our packaging policies, we proposed to continue to pay separately for Medicare Part B vaccine administration services. In addition, at that time, we did not propose to package any drug administration services in APC 5693 (Level 3 Drug Administration) or APC 5694 (Level 4 Drug Administration), but indicated our interest in public comments pertaining to whether payment for the services in these APCs may be appropriate for packaging. The proposed status indicators for drug administration services in APC 5691 and APC 5692 were listed in Table 7 of the proposed rule.

Comment: Numerous commenters disagreed with CMS' proposal to conditionally package low-cost drug administration services assigned to APC 5691 and APC 5692. The commonly cited concerns among the commenters who opposed the proposal were as follows:

- Low-cost drug administration services are dissimilar from other low cost ancillary services in that drug administration services are separate and distinct stand-alone services and not adjunctive, supportive, or dependent to a primary procedure.
- The proposal would not promote equitable payment between the physician's office and the hospital outpatient department because, in accordance with CMS guidelines, there are clinical circumstances where a physician may receive payment for both a drug administration service and an office visit.
- Because all drugs are separately payable in the physician's office, unlike under the OPPS, the proposal, if implemented, would exacerbate differences in payment between the hospital outpatient department and the physician office setting. Commenters expressed doubt that the full cost of a packaged drug administration service or drug would be appropriately and accurately reflected in the payment for another separately payable procedure.
- Packaging drug administration services with other services could result in hospitals scheduling patients for multiple visits, thereby reducing access to care and quality of care.
- Further analysis of the impact packaging drug administration services would have on APCs should be conducted prior to making a policy change.
- In general, packaging discourages full reporting of hospital costs, which impacts the accuracy of cost data that are used to calculate OPPS payment rates.

In addition, at the summer 2017 meeting of the HOP Panel, the HOP Panel recommended that CMS not implement its proposal to package drug administration services described under APC 5691 (Level 1 Drug Administration) and APC 5692 (Level 2 Drug Administration).

Response: We appreciate the detailed responses to our proposal and agree with the statements concerning the importance of payment accuracy to maintain access to care. However, we disagree that conditional packaging of low-level drug administration services, which are commonly furnished both in the hospital outpatient setting and in the physician office setting, would lead to payment inaccuracy for hospital rates for these services (which would include the packaged costs of these services) or to decreased access to drug administration services. As stated in the proposed rule, we believe it is no longer necessary to exclude low-cost drug administration services from packaging under the ancillary services packaging policy adopted in CY 2015, which is supported by our analysis of drug administration billing patterns. As described earlier in the introduction to this section, our analysis of CY 2016 OPPS claims data showed that low-cost drug administration services are currently being provided as part of another separately payable service for which two separate payments are made, and supported a policy that packaging low-cost drug administration services, when they are reported with another separately payable service, is appropriate. In response to the commenters who raised concerns regarding potential behavioral changes by providers as a consequence of the proposal, we will continue to monitor the data for changes in drug administration billing patterns.

Furthermore, regarding the comments that low-cost drug administration services are separate and distinct standalone services and not adjunctive, supportive, or dependent to a primary procedure, we disagree based on typical billing patterns for these services. As stated earlier in the introduction to this section, ancillary services are often performed with a primary service. Because these low-cost drug administration services are typically furnished with another primary service and are assigned to APCs with a geometric mean cost of less than or equal to $100 (prior to the application of the conditional packaging status indicator), we believe these services fall under the ancillary services packaging policy.

In addition, as stated in the proposed rule, we believe that conditional packaging of drug administration services will promote equitable payment between the physician office and the hospital outpatient department. However, we clarify that while typically physicians are not eligible to receive payment for an office visit when a drug administration service is also provided, we acknowledge that Medicare will pay for both services when the office visit CPT code is reported with Modifier 25 (Significant, separately identifiable evaluation and management services by the same physician on the day of the procedure).

With respect to data availability and general requests for further CMS analysis, we believe that the data made available to the public as part of the proposed rule were appropriate, clear, and sufficient for interested parties to conduct analyses to evaluate facility-specific impacts of the proposed policy. It is unclear what the commenters meant by requesting that CMS further analyze the effects of the proposal on APCs, as the commenters did not specify any particular analysis that CMS should conduct or data that CMS should provide that is not already available to the public. Because the OPPS is a budget neutral payment system, packaging a procedure does not remove its costs from ratesetting.

With respect to commenters' concerns on reporting of hospital costs for packaged services, we remind commenters that hospitals are expected to report all HCPCS codes that describe the services provided, regardless of whether or not those services are separately paid or their payment is packaged. The calculation of OPPS relative payment weights that reflect the relative resources required for HOPD services is the foundation of the OPPS. We rely on hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report charges on claims and charges and costs on their Medicare hospital cost report appropriately (77 FR 68324).

Therefore, for the reasons stated above, we believe that it is appropriate, and a logical expansion of our ancillary services policy, to finalize our proposal to unconditionally package low-cost drug administration services assigned to APCs 5691 and 5692. Accordingly, we are not accepting the HOP Panel's recommendation to not finalize our proposal.

Comment: One commenter stated that the packaging proposal is a logical expansion of the current ancillary packaging policy but recommended a 1-year implementation delay to allow providers time to assess the administrative and fiscal impact.

Response: We appreciate the commenter's support. Packaging is a longstanding payment principle under the OPPS and CMS has packaged a number of items and services through the years and makes OPPS data available to all interested parties on its Web site. Therefore, we do not see a reason to delay implementation of the policy. With each proposed and final rule release, CMS posts on its Web site various public use files (PUFs), including payment rates and cost statistics for applicable items and procedures. Stakeholders interested in a more comprehensive analysis of OPPS claims data used to derive the CY 2018 OPPS/ASC payment rates may purchase the ''OPPS Limited Data Set'' (LDS) that is available on the CMS Web site at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/HospitalOPPS.html*. We believe the information contained in the PUF and LDS files is sufficient to allow stakeholders to analyze the effects of our policies on their areas of interest. Therefore, we are finalizing our proposal to conditionally package low-cost drug administration services assigned to APC 5691 and APC 5692, effective January 1, 2018.

Comment: Some commenters believed that the proposal would conditionally package Medicare Part B vaccine administration. In addition, some commenters believed that if a hospital provides a low-cost drug administration service for a drug that is unconditionally packaged, CMS would make no payment to the hospital.

Response: We believe that some commenters may have misunderstood the proposal. Consistent with our existing policy to exclude preventive services from packaging, administration of Part B vaccines—influenza, pneumococcal, and hepatitis B—are exempt from packaging and will continue to be paid separately. With respect to payment for a conditionally packaged low-cost drug administration service and an unconditionally packaged drug, the drug administration service is separately payable when not billed on the same claim as a HCPCS code with status indicator ''S'', ''T'', or ''V''. Payment for the threshold-packaged drug would be packaged with the payment for the highest paying separately payable procedure reported on the claim. For example, if a threshold-packaged drug, a low-cost drug administration service, and a clinic visit are reported on the same claim, payment for the drug and drug administration service would be packaged with the clinic visit payment.

In summary, after consideration of the public comments we received, we are finalizing, without modification, the proposed policy to conditionally package low-cost drug administration services assigned to APC 5691 and APC 5692.

Because preventive services are excluded from our packaging policies, we are continuing to pay separately for Medicare Part B vaccine administration services. In addition, at this time, we are not packaging any drug administration services assigned to APC 5693 (Level 3 Drug Administration) or APC 5694 (Level 4 Drug Administration). The status indicators for drug administration services in APC 5691 and APC 5692 for CY 2018 are listed in Table 8 below.

TABLE 8—CY 2018 STATUS INDICATORS FOR DRUG ADMINISTRATION SERVICES IN LEVEL 1 AND LEVEL 2 DRUG ADMINISTRATION APCS

HCPCS code	Short descriptor	CY 2018 status indicator
APC 5691—Level 1 Drug Administration		
95115	Immunotherapy one injection	Q1
95117	Immunotherapy injections	Q1
95144	Antigen therapy services	Q1
95145	Antigen therapy services	Q1
95146	Antigen therapy services	Q1
95165	Antigen therapy services	Q1
95170	Antigen therapy services	Q1
96361	Hydrate iv infusion add-on	S
96366	Ther/proph/diag iv inf addon	S
96370	Sc ther infusion addl hr	S
96375	Tx/pro/dx inj new drug addon	S
96377	Application on-body injector	Q1
96379	Ther/prop/diag inj/inf proc	Q1
96423	Chemo ia infuse each addl hr	S
96549	Chemotherapy unspecified	Q1
G0008	Admin influenza virus vac	S
G0009	Admin pneumococcal vaccine	S
G0010	Admin hepatitis b vaccine	S
APC 5692—Level 2 Drug Administration		
90471	Immunization admin	Q1
90473	Immune admin oral/nasal	Q1
95147	Antigen therapy services	Q1
95148	Antigen therapy services	Q1
95149	Antigen therapy services	Q1
96367	Tx/proph/dg addl seq iv inf	S

TABLE 8—CY 2018 STATUS INDICATORS FOR DRUG ADMINISTRATION SERVICES IN LEVEL 1 AND LEVEL 2 DRUG ADMINISTRATION APCS—Continued

HCPCS code	Short descriptor	CY 2018 status indicator
96371	Sc ther infusion reset pump	Q1
96372	Ther/proph/diag inj sc/im	Q1
96401	Chemo anti-neopl sq/im	Q1
96402	Chemo hormon antineopl sq/im	Q1
96405	Chemo intralesional up to 7	Q1
96411	Chemo iv push addl drug	S
96415	Chemo iv infusion addl hr	S
96417	Chemo iv infus each addl seq	S

(3) Discussion of Comment Solicitation Regarding Unconditionally Packaging Drug Administration Add-On Codes

With respect to drug administration add-on codes, as discussed in the CY 2014 OPPS/ASC proposed rule (78 FR 43573), we proposed to unconditionally package all drug administration services described by add-on codes. In response to the proposal, commenters objected to packaging drug administration add-on codes, which typically describe each additional hour of infusion or each additional intravenous push, among others, in addition to the initial drug administration service. The commenters believed that such a policy could disadvantage providers of longer drug administration services, which are often protocol-driven and are not necessarily dictated by the hospital, but by the characteristics of the specific drug or biological being administered to the patient. In response to these comments, we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74945) that, given the frequency of drug administration services in the hospital outpatient department and their use in such a wide variety of different drug treatment protocols for various diseases in all types of hospitals, further study of the payment methodology for these services was warranted at that time. Therefore, we did not finalize our proposal to package the drug administration add-on codes in CY 2014. However, we stated we would continue to explore other payment options, including packaging and variations on packaging, in future years.

In the CY 2018 OPPS/ASC proposed rule, we did not propose to package drug administration add-on codes for CY 2018 because we wanted stakeholder input on a payment methodology that supports the principles of a prospective payment system while ensuring patient access to prolonged infusion services. Instead, we solicited public comment on whether conditionally or unconditionally packaging such codes would create access to care issues or have other unintended consequences. Specifically, we requested public comments on the following: (1) Whether we should conditionally or unconditionally package drug administration services add-on codes; (2) how we should consider or incorporate the varied clinical drug protocols that result in different infusion times into a drug administration service add-on code payment proposal; and (3) other recommendations on an encounter-based payment approach for drug administration services that are described by add-on codes when furnished in the hospital outpatient department setting.

Comment: Many commenters raised concerns about the appropriateness of packaging drug administration services add-on codes, given the variation in clinical treatment protocols. The commenters believed that packaging drug administration services add-on codes could create a barrier to access for drugs or biologicals with a long infusion time. Without explicit incremental payment for additional hours of infusion, some commenters suggested hospitals could discontinue offering the infusion. A few commenters suggested that CMS consider the creation of a drug administration C–APC for common drug administration encounters but did not provide details on what specific services should comprise the C–APC.

Response: We appreciate the comments we received on this topic and will take them into consideration for future rulemaking.

c. Analysis of Packaging of Pathology Services in the OPPS

At the August 22, 2016 HOP Panel meeting, a stakeholder expressed concern regarding conditional packaging of multiple pathology services. When multiple conditionally packaged services are billed on the same claim, the costs of the lowest paying services are bundled into the cost of the highest paying service and payment is made based on the highest single payable service. The stakeholder requested that CMS create a pathology composite APC to more appropriately pay for claims with only multiple pathology services and no other separately payable service such as a surgical procedure or a clinic visit. The HOP panel recommended that CMS develop a composite APC for pathology services when multiple pathology services are provided on a claim with no other payable services. The HOP Panel also requested that CMS take into consideration the stakeholder presentation comments made at the August 22, 2016 HOP Panel meeting regarding hospital pathology laboratories as CMS evaluates conditional packaging to determine whether an accommodation can be made. Specifically, the stakeholder expressed concern with conditional packaging of pathology services, particularly when payment is limited to the single highest paying code, regardless of the number of services provided or specimens tested.

In response to these HOP Panel requests and recommendation, we stated that we may consider the stakeholders' request for a pathology composite APC as well as additional composite APCs for future rulemaking (81 FR 79588). In light of these requests and recommendation, in development of the CY 2018 OPPS/ASC proposed rule, we evaluated and considered a pathology composite APC when multiple pathology services are performed and billed without a separately payable service on the same claim. To understand the frequency of billing multiple pathology services and no other separately payable codes on the same claim by hospital outpatient departments, we examined currently available claims data to identify the frequency distribution of pathology codes within the CPT code range 88300

to 88361. The claim frequency breakdown was displayed in Table 8 of the proposed rule (82 FR 33587).

Based on our analysis of claims data for the proposed rule, the majority of pathology only OPPS claims are reported with one pathology code. Therefore, as we stated in the CY 2018 OPPS/ASC proposed rule (82 FR 33588), we believe that it is neither a frequent occurrence nor a common occurrence for a provider to submit a claim for payment under the OPPS with multiple pathology services and no other separately payable service.

With regard to the HOP Panel's recommendation to develop a composite APC for pathology services when multiple pathology services are provided on a claim with no other payable services, we used CY 2016 claims data available for the CY 2018 OPPS/ASC proposed rule to model four hypothetical pathology composite APCs. That is, following our standard packaging methodology, we modeled four hypothetical pathology composite APCs based on the following clinical scenarios that were specifically requested by a stakeholder at the August 2016 HOP Panel meeting:

- Hypothetical Composite APC A: Claims that contain 2–4 pathology units (CPT codes 88302 through 88309) with or without special stains (CPT codes 88312 through 88314);
- Hypothetical Composite APC B: Claims that contain 5 or more pathology units (CPT codes 88302 through 88309) with or without special stains (CPT codes 88312 through 88314);
- Hypothetical Composite APC C: Claims that contain 2–4 pathology units (CPT codes 88302 through 88309) with immunostains (CPT codes 88341, 88342, 88346, 88350, 88360, 88361); and
- Hypothetical Composite APC D: Claims that contain 5 or more pathology units (CPT codes 88302 through 88309) with immunostains (CPT codes 88341, 88342, 88346, 88350, 88360, 88361).

In addition, for the proposed rule, we evaluated the volume of services and costs for each hypothetical composite. Results from modeling the four composite scenarios showed low claim volume, which indicates that the suggested pathology code combinations are infrequently billed by hospital outpatient departments and which may mean that these are not likely clinical scenarios in hospital outpatient departments. A summary of the results from our composite analysis was presented in Table 9 of the proposed rule (82 FR 33587). We refer readers to Addendum B to the CY 2018 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site) for the CPT code descriptors.

As we move toward larger payment bundles under the OPPS, the necessity of composite APCs diminishes. For example, in the CY 2018 OPPS/ASC proposed rule, we proposed to delete composite APC 8001 (LDR Prostate Brachytherapy Composite) and to provide payment for the component procedures through the C–APC payment methodology. Composite APCs were a precursor to C–APCs. In CY 2008, we implemented composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service (72 FR 66650 through 66652). Because a C–APC would treat all individually reported codes as representing components of the comprehensive service, all of the elements of the composite service are included in the C–APC payment. In addition, given the infrequent occurrence of multiple pathology services on the same claim without a separately payable service, we do not believe a composite APC is necessary or warranted.

Therefore, for CY 2018, we did not propose to create a pathology composite APC or additional composite APCs for stakeholder-requested services, such as X-ray services, respiratory services, cardiology services, or allergy testing services. However, we solicited public comments on our packaging policies, as discussed under section II.A.3.d. of this final rule with comment period.

We did not receive any public comments on our analysis of packaging of pathology services.

d. Summary of Public Comments and Our Responses Regarding Packaging of Items and Services Under the OPPS

As previously noted, packaging is an inherent principle of a prospective payment system. The OPPS, like other prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated costs of providing a service or package of services for a particular patient, but with the exception of outlier cases, is adequate to ensure access to appropriate care. Packaging and bundling payments for multiple interrelated services into a single payment create incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment. Decisions about packaging and bundling payment involve a balance between ensuring some separate payment for individual services or items while establishing incentives for efficiency through larger units of payment.

As the OPPS continues to move toward prospectively determined encounter-based payments and away from separate fee schedule-like payments, we continue to hear concerns from stakeholders that our packaging policies may be hampering patient access or resulting in other undesirable consequences. However, we have not observed significant fluctuations in our data that show a sharp decline of the volume of packaged items and services, nor have we heard from Medicare beneficiaries specifically about access issues or other concerns with packaged items and services. However, given that aggregate spending and utilization continue to increase for covered hospital outpatient services, it is unclear what, if any, adverse effect packaging has on beneficiary access to care. Specifically, in the CY 2018 OPPS/ASC proposed rule (82 FR 33588), within the framework of existing packaging categories, such as drugs that function as supplies in a surgical procedure or diagnostic test or procedure, we expressed interest in stakeholder feedback on common clinical scenarios involving currently packaged HCPCS codes for which stakeholders believe packaged payment is not appropriate under the OPPS. Likewise, outside the framework of existing packaging categories, we expressed interest in stakeholder feedback on common clinical scenarios involving separately payable HCPCS codes for which payment would be most appropriately packaged under the OPPS. In the proposed rule, we solicited public comments from a broad cross-section of stakeholders, including beneficiaries, patient advocates, hospital providers, clinicians, manufacturers, and other interested parties.

Comment: Commenters expressed a variety of views on packaging under the OPPS. The comments ranged from requests to unpackage most items and services that are either conditionally or unconditionally packaged under the OPPS, including drugs and devices, to specific requests to unpackage a specific drug or device.

Response: We appreciate the comments received and will review them as we continue to explore and evaluate packaging policies that apply under the OPPS and take them into consideration for future rulemaking.

4. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79594 through 79595), we applied this policy and calculated the relative payment weights for each APC for CY 2017 that were shown in Addenda A and B to that final rule with comment period (which were made available via the Internet on the CMS Web site) using the APC costs discussed in sections II.A.1. and II.A.2. of that final rule with comment period. For CY 2018, as we did for CY 2017, we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2018 using geometric mean-based APC costs (82 FR 33588).

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70351). In the CY 2018 OPPS/ASC proposed rule (82 FR 33588), for CY 2018, as we did for CY 2017, we proposed to continue to standardize all of the relative payment weights to APC 5012. We stated that we believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2018, as we did for CY 2017, we proposed to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

We did not receive any public comments on our proposal to use the geometric mean cost of APC 5012 to standardize relative payment weights for CY 2018. Therefore, we are finalizing our proposal and assigning APC 5012 the relative payment weight of 1.00, and using the relative payment weight for APC 5012 to derive the unscaled relative payment weight for each APC for CY 2018.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2018 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, in the CY 2018 OPPS/ASC proposed rule (82 FR 33588), we proposed to compare the estimated aggregate weight using the CY 2017 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2018 unscaled relative payment weights.

For CY 2017, we multiplied the CY 2017 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2016 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2018, we proposed to apply the same process using the estimated CY 2018 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scalar by dividing the CY 2017 estimated aggregate weight by the unscaled CY 2018 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Click on the CY 2018 OPPS final rule link and open the claims accounting document link at the bottom of the page.

We proposed to compare the estimated unscaled relative payment weights in CY 2018 to the estimated total relative payment weights in CY 2017 using CY 2016 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we proposed to adjust the calculated CY 2018 unscaled relative payment weights for purposes of budget neutrality. We proposed to adjust the estimated CY 2018 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.328 to ensure that the proposed CY 2018 relative payment weights are scaled to be budget neutral. The proposed CY 2018 relative payment weights listed in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site) were scaled and incorporated the recalibration adjustments discussed in sections II.A.1. and II.A.2. of the proposed rule.

The final CY 2018 relative payment weights listed in Addenda A and B to the final rule with comment period (which are available via the Internet on the CMS Web site) were scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this final rule with comment period.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2. of this final rule with comment period) is included in the budget neutrality calculations for the CY 2018 OPPS.

We did not receive any public comments on the proposed weight scalar calculation. Therefore, we are finalizing our proposal to use the calculation process described in the proposed rule, without modification, for CY 2018. Using updated final rule claims data, we are updating the estimated CY 2018 unscaled relative payment weights by multiplying them by a weight scalar of 1.4457 to ensure that the final CY 2018 relative payment weights are scaled to be budget neutral.

B. Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the

conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. As stated in the CY 2018 OPPS/ASC proposed rule, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19931), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2016 forecast of the FY 2018 market basket increase, the proposed FY 2018 IPPS market basket update was 2.9 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(v) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), provide adjustments to the OPD fee schedule increase factor for CY 2018.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment, and then revised this methodology as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19931 through 19932), the proposed MFP adjustment for FY 2018 was 0.4 percentage point.

In the CY 2018 OPPS/ASC proposed rule, we proposed that if more recent data became subsequently available after the publication of the proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such updated data, if appropriate, to determine the CY 2018 market basket update and the MFP adjustment, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in this CY 2018 OPPS/ASC final rule with comment period. Consistent with that proposal, and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38177), we applied the final FY 2018 market basket percentage increase (2.7 percent) and the final FY 2018 MFP adjustment (0.6 percent) to the OPD fee schedule increase factor for the CY 2018 OPPS.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that, for each of years 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 2018, section 1833(t)(3)(G)(v) of the Act provides a 0.75 percentage point reduction to the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act. Therefore, in accordance with sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act, in the CY 2018 OPPS/ASC proposed rule, we proposed to apply a 0.75 percentage point reduction to the OPD fee schedule increase factor for CY 2018.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we are applying an OPD fee schedule increase factor of 1.35 percent for the CY 2018 OPPS (which is 2.7 percent, the final estimate of the hospital inpatient market basket percentage increase, less the final 0.6 percentage point MFP adjustment, and less the 0.75 percentage point additional adjustment).

Hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIII. of this final rule with comment period.

In the CY 2018 OPPS/ASC proposed rule, we proposed to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (*9*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2018, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS, and to reflect the requirement in section 1833(t)(3)(G)(v) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by an additional 0.75 percentage point for CY 2018.

We did not receive any public comments on our proposal. Therefore, we are implementing our proposal without modification.

To set the OPPS conversion factor for the CY 2018 OPPS/ASC proposed rule, we proposed to increase the CY 2017 conversion factor of $75.001 by 1.75 percent (82 FR 33589). In accordance with section 1833(t)(9)(B) of the Act, we proposed further to adjust the conversion factor for CY 2018 to ensure that any revisions made to the wage index and rural adjustment were made on a budget neutral basis. We proposed to calculate an overall budget neutrality factor of 0.9999 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2018 IPPS wage indexes to those payments using the FY 2017 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For the CY 2018 OPPS/ASC proposed rule, we proposed to maintain the current rural adjustment policy, as discussed in section II.E. of this final rule with comment period. Therefore, the proposed budget neutrality factor for the rural adjustment was 1.0000.

For the CY 2018 OPPS/ASC proposed rule, we proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this final rule with comment period. We proposed to calculate a CY 2018 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2018 payments under section 1833(t) of the Act, including the proposed CY 2018 cancer hospital payment adjustment, to estimated CY 2018 total payments using the CY 2017 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The CY 2018 proposed estimated payments applying the proposed CY 2018 cancer hospital payment adjustment were less than estimated payments applying the CY 2017 final cancer hospital payment adjustment. Therefore, we proposed to apply a budget neutrality adjustment factor of 1.0003 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 16002(b) of the 21st Century Cures Act, we stated in the proposed rule that we

are applying a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we are applying as stated in section II.F. of the proposed rule.

For the CY 2018 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2018 would equal approximately $26.2 million, which represented 0.04 percent of total projected CY 2018 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.26 percent estimate of pass-through spending for CY 2017 and the 0.04 percent estimate of proposed pass-through spending for CY 2018, resulting in a proposed adjustment for CY 2018 of 0.22 percent. Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2018. We estimated for the proposed rule that outlier payments would be 1.04 percent of total OPPS payments in CY 2017; the 1.0 percent for proposed outlier payments in CY 2018 would constitute a 0.04 percent decrease in payment in CY 2018 relative to CY 2017.

For the CY 2018 OPPS/ASC proposed rule, we also proposed that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we proposed to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of −0.25 percent (that is, the proposed OPD fee schedule increase factor of 1.75 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2018 of $74.953 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.530 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2018, we proposed to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (*9*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2018 to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(v) of the Act. We proposed to use a reduced conversion factor of $74.953 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.530 in the conversion factor relative to hospitals that met the requirements).

For CY 2018, we proposed to use a conversion factor of $76.483 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 1.75 percent for CY 2018, the required proposed wage index budget neutrality adjustment of approximately 0.9999, the proposed cancer hospital payment adjustment of 1.0003, and the proposed adjustment of 0.22 percentage point of projected OPPS spending for the difference in the pass-through spending and outlier payments that resulted in a proposed conversion factor for CY 2018 of $76.483.

We invited public comments on these proposals. However, we did not receive any public comments. Therefore, we are finalizing these proposals without modification, as discussed below.

For CY 2018, we proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this final rule with comment period. Based on the updated claims data for this final rule with comment period used in calculating the cancer hospital payment adjustment in section II.F. of this final rule with comment period, the target PCR for the cancer hospital payment adjustment, which was 0.91 for CY 2017, is 0.88 for CY 2018. Because we budget neutralize using the target PCR ratio prior to implementation of section 16002 (b) of the 21st Century Cures Act, we are applying a budget neutrality adjustment factor of 1.0008 to the conversion factor for the cancer hospital payment adjustment for CY 2018.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33712), we estimated a 1.4 percent adjustment to nondrug OPPS payment rates as a result of the proposed payment adjustment to separately payable nonpass-through drugs purchased under the 340B Program. As part of that proposed policy, we noted that our adjustment in the final rule could potentially change as a result of changes such as updated data, modifications to the estimate methodology, and other factors. Applying the final payment policy for drugs purchased under the 340B Program, as described in section V.B.7. of this final rule with comment period, results in an estimated reduction of approximately $1.6 billion in separately paid OPPS drug payments. To ensure budget neutrality under the OPPS after applying this alternative payment methodology for drugs purchased under the 340B Program, we applied an offset of approximately $1.6 billion into the OPPS conversion factor, which results in a final adjustment of 1.0319 to the OPPS conversion factor.

As a result of these finalized policies, the OPD fee schedule increase factor for the CY 2018 OPPS is 1.35 percent (which is 2.7 percent, the estimate of the hospital inpatient market basket percentage increase, less the 0.6 percentage point MFP adjustment, and less the 0.75 percentage point additional adjustment). For CY 2018, we are using a conversion factor of $78.636 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the OPD fee schedule increase factor of 1.35 percent for CY 2018, the required wage index budget neutrality adjustment of approximately 0.9997, the cancer hospital payment adjustment of 1.0008, the adjustment for drugs purchased under the 340B Program of 1.0319, and the adjustment of 0.2 percentage point of projected OPPS spending for the difference in the pass-through spending and outlier payments that result in a conversion factor for CY 2018 of $78.636.

C. Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of this final rule with comment period.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). In the CY 2018 OPPS/ASC proposed rule (82 FR 33590), we proposed to continue this policy for the CY 2018 OPPS. We refer readers to section II.H. of this final rule with comment period for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital. We did not receive any public comments on

this proposal. Therefore, for the reasons discussed above and in the CY 2018 OPPS/ASC proposed rule (82 FR 33590), we are finalizing our proposal to continue this policy as discussed above for the CY 2018 OPPS without modification.

As discussed in the claims accounting narrative included with the supporting documentation for this final rule with comment period (which is available via the Internet on the CMS Web site), for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2018 pre-reclassified wage index that the IPPS uses to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For the CY 2018 OPPS, we proposed to implement this provision in the same manner as we have since CY 2011 (82 FR 33591). Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00 (as discussed below and in the CY 2018 OPPS/ASC proposed rule (82 FR 33591 through 33592)), we proposed not to extend the imputed floor under the OPPS for CY 2018 and subsequent years, consistent with our proposal in the FY 2018 IPPS/LTCH PPS proposed rule (81 FR 19904 through 19905) not to extend the imputed floor under the IPPS for FY 2018 and subsequent fiscal years). Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, we stated that the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. In the proposed rule (82 FR 33591), we referred readers to the FY 2011 through FY 2017 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of ''frontier States'' as provided for in section 1886(d)(3)(E)(iii)(II) of the Act. We invited public comments on this proposal.

We did not receive any public comments on this proposal. Therefore, for the reasons discussed above and in the CY 2018 OPPS/ASC proposed rule (82 FR 33591), we are finalizing our proposal to implement the frontier State floor under the OPPS in the same manner as we have since CY 2011. We note that, after we made our proposal in the FY 2018 IPPS/LTCH PPS proposed rule not to extend the imputed floor under the IPPS for FY 2018 and subsequent fiscal years (82 FR 19904 through 19905), and our proposal in the CY 2018 OPPS/ASC proposed rule not to extend the imputed floor under the OPPS for CY 2018 and subsequent years (82 FR 33592), we decided in the FY 2018 IPPS/LTCH PPS final rule not to finalize our proposal to discontinue the imputed floor under the IPPS (82 FR 38138 through 38142). As discussed below, consistent with the FY 2018 IPPS/LTCH PPS final rule, we are not finalizing our proposal to discontinue application of the imputed floor under the OPPS. This means that the applicable wage index, which can be superseded by the frontier State wage index if the applicable criteria are met, could also be affected by the imputed floor. We discuss our policy on the extension of the imputed floor under the IPPS as finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38142), and under the OPPS as finalized in this rule, in more detail later in this section.

In addition to the changes required by the Affordable Care Act, we note that the FY 2018 IPPS wage indexes continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). In the CY 2018 OPPS/ASC proposed rule, we referred readers to the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19898 through 19915) for a detailed discussion of all proposed changes to the FY 2018 IPPS wage indexes. We note that, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19905), we proposed not to apply the imputed floor to the IPPS wage index computations for FY 2018 and subsequent fiscal years. Consistent with this, we proposed in the CY 2018 OPPS/ASC proposed rule (82 FR 33592) not to extend the imputed floor policy under the OPPS beyond December 31, 2017 (the date the imputed floor policy is set to expire under the OPPS). However, in the FY 2018 IPPS/LTCH PPS final rule, we did not finalize our proposal to discontinue the imputed floor under the IPPS, and instead decided to temporarily extend the imputed floor for an additional year through FY 2018, while we continue to assess the effects of this policy and whether to continue or discontinue the imputed floor for the long term. As discussed below, consistent with the FY 2018 IPPS/LTCH PPS final rule, we are not finalizing our proposal to discontinue application of the imputed floor under the OPPS, but are instead continuing the imputed floor policy under the OPPS for an additional year, through December 31, 2018. We refer readers to the FY 2018 IPPS/LTCH PPS proposed and final rules (82 FR 19898 through 19915 and 82 FR 38129 through 38157, respectively) for a detailed discussion of all proposed and final changes to the FY 2018 IPPS wage indexes (including our proposed and final policy regarding the imputed floor for FY 2018 and subsequent fiscal years). In addition, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65842 through 65844) and subsequent OPPS rules for a detailed discussion of the history of these wage index adjustments as applied under the OPPS.

Summarized below are comments we received regarding the application of the rural and imputed floor policies under the OPPS, along with our responses.

Comment: One commenter opposed applying budget neutrality for the rural floor under the OPPS on a national basis. The commenter believed applying budget neutrality on a national basis

disadvantages hospitals in most States while benefiting hospitals in a few States that have taken advantage of the system where a rural hospital has a wage index higher than most or all urban hospitals in a State. The commenter stated that rural floor budget neutrality currently requires all wage indexes for hospitals throughout the nation to be reduced. However, hospitals in those States that have higher wage indexes because of the rural floor are not substantially affected by the wage index reductions. Therefore, the commenter supported calculating rural floor budget neutrality under the OPPS for each individual State.

Response: We appreciate this comment. We acknowledge that the application of the wage index and applicable wage index adjustments to OPPS payment rates may create distributional payment variations, especially within a budget neutral system. However, we continue to believe it is reasonable and appropriate to continue the current policy of applying budget neutrality for the rural floor under the OPPS on a national basis, consistent with the IPPS. We believe that hospital inpatient and outpatient departments are subject to the same labor cost environment, and therefore, the wage index and any applicable wage index adjustments (including the rural floor and rural floor budget neutrality) should be applied in the same manner under the IPPS and OPPS. Furthermore, we believe that applying the rural floor and rural floor budget neutrality in the same manner under the IPPS and OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In addition, we believe the application of different wage indexes and wage index adjustments under the IPPS and OPPS would add a level of administrative complexity that is overly burdensome and unnecessary. Therefore, we are continuing the current policy of applying budget neutrality for the rural floor under the OPPS on a national basis, consistent with the IPPS.

Comment: One commenter supported the proposal to not apply the imputed floor to the IPPS wage index computations for FY 2018 and subsequent fiscal years when calculating the hospital wage indexes for the OPPS.

Response: In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19905), we proposed not to apply the imputed floor to the IPPS wage index computations for FY 2018 and subsequent fiscal years. Consistent with this proposal, we proposed in the CY 2018 OPPS/ASC proposed rule (82 FR 33592) not to extend the imputed floor policy under the OPPS beyond December 31, 2017 (the date the imputed floor policy is set to expire under the OPPS). As discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38138 through 38142), after consideration of the many comments we received both in support of and against our proposal to discontinue the imputed floor under the IPPS, we decided to temporarily extend the imputed floor for an additional year under the IPPS through FY 2018, while we continue to assess the effects of this policy and whether to continue or discontinue the imputed floor for the long term. Therefore, in the FY 2018 IPPS/LTCH PPS final rule, we extended the imputed floor policy under both the original methodology and the alternative methodology for an additional year, through September 30, 2018. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38138 through 38142) for a detailed discussion of our final policy and rationale regarding application of the imputed floor under the IPPS for FY 2018. Given the inseparable, subordinate status of the HOPD within the hospital overall, we believe that using the IPPS wage index and wage index adjustments, including the imputed floor, as the source of an adjustment factor for the OPPS is reasonable and logical. Furthermore, as we previously stated, we believe that hospital inpatient and outpatient departments are subject to the same labor cost environment and, therefore, the wage index and any applicable wage index adjustments (including the imputed floor) should be applied in the same manner under the IPPS and OPPS. In addition, as discussed above, we believe the application of different wage index adjustments under the IPPS and OPPS would add a level of administrative complexity that is overly burdensome and unnecessary. Thus, as discussed further below, consistent with the FY 2018 IPPS/LTCH PPS final rule, we are not finalizing our proposal to discontinue application of the imputed floor under the OPPS, and instead are temporarily extending the imputed floor policy under the OPPS for an additional year.

After consideration of the public comments we received and for the reasons discussed above, consistent with the FY 2018 IPPS/LTCH PPS final rule, we have decided to extend the imputed floor policy under the OPPS for an additional year, through December 31, 2018, while we continue to assess the effects of this policy and whether to continue or discontinue the imputed floor for the long term. Therefore, we are not finalizing our proposal to discontinue the imputed floor policy under the OPPS. We continue to believe that using the final fiscal year IPPS post-reclassified wage index, inclusive of any adjustments (including the imputed floor), as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49488 through 49489 and 49494 through 49496), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), the Office of Management and Budget (OMB) issued revisions to the labor market area delineations on February 28, 2013 (based on 2010 Decennial Census data), that included a number of significant changes such as new Core Based Statistical Areas (CBSAs), urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart (OMB Bulletin 13–01). This bulletin can be found at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf.* In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49985), we adopted the use of the OMB labor market area delineations contained in OMB Bulletin No. 13–01, effective October 1, 2014. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted revisions to statistical areas contained in OMB Bulletin No. 15–01, issued on July 15, 2015, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. We believe that it is important for the OPPS to use the latest labor market area delineations available as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. Therefore, for purposes of the OPPS, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79598), we adopted the revisions to the OMB statistical area delineations contained in OMB Bulletin No. 15–01, effective January 1, 2017, beginning with the CY 2017 OPPS wage indexes.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19898 through 19899) and final rule (82 FR 38130) discuss the two different lists of

codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS has listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. In the FY 2018 IPPS/LTCH PPS proposed rule (81 FR 19898), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we proposed to discontinue the use of the SSA county codes and begin using only the FIPS county codes. (We note that we finalized the proposal to discontinue use of SSA county codes and begin using only the FIPS county codes for purposes of crosswalking counties to CBSAs in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130)). Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC proposed rule (82 FR 33591), we proposed to discontinue the use of SSA county codes and begin using only the FIPS county codes. We invited public comments on this proposal. We did not receive any public comments on this proposal. Thus, for the reasons discussed above and in the CY 2018 OPPS/ASC proposed rule (82 FR 33591), we are finalizing, without modification, our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes for the purposes of crosswalking counties to CBSAs for the OPPS wage index.

The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the Web site at: *https://www.census.gov/geo/reference/county-changes.html.* In our proposed transition to using only FIPS codes for counties for the IPPS wage index, in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19899), we proposed to update the FIPS codes used for crosswalking counties to CBSAs for the IPPS wage index effective October 1, 2017, to incorporate changes to the counties or county equivalent entities included in the Census Bureau's most recent list. We proposed to include these updates to calculate the area wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule. Based on information included in the Census Bureau's Web site, since 2010, the Census Bureau has made the following updates to the FIPS codes for counties or county equivalent entities:

- Petersburg Borough, AK (FIPS State County Code 02–195), CBSA 02, was created from part of former Petersburg Census Area (02–195) and part of Hoonah-Angoon Census Area (02–105). The CBSA code remains 02.
- The name of La Salle Parish, LA (FIPS State County Code 22–059), CBSA 14, is now LaSalle Parish, LA (FIPS State County Code 22–059). The CBSA code remains as 14.
- The name of Shannon County, SD (FIPS State County Code 46–113), CBSA 43, is now Oglala Lakota County, SD (FIPS State County Code 46–102). The CBSA code remains as 43.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for the IPPS, we finalized our proposal to implement these FIPS code updates, effective October 1, 2017, beginning with the FY 2018 wage indexes. We note that while the county update changes listed earlier changed the county names, the CBSAs to which these counties map did not change from the prior counties. Therefore, there is no impact or change to hospitals in these counties; they continue to be considered rural for the IPPS wage index under these changes. Consistent with the FY 2018 IPPS/LTCH PPS proposed rule, in the CY 2018 OPPS/ASC proposed rule (82 FR 33592), we proposed to implement these revisions for purposes of the OPPS, effective January 1, 2018, beginning with the CY 2018 OPPS wage indexes. We stated that we believe it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the OPPS wage index. In addition, we stated we believe that using the latest FIPS codes will allow us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We invited public comments on this proposal.

We did not receive any public comments on this proposal. Therefore, for the reasons discussed above and in the CY 2018 OPPS/ASC proposed rule (82 FR 33591 through 33592), we are finalizing our proposal, without modification, to implement the FIPS code updates described above, effective January 1, 2018, beginning with the CY 2018 OPPS wage indexes. Tables 2 and 3 associated with the FY 2018 IPPS/LTCH PPS final rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS Web site reflect these county changes.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33592), we proposed to use the FY 2018 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2018. Therefore, we stated in the proposed rule that any adjustments for the FY 2018 IPPS post-reclassified wage index would be reflected in the final CY 2018 OPPS wage index. (We refer readers to the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19898 through 19915) and final rule (82 FR 38129 through 38157), and the proposed and final FY 2018 hospital wage index files posted on the CMS Web site.) We invited public comments on this proposal. As discussed above, we received public comments regarding the application of the rural and imputed floors under the OPPS. We refer readers to our earlier discussion of these comments and our responses. After consideration of these comments, for the reasons discussed above and in the CY 2018 OPPS/ASC proposed rule (82 FR 33592), we are finalizing this proposal without modification. As stated earlier, we continue to believe that using the final fiscal year IPPS post-reclassified wage index, inclusive of any adjustments, as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. In the CY 2018 OPPS/ASC proposed rule, we proposed to continue this policy for CY 2018, and included a brief summary of the major proposed FY 2018 IPPS wage index policies and adjustments that we proposed to apply to these hospitals under the OPPS for CY 2018. These proposals are summarized below. We invited public comments on these proposals.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare

Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that applies if the hospital were paid under the IPPS. For CY 2018, we proposed to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). We did not receive any public comments on this proposal. Therefore, for the reasons discussed above and in the CY 2018 OPPS/ASC proposed rule (82 FR 33592), we are finalizing this proposal without modification.

As stated earlier, in the FY 2015 IPPS/LTCH PPS final rule, we adopted the OMB labor market area delineations issued by OMB in OMB Bulletin No. 13–01 on February 28, 2013, based on standards published on June 28, 2010 (75 FR 37246 through 37252) and the 2010 Census data to delineate labor market areas for purposes of the IPPS wage index. For IPPS wage index purposes, for hospitals that were located in urban CBSAs in FY 2014 but were designated as rural under these revised OMB labor market area delineations, we generally assigned them the urban wage index value of the CBSA in which they were physically located for FY 2014 for a period of 3 fiscal years (79 FR 49957 through 49960). To be consistent, we applied the same policy to hospitals paid under the OPPS but not under the IPPS so that such hospitals will maintain the wage index of the CBSA in which they were physically located for FY 2014 for 3 calendar years (until December 31, 2017). Because this 3-year transition will end at the end of CY 2017, it will no longer be applied in CY 2018.

In addition, under the IPPS, the imputed floor policy was set to expire effective October 1, 2017. However, as discussed above and in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38138 through 38142), we did not finalize our proposal not to extend the imputed floor policy under the IPPS for FY 2018 and subsequent fiscal years (82 FR 38132), and instead decided to extend the imputed floor policy for one additional year, through FY 2018. For purposes of the CY 2018 OPPS, we proposed not to extend the imputed floor policy beyond December 31, 2017. However, consistent with the FY 2018 IPPS/LTCH PPS final rule, as discussed above, we are extending the imputed floor policy under the OPPS for one additional year, through December 31, 2018. Therefore, for CY 2018, for hospitals paid under the OPPS but not under the IPPS, the imputed floor policy will continue to apply through December 31, 2018.

For CMHCs, for CY 2018, we proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. As with OPPS hospitals and for the same reasons, for CMHCs previously located in urban CBSAs that were designated as rural under the revised OMB labor market area delineations in OMB Bulletin No. 13–01, we finalized a policy to maintain the urban wage index value of the CBSA in which they were physically located for CY 2014 for 3 calendar years (until December 31, 2017). Because this 3-year transition will end at the end of CY 2017, it will not be applied in CY 2018. Furthermore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33592), we proposed that the wage index that applies to CMHCs would include the rural floor adjustment, but not the imputed floor adjustment, given that we had proposed not to extend the imputed floor policy under the OPPS beyond December 31, 2017 (the expiration date for the imputed floor under the OPPS). We also proposed that the wage index that applies to CMHCs would not include the out-migration adjustment because that adjustment only applies to hospitals. We did not receive any public comments regarding these proposals, and are finalizing these proposals with the following modification. Because, as discussed above, we are extending the application of the imputed floor under the OPPS for an additional year, through December 31, 2018, the wage index that applies to CMHCs will continue to include the imputed floor adjustment through December 31, 2018.

Table 2 associated with the FY 2018 IPPS/LTCH PPS final rule (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) identifies counties eligible for the out-migration adjustment and IPPS hospitals that will receive the adjustment for FY 2018. We are including the out-migration adjustment information from Table 2 associated with the FY 2018 IPPS/LTCH PPS final rule as Addendum L to this final rule with comment period with the addition of non-IPPS hospitals that will receive the section 505 out-migration adjustment under the CY 2018 OPPS. Addendum L is available via the Internet on the CMS Web site. We refer readers to the CMS Web site for the OPPS at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* At this link, readers will find a link to the final FY 2018 IPPS wage index tables and Addendum L.

D. Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for ratesetting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. MACs cannot calculate a CCR for some hospitals because there is no cost report available. For these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned earlier until a hospital's MAC is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report. These hospitals include, but are not limited to, hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a biased CCR (that is, the CCR falls outside the predetermined ceiling threshold for a valid CCR) or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11).

In the CY 2018 OPPS/ASC proposed rule (82 FR 33593), we proposed to update the default ratios for CY 2018 using the most recent cost report data. We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For detail on our process for calculating the statewide average CCRs, we referred readers to the CY 2018 OPPS proposed rule Claims Accounting Narrative that is posted on the CMS Web site. Table 10 published in the proposed rule (82 FR 33593 through 33594) listed the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2018, based on proposed rule data.

We did not receive any public comments on our proposal to use statewide average default CCRs if a MAC cannot calculate a CCR for a hospital and to use these CCRs to adjust charges to costs on claims data for setting the final CY 2018 OPPS relative payment weights. Therefore, we are finalizing our proposal without modification.

Table 9 below lists the statewide average default CCRs for OPPS services furnished on or after January 1, 2018, based on final rule data.

TABLE 9—CY 2018 STATEWIDE AVERAGE CCRS

State	Urban/rural	CY 2018 default CCR	Previous default CCR (CY 2017 OPPS final rule)
ALASKA	RURAL	0.659	0.449
ALASKA	URBAN	0.218	0.237
ALABAMA	RURAL	0.190	0.196
ALABAMA	URBAN	0.155	0.158
ARKANSAS	RURAL	0.186	0.196
ARKANSAS	URBAN	0.200	0.205
ARIZONA	RURAL	0.232	0.238
ARIZONA	URBAN	0.160	0.176
CALIFORNIA	RURAL	0.181	0.179
CALIFORNIA	URBAN	0.193	0.188
COLORADO	RURAL	0.346	0.354
COLORADO	URBAN	0.204	0.208
CONNECTICUT	RURAL	0.324	0.402
CONNECTICUT	URBAN	0.249	0.253
DISTRICT OF COLUMBIA	URBAN	0.279	0.286
DELAWARE	URBAN	0.295	0.288
FLORIDA	RURAL	0.158	0.169
FLORIDA	URBAN	0.138	0.143
GEORGIA	RURAL	0.222	0.230
GEORGIA	URBAN	0.198	0.196
HAWAII	RURAL	0.332	0.338
HAWAII	URBAN	0.322	0.319
IOWA	RURAL	0.296	0.291
IOWA	URBAN	0.254	0.252
IDAHO	RURAL	0.339	0.341
IDAHO	URBAN	0.369	0.401
ILLINOIS	RURAL	0.214	0.241
ILLINOIS	URBAN	0.208	0.209
INDIANA	RURAL	0.299	0.272
INDIANA	URBAN	0.213	0.218
KANSAS	RURAL	0.264	0.269
KANSAS	URBAN	0.199	0.194
KENTUCKY	RURAL	0.184	0.194
KENTUCKY	URBAN	0.187	0.189
LOUISIANA	RURAL	0.212	0.217
LOUISIANA	URBAN	0.195	0.201
MASSACHUSETTS	RURAL	0.322	0.316
MASSACHUSETTS	URBAN	0.348	0.345
MAINE	RURAL	0.419	0.425
MAINE	URBAN	0.422	0.413
MARYLAND	RURAL	0.258	0.264
MARYLAND	URBAN	0.227	0.229
MICHIGAN	RURAL	0.302	0.295
MICHIGAN	URBAN	0.318	0.324
MINNESOTA	RURAL	0.379	0.398
MINNESOTA	URBAN	0.302	0.319
MISSOURI	RURAL	0.220	0.222
MISSOURI	URBAN	0.240	0.261
MISSISSIPPI	RURAL	0.213	0.224
MISSISSIPPI	URBAN	0.160	0.167
MONTANA	RURAL	0.486	0.450
MONTANA	URBAN	0.350	0.368
NORTH CAROLINA	RURAL	0.206	0.216
NORTH CAROLINA	URBAN	0.212	0.223
NORTH DAKOTA	RURAL	0.366	0.411
NORTH DAKOTA	URBAN	0.369	0.334
NEBRASKA	RURAL	0.313	0.294
NEBRASKA	URBAN	0.233	0.238
NEW HAMPSHIRE	RURAL	0.307	0.320
NEW HAMPSHIRE	URBAN	0.255	0.279
NEW JERSEY	URBAN	0.200	0.195
NEW MEXICO	RURAL	0.224	0.225

TABLE 9—CY 2018 STATEWIDE AVERAGE CCRS—Continued

State	Urban/rural	CY 2018 default CCR	Previous default CCR (CY 2017 OPPS final rule)
NEW MEXICO	URBAN	0.284	0.280
NEVADA	RURAL	0.175	0.196
NEVADA	URBAN	0.114	0.123
NEW YORK	RURAL	0.299	0.309
NEW YORK	URBAN	0.303	0.292
OHIO	RURAL	0.280	0.292
OHIO	URBAN	0.203	0.207
OKLAHOMA	RURAL	0.215	0.231
OKLAHOMA	URBAN	0.169	0.180
OREGON	RURAL	0.290	0.280
OREGON	URBAN	0.336	0.344
PENNSYLVANIA	RURAL	0.267	0.274
PENNSYLVANIA	URBAN	0.173	0.179
PUERTO RICO	URBAN	0.577	0.527
RHODE ISLAND	URBAN	0.276	0.291
SOUTH CAROLINA	RURAL	0.170	0.185
SOUTH CAROLINA	URBAN	0.191	0.190
SOUTH DAKOTA	RURAL	0.391	0.383
SOUTH DAKOTA	URBAN	0.242	0.229
TENNESSEE	RURAL	0.173	0.181
TENNESSEE	URBAN	0.174	0.180
TEXAS	RURAL	0.205	0.214
TEXAS	URBAN	0.168	0.177
UTAH	RURAL	0.391	0.349
UTAH	URBAN	0.304	0.315
VIRGINIA	RURAL	0.177	0.191
VIRGINIA	URBAN	0.215	0.226
VERMONT	RURAL	0.393	0.426
VERMONT	URBAN	0.378	0.340
WASHINGTON	RURAL	0.256	0.271
WASHINGTON	URBAN	0.323	0.294
WISCONSIN	RURAL	0.348	0.354
WISCONSIN	URBAN	0.308	0.290
WEST VIRGINIA	RURAL	0.253	0.266
WEST VIRGINIA	URBAN	0.297	0.285
WYOMING	RURAL	0.407	0.429
WYOMING	URBAN	0.327	0.311

E. Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2018

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 419.43(g) of the regulations to clarify that essential access community hospitals (EACHs) also are eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Public Law 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2017. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33594 through 33595), for the CY 2018 OPPS, we proposed to continue our policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

Comment: Commenters supported the proposed payment adjustment for rural SCHs and EACHs, and stated that this adjustment would support access to care in rural areas and provide additional resources for rural SCHs and EACHs.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing the proposal for CY 2017 to continue our policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. Payment Adjustment for Certain Cancer Hospitals for CY 2018

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), Congress established section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (often referred to as ''held harmless'').

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount'' and the determination of the base PCR are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, respectively) as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. For CYs 2012 and 2013, the target PCR for purposes of the cancer hospital payment adjustment was 0.91. For CY 2014, the target PCR for purposes of the cancer hospital payment adjustment was 0.89. For CY 2015, the target PCR was 0.90. For CY 2016, the target PCR was 0.92, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70362 through 70363). For CY 2017, the target PCR was 0.91, as discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79603 through 7960).

2. Proposed and Finalized Policy for CY 2018

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying 42 CFR 419.43(i), that is, the payment adjustment for certain cancer hospitals, for services furnished on or after January 1, 2018, the target PCR adjustment be reduced by 1.0 percentage point less than what would otherwise apply. Section 16002(b) also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act. In the CY 2018 OPPS/ASC proposed rule (82 FR 33595), for CY 2018, we proposed to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or ''target PCR'') for the

other OPPS hospitals using the most recent submitted or settled cost report data that were available at the time of the development of the proposed rule, reduced by 1.0 percentage point to comply with section 16002(b) of the 21st Century Cures Act. We did not propose an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) for CY 2018. To calculate the proposed CY 2018 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of the proposed rule, used to estimate costs for the CY 2018 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2016 claims data that we used to model the impact of the proposed CY 2018 APC relative payment weights (3,701 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2018 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2013 to 2016. We then removed the cost report data of the 49 hospitals located in Puerto Rico from our dataset because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 16 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,636 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 90 percent of reasonable cost (weighted average PCR of 0.90). Therefore, after applying the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act, we proposed that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.89 for each cancer hospital.

Table 11 of the proposed rule indicated the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2018 due to the cancer hospital payment adjustment policy. We stated in the proposed rule that the actual amount of the CY 2018 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2018 payments and costs. We noted that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

Comment: Several commenters supported the proposed cancer hospital payment adjustment for CY 2018.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our cancer hospital payment adjustment methodology as proposed. For this final rule with comment period, we are using the most recent cost report data through June 30, 2017 to update the adjustment. This update yields a target PCR of 0.88. We limited the dataset to the hospitals with CY 2016 claims data that we used to model the impact of the CY 2018 APC relative payment weights (3,724 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2018 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2012 to 2017. We then removed the cost report data of the 49 hospitals located in Puerto Rico from our dataset because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 14 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to an analytic file of 3,661 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated a target PCR of 0.89. Therefore, after applying the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act, we are finalizing that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement will be the additional payment needed to result in a PCR equal to 0.88 for each cancer hospital. Table 10 below indicates the estimated percentage increase in OPPS payments to each cancer hospital for CY 2018 due to the cancer hospital payment adjustment policy. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 10—ESTIMATED CY 2018 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider No.	Hospital name	Estimated percentage increase in OPPS payments for CY 2018 due to payment adjustment
050146	City of Hope Comprehensive Cancer Center	31.5
050660	USC Norris Cancer Hospital	16.4
100079	Sylvester Comprehensive Cancer Center	22.9
100271	H. Lee Moffitt Cancer Center & Research Institute	21.7

TABLE 10—ESTIMATED CY 2018 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT—Continued

Provider No.	Hospital name	Estimated percentage increase in OPPS payments for CY 2018 due to payment adjustment
220162	Dana-Farber Cancer Institute	44.2
330154	Memorial Sloan-Kettering Cancer Center	46.9
330354	Roswell Park Cancer Institute	20.0
360242	James Cancer Hospital & Solove Research Institute	27.5
390196	Fox Chase Cancer Center	7.6
450076	M.D. Anderson Cancer Center	74.9
500138	Seattle Cancer Care Alliance	52.2

G. Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2017, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $3,825 (the fixed-dollar amount threshold) (81 FR 79604 through 79606). If the cost of a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2016 OPPS payments, using CY 2016 claims available for this proposed rule, is approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2016, we estimate that we paid the outlier target of 1.0 percent of total aggregated OPPS payments.

As stated in the proposed rule, using CY 2016 claims data and CY 2017 payment rates, we estimated that the aggregate outlier payments for CY 2017 would be approximately 1.0 percent of the total CY 2017 OPPS payments. Using an updated claims dataset and OPPS ancillary CCRs, we estimate that we paid approximately 1.11 percent of the total CY 2017 OPPS payments, in OPPS outliers. We provided estimated CY 2018 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital-Specific Impacts—Provider-Specific Data file on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

2. Outlier Calculation for CY 2018

In the CY 2018 OPPS/ASC proposed rule (82 FR 33596), for CY 2018, we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We proposed that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.C. of the proposed rule, we proposed to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under APC 5853 (Partial Hospitalization for CMHCs), exceeds 3.40 times the payment rate for proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC 5853 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.D. of the proposed rule.

To ensure that the estimated CY 2018 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $4,325.

We calculated the proposed fixed-dollar threshold of $4,325 using the standard methodology most recently used for CY 2017 (81 FR 79604 through 79605). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2017 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2018 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2016 claims using the same inflation factor of 1.104055 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2018 IPPS/LTCH

PPS proposed rule (82 FR 20173). We used an inflation factor of 1.05074 to estimate CY 2017 charges from the CY 2016 charges reported on CY 2016 claims. The methodology for determining this charge inflation factor is discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57286). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we proposed to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2018 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2018 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2018, we proposed to apply an adjustment factor of 0.979187 to the CCRs that were in the April 2017 OPSF to trend them forward from CY 2017 to CY 2018. The methodology for calculating this proposed adjustment was discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20173).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2017 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.979187 to approximate CY 2018 CCRs) to charges on CY 2016 claims that were adjusted (using the proposed charge inflation factor of 1.104055 to approximate CY 2018 charges). We simulated aggregated CY 2018 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2018 OPPS payments. We estimated that a proposed fixed-dollar threshold of $4,325, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we proposed that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we proposed to continue the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we referred readers to section XIII. of the proposed rule.

We did not receive any public comments on our hospital outpatient outlier payment methodology. Therefore, we are finalizing our proposal to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS and to use our established methodology to set the OPPS outlier fixed-dollar loss threshold for CY 2018.

3. Final Outlier Calculation

Consistent with historical practice, we used updated data for this final rule with comment period for outlier calculations. For CY 2018, we are applying the overall CCRs from the July 2017 OPSF file after adjustment (using the CCR inflation adjustment factor of 0.9856 to approximate CY 2018 CCRs) to charges on CY 2016 claims that were adjusted using a charge inflation factor of 1.0936 to approximate CY 2018 charges. These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar thresholds for the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527). We simulated aggregated CY 2018 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments will continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payment equaled 1.0 percent of aggregated estimated total CY 2018 OPPS payments. We estimate that a fixed-dollar threshold of $4,150, combined with the multiple threshold of 1.75 times the APC payment rate, will allocate 1.0 percent of aggregated total OPPS payments to outlier payments. We note that the difference in our calculation of the final fixed-dollar threshold of $4,150 and the proposed fixed-dollar threshold of $4,350 is largely attributed to finalized proposals related to reducing payments for drugs purchased under the 340B drug program for CY 2018, as discussed in section V.B.7. of this final rule with comment period.

For CMHCs, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times APC 5853.

H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2018 OPPS/ASC final rule with comment period, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this final rule with comment period and the relative payment weight determined under section II.A. of this final rule with comment period. Therefore, the national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site) was calculated by multiplying the CY 2018 scaled weight for the APC by the CY 2018 conversion factor. We note that this is the same methodology proposed in the CY 2018 OPPS/ASC proposed rule (82 FR 33598), on which

we did not receive any public comments.

We note that section 1833(t)(17) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIII. of this final rule with comment period.

We demonstrate below the steps on how to determine the APC payments that will be made in a calendar year under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''Q4'', ''R'', ''S'', ''T'', ''U'', or ''V'' (as defined in Addendum D1 to this final rule with comment period, which is available via the Internet on the CMS Web site), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the full CY 2018 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

X = .60 * (national unadjusted payment rate).

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that, under the CY 2018 OPPS policy for continuing to use the OMB labor market area delineations based on the 2010 Decennial Census data for the wage indexes used under the IPPS, a hold harmless policy for the wage index may apply, as discussed in section II.C. of this final rule with comment period. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2018 under the IPPS, reclassifications through the Metropolitan Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Public Law 98–21. For further discussion of the changes to the FY 2018 IPPS wage indexes, as applied to the CY 2018 OPPS, we refer readers to section II.C. of this final rule with comment period. We are continuing to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act of 2010.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this final rule with comment period (which is available via the Internet on the CMS Web site) contains the qualifying counties and the associated wage index increase developed for the FY 2018 IPPS, which are listed in Table 2 in the FY 2018 IPPS/LTCH PPS final rule available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* (Click on the link on the left side of the screen titled ''FY 2018 IPPS Final Rule Home Page'' and select ''FY 2018 Final Rule Tables.'') This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = .60 * (national unadjusted payment rate) * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not

attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = .40 * (national unadjusted payment rate).

Adjusted Medicare Payment = $Y + X_a$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we used a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The CY 2018 full national unadjusted payment rate for APC 5071 is approximately $572.81. The reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is approximately $561.35. This reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 5071.

The FY 2018 wage index for a provider located in CBSA 35614 in New York is 1.2876. The labor-related portion of the full national unadjusted payment is approximately $442.53 (.60 * $572.81 * 1.2876). The labor-related portion of the reduced national unadjusted payment is approximately $433.68 (.60 * $561.35 * 1.2876). The nonlabor-related portion of the full national unadjusted payment is approximately $229.12 (.40 * $572.81). The nonlabor-related portion of the reduced national unadjusted payment is approximately $224.54 (.40 * $561.35). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is approximately $671.65 ($442.53 + $229.12). The sum of the portions of the reduced national adjusted payment is approximately $658.22 ($433.68 + $224.54).

I. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in calendar years thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, may be found in section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. OPPS Copayment Policy

In the CY 2018 OPPS/ASC proposed rule (82 FR 33599), for CY 2018, we proposed to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we proposed to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2018 were included in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site).

We did not receive any public comments on the proposed copayment amounts for new and revised APCs using the same methodology we implemented beginning in CY 2004 or the standard rounding principles we apply to our copayment amounts. Therefore, we are finalizing our proposed copayment policies, without modification.

As discussed in section XIII.E. of this final rule with comment period, for CY 2018, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment

amount would be 20 percent of the APC payment rate.

- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

3. Calculation of an Adjusted Copayment Amount for an APC Group

As we stated in the CY 2018 OPPS/ASC proposed rule (82 FR 33600), individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, $114.57 is approximately 20 percent of the full national unadjusted payment rate of $572.81. For APCs with only a minimum unadjusted copayment in Addenda A and B to this final rule with comment period rule (which are available via the Internet on the CMS Web site), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this final rule with comment period. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this final rule with comment period.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this final rule with comment period, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B.*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B.*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.980.

The unadjusted copayments for services payable under the OPPS that will be effective January 1, 2018, are shown in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site). We note that the national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the CY 2018 OPD fee schedule increase factor discussed in section II.B. of this final rule with comment period.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New CPT and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures and medical services;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS

quarterly update CRs. Based on our review, we assign the new CPT and Level II HCPCS codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that may more accurately describe items or services furnished and provides payment or more accurate payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. Those items, procedures, or services not paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment, while other payment status indicators do not. Section XI. of this final rule with comment period discusses the various status indicators used under the OPPS.

As we did in the CY 2018 OPPS/ASC proposed rule, in Table 11 below, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS.

TABLE 11—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2017	Level II HCPCS Codes	April 1, 2017	CY 2018 OPPS/ASC proposed rule.	CY 2018 OPPS/ASC final rule with comment period.
July 1, 2017	Level II HCPCS Codes	July 1, 2017	CY 2018 OPPS/ASC proposed rule.	CY 2018 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2017	CY 2018 OPPS/ASC proposed rule.	CY 2018 OPPS/ASC final rule with comment period.
October 1, 2017	Level II HCPCS Codes	October 1, 2017	CY 2018 OPPS/ASC final rule with comment period.	CY 2019 OPPS/ASC final rule with comment period.
January 1, 2018	Level II HCPCS Codes	January 1, 2018	CY 2018 OPPS/ASC final rule with comment period.	CY 2019 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2018	CY 2018 OPPS/ASC proposed rule.	CY 2018 OPPS/ASC final rule with comment period.

1. Treatment of New HCPCS Codes That Were Effective April 1, 2017 for Which We Solicited Public Comments in the CY 2018 OPPS/ASC Proposed Rule

Through the April 2017 OPPS quarterly update CR (Transmittal 3728, Change Request 10005, dated March 3, 2017), we made effective five new Level II HCPCS codes for separate payment under the OPPS. In the CY 2018 OPPS/ASC proposed rule (82 FR 33601), we solicited public comments on the proposed APC and status indicator assignments for these Level II HCPCS codes, which were displayed in Table 13 of the proposed rule and are now listed in Table 12 of this final rule with comment period. Specifically, we solicited public comments on HCPCS codes C9484, C9485, C9486, C9487, and C9488. We note that HCPCS code C9487 was deleted on June 30, 2017, and replaced with HCPCS code Q9989, effective July 1, 2017. We indicated that the proposed payment rates for these codes were included in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site).

TABLE 12—NEW LEVEL II HCPCS CODES EFFECTIVE APRIL 1, 2017

CY 2017 HCPCS code	CY 2018 HCPCS code	CY 2018 long descriptor	Final CY 2018 SI	Final CY 2018 APC
C9484	J1428	Injection, eteplirsen, 10 mg	G	9484
C9485	J9285	Injection, olaratumab, 10 mg	G	9485
C9486	J1627	Injection, granisetron, extended-release, 0.1 mg	G	9486
C9487*	J3358	Ustekinumab, for intravenous injection, 1 mg	G	9487
C9488	C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488

*HCPCS code C9487, which was effective April 1, 2017, was deleted June 30, 2017 and replaced with HCPCS code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017.

We did not receive any public comments on the proposed APC and status indicator assignments for the new Level II HCPCS codes implemented in April 2017. Therefore, we are finalizing the proposed APC and status indicator assignments for these codes, as indicated in Table 12 above. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes effective January 1, 2018. Their replacement codes are listed in Table 12 above. The final payment rates for these codes can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site). In addition, the status indicator meanings can be found in Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site).

2. Treatment of New HCPCS Codes That Were Effective July 1, 2017 for Which We Solicited Public Comments in the CY 2018 OPPS/ASC Proposed Rule

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33602), through the July 2017 OPPS quarterly update CR (Transmittal 3783, Change Request 10122, dated May 26, 2017), we made 10 new Category III CPT codes and 13 Level II HCPCS codes effective July 1, 2017, and assigned them to appropriate interim OPPS status indicators and APCs. In the CY 2018 OPPS/ASC proposed rule, we solicited public comments on the proposed APC and status indicator assignments for CY 2018 for the CPT and Level II HCPCS codes implemented on July 1, 2017, all of which were displayed in Table 14 of the proposed rule, and are now listed in Table 13 of this final rule with comment period. We note that three of the new HCPCS codes effective July 1, 2017 replaced four existing HCPCS codes. Specifically, HCPCS code Q9986 replaced HCPCS code J1725 (Injection, hydroxyprogesterone caproate, 1 mg), HCPCS codes Q9987 and Q9988 replaced HCPCS code P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit), and HCPCS code Q9989 replaced HCPCS code C9487 (Ustekinumab, for intravenous injection, 1 mg). With the establishment of HCPCS codes Q9986, Q9987, and Q9988, we made their predecessor HCPCS codes J1725 and P9072 inactive for reporting and revised the status indicators for both codes to ''E1'' (Not Payable by Medicare) effective July 1, 2017. In addition, because HCPCS code Q9989 describes the same drug as HCPCS code C9487, in the CY 2018 OPPS/ASC proposed rule, we proposed to continue the drug's pass-through payment status and to assign HCPCS code Q9989 to the same APC and status indicator as its predecessor HCPCS code C9487, as shown in Table 14 of the proposed rule. The proposed payment rates and status indicators for these codes, where applicable, were included in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site).

We did not receive any public comments on the proposed APC and status indicator assignments for the new Category III CPT codes and Level II HCPCS codes implemented in July 2017. Therefore, we are finalizing the proposed APC and status indicator assignments for these codes, as indicated in Table 13 below. We note that several of the HCPCS C and Q-codes have been replaced with HCPCS J-codes effective January 1, 2018. Their replacement codes are listed in Table 13 below. The final payment rates for these codes can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site). In addition, the status indicator meanings can be found in Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 13—NEW CATEGORY III CPT AND LEVEL II HCPCS CODES EFFECTIVE JULY 1, 2017

CY 2017 HCPCS code	CY 2018 HCPCS code	CY 2018 long descriptor	Final CY 2018 SI	Final CY 2018 APC
C9489	J2326	Injection, nusinersen, 0.1 mg	G	9489
C9490	J0565	Injection, bezlotoxumab, 10 mg	G	9490
C9745	C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube	J1	5165
C9746	C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed.	J1	5377
C9747	C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance.	J1	5376
K0553	K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit Of Service.	Y	N/A
K0554	K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system.	Y	N/A
Q9984	J7296	Levonorgestrel-releasing intrauterine contraceptive system (Kyleena), 19.5 mg.	E1	N/A
Q9985	J1729	Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg	N	N/A
Q9986	J1726	Injection, hydroxyprogesterone caproate (Makena), 10 mg	K	9074
Q9987	P9100	Pathogen(s) test for platelets	S	1493
Q9988	P9073	Platelets, pheresis, pathogen reduced, each unit	R	9536
Q9989	J3358	Ustekinumab, for intravenous injection, 1 mg	G	9487
0469T	0469T	Retinal polarization scan, ocular screening with on-site automated results, bilateral.	E1	N/A
0470T	0470T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; first lesion.	M	N/A
0471T	0471T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; each additional lesion (List separately in addition to code for primary procedure).	N	N/A
0472T	0472T	Device evaluation, interrogation, and initial programming of intra- ocular retinal electrode array (eg, retinal prosthesis), in person, with iterative adjustment of the implantable device to test functionality, select optimal permanent programmed values with analysis, including visual training, with review and report by a qualified health care professional.	Q1	5743
0473T	0473T	Device evaluation and interrogation of intra-ocular retinal electrode array (eg, retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional.	Q1	5742
0474T	0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space.	J1	5492
0475T	0475T	Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording and storage, data scanning with signal extraction, technical analysis and result, as well as supervision, review, and interpretation of report by a physician or other qualified health care professional.	M	N/A

TABLE 13—NEW CATEGORY III CPT AND LEVEL II HCPCS CODES EFFECTIVE JULY 1, 2017—Continued

CY 2017 HCPCS code	CY 2018 HCPCS code	CY 2018 long descriptor	Final CY 2018 SI	Final CY 2018 APC
0476T	0476T	Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording, data scanning, with raw electronic signal transfer of data and storage.	Q1	5734
0477T	0477T	Recording of fetal magnetic cardiac signal using at least 3 channels; signal extraction, technical analysis, and result.	Q1	5734
0478T	0478T	Recording of fetal magnetic cardiac signal using at least 3 channels; review, interpretation, report by physician or other qualified health care professional.	M	N/A

3. Process for New Level II HCPCS Codes That Became Effective October 1, 2017 and New Level II HCPCS Codes That Will Be Effective January 1, 2018 for Which We Are Soliciting Public Comments in This CY 2018 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective October 1 and January 1 in the final rule with comment period, thereby updating the OPPS for the following calendar year, as displayed in Table 11 of this final rule with comment period. These codes are released to the public through the October and January OPPS quarterly update CRs and via the CMS HCPCS Web site (for Level II HCPCS codes). For CY 2018, these codes are flagged with comment indicator ''NI'' in Addendum B to this OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. Specifically, the status indicators and the APC assignments for codes flagged with comment indicator ''NI'' are open to public comment in this final rule with comment period, and we will respond to these public comments in the OPPS/ASC final rule with comment period for the next year's OPPS/ASC update. In the CY 2018 OPPS/ASC proposed rule (82 FR 33603), we proposed to continue this process for CY 2018. Specifically, for CY 2018, we proposed to include in Addendum B to the CY 2018 OPPS/ASC final rule with comment period the following new HCPCS codes:

- New Level II HCPCS codes effective October 1, 2017, that would be incorporated in the October 2017 OPPS quarterly update CR; and
- New Level II HCPCS codes effective January 1, 2018, that would be incorporated in the January 2018 OPPS quarterly update CR.

As stated above, the October 1, 2017 and January 1, 2018 codes are flagged with comment indicator ''NI'' in Addendum B to this CY 2018 OPPS/ASC final rule with comment period to indicate that we have assigned these codes an interim OPPS payment status for CY 2018. We are inviting public comments on the interim status indicator and APC assignments for these codes, if applicable, that will be finalized in the CY 2019 OPPS/ASC final rule with comment period.

4. Treatment of New and Revised Category I and III CPT Codes That Will Be Effective January 1, 2018 for Which We Solicited Public Comments in the CY 2018 OPPS/ASC Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the MPFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid the resort to HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), solicit public comments, and finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2018 OPPS update, we received the CY 2018 CPT codes from AMA in time for inclusion in the CY 2018 OPPS/ASC proposed rule. The new, revised, and deleted CY 2018 Category I and III CPT codes were included in Addendum B to the CY 2018 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site). We noted in the proposed rule that the new and revised codes are assigned to new comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, in the CY 2018 OPPS/ASC proposed rule, we reminded readers that the CPT code descriptors that appear in Addendum B are short descriptors and do not fully describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors for the new and revised CY 2018 CPT codes in Addendum O to the proposed rule (which is available via the Internet on the CMS Web site) so that the public could adequately comment on our proposed APCs and status indicator assignments. We indicated that the 5-digit placeholder codes were included in Addendum O, specifically under the column labeled ''CY 2018 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code,'' to the

proposed rule. We stated that the final CPT code numbers will be included in the CY 2018 OPPS/ASC final rule with comment period. We noted that not every code listed in Addendum O is subject to comment. For the new and revised Category I and III CPT codes, we requested comments on only those codes that are assigned to comment indicator ''NP''. We indicated that public comments would not be accepted for new Category I CPT laboratory codes that were not assigned to the ''NP'' comment indicator in Addendum O to the proposed rule. We stated that comments to these codes must be submitted at the Clinical Laboratory Fee Schedule (CLFS) Public Meeting, which was scheduled on July 31–August 1, 2017.

In summary, we solicited public comments on the proposed APC and status indicator assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2018. The CPT codes were listed in Addendum B to the proposed rule with short descriptors only. We listed them again in Addendum O to the proposed rule with long descriptors. We also proposed to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2018 OPPS/ASC final rule with comment period.

Commenters addressed several of the new CPT codes that were assigned to comment indicator ''NP'' in Addendum B to the CY 2018 OPPS/ASC proposed rule. We have responded to those public comments in sections II.A.2.b. (Comprehensive APCs), III.D. (OPPS APC-Specific Policies), V. (OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals), and XII. (Updates to the ASC Payment System) of this CY 2018 OPPS/ASC final rule with comment period.

The final status indicators, APC assignments, and payment rates for the new CPT codes that are effective January 1, 2018 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site). In addition, the status indicator meanings can be found in Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site).

B. OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in § 419.31 of the regulations. We use Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in § 419.2(b) of the regulations. A further discussion of packaged services is included in section II.A.3. of this final rule with comment period.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. In the CY 2018 OPPS/ASC proposed rule (82 FR 33604), for CY 2018, we proposed that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the HOP Panel recommendations for specific services for the CY 2018 OPPS and our responses to them are discussed in the relevant specific sections throughout this final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act).

Therefore, in accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine if there are any APC violations of the 2 times rule and whether there are any appropriate revisions to APC assignments that may be necessary or exceptions to be made. In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims (or less than 1,000 claims) is negligible within

the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost. In the CY 2018 OPPS/ASC proposed rule (81 FR 33604 through 33605), we proposed to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services.

For the CY 2018 OPPS update, we identified the APCs with violations of the 2 times rule, and we proposed changes to the procedure codes assigned to these APCs in Addendum B to the CY 2018 OPPS/ASC proposed rule. We noted that Addendum B did not appear in the printed version of the **Federal Register** as part of the CY 2018 OPPS/ASC proposed rule. Rather, it was published and made available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. In these cases, to eliminate a violation of the 2 times rule or to improve clinical and resource homogeneity, in the CY 2018 OPPS/ASC proposed rule (81 FR 33604 through 33605), we proposed to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2018 included in the proposed rule are related to changes in costs of services that were observed in the CY 2016 claims data newly available for CY 2018 ratesetting. We also proposed changes to the status indicators for some procedure codes that were not specifically and separately discussed in the proposed rule. In these cases, we proposed to change the status indicators for these procedure codes because we believe that another status indicator would more accurately describe their payment status from an OPPS perspective based on the policies that we proposed for CY 2018. Addendum B to the CY 2018 OPPS/ASC proposed rule identified with the comment indicator ''CH'' those procedure codes for which we proposed a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2017 OPPS Addendum B update (available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html*). Addendum B to this final rule with comment period (available via the Internet on the CMS Web site) identifies with the ''CH'' comment indicator the final CY 2018 changes compared to the HCPCS codes' status as reflected in the October 2017 Addendum B update.

3. APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we proposed for CY 2018, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

Based on the CY 2016 claims data available for the CY 2018 proposed rule, we found 12 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we proposed to make exceptions under the 2 times rule for CY 2018, and found that all of the 12 APCs we identified met the criteria for an exception to the 2 times rule based on the CY 2016 claims data available for the proposed rule. We did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with 2 times rule violations.

We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we may accept the HOP Panel's recommendation because those recommendations are based on explicit consideration (that is, a review of the latest OPPS claims data and group discussion of the issue) of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 16 of the proposed rule listed the 12 APCs for which we proposed to make exceptions under the 2 times rule for CY 2018 based on the criteria cited above and claims data submitted between January 1, 2016, and December 31, 2016, that were processed on or before December 31, 2016. We indicated that, for the final rule with comment period, we intended to use claims data for dates of service between January 1, 2016, and December 31, 2016, that were processed on or before June 30, 2017, and updated CCRs, if available.

Based on the updated final rule CY 2016 claims data used for this CY 2018 final rule with comment period, we were able to remedy 6 APC violations out of the 12 APCs that appeared in Table 16 of the CY 2018 OPPS/ASC proposed rule. Specifically, we found that the following 6 APCs no longer met the criteria for exception to the 2 times rule in this final rule with comment period:

- APC 5161 (Level 1 ENT Procedures);
- APC 5311 (Level 1 Lower GI Procedures);
- APC 5461 (Level 1 Neurostimulator and Related Procedures);
- APC 5573 (Level 3 Imaging with Contrast);
- APC 5611 (Level 1 Therapeutic Radiation Treatment Preparation); and
- APC 5735 (Level 5 Minor Procedures).

Secondly, based on our analysis of the final rule claims data, we found a total of 11 APCs with violations of the 2 times rule. Of these 11 total APCs, 6 were identified in the proposed rule and 5 are newly identified APCs. Specifically, we found the following 6 APCs from the proposed rule continued to have violations of the 2 times rule for this final rule with comment period:

- APC 5112 (Level 2 Musculoskeletal Procedures);
- APC 5521 (Level 1 Imaging without Contrast);
- APC 5691 (Level 1 Drug Administration);
- APC 5731 (Level 1 Minor Procedures);
- APC 5771 (Cardiac Rehabilitation); and
- APC 5823 (Level 3 Health and Behavior Services).

In addition, we found that the following 5 additional APCs violated the 2 times rule using the final rule with comment period claims data:

- APC 5522 (Level 2 Imaging without Contrast);
- APC 5524 (Level 4 Imaging without Contrast);
- APC 5571 (Level 1 Imaging with Contrast);
- APC 5721 (Level 1 Diagnostic Tests and Related Services); and
- APC 5732 (Level 2 Minor Procedures).

Comment: Some commenters requested that CMS not adopt the exception to C–APCs, including C–APC

5112 (Level 2 Musculoskeletal Procedures), because they believed it would result in lowering the payments for the procedures assigned to C–APCs. According to the commenters, because C–APCs involve complex combinations of items and services where appropriate valuation is critical, CMS should not adopt exceptions that have the result of lowering the overall payment rate for associated procedures. Instead, as one commenter suggested, CMS should establish additional APC levels to avoid any exceptions to the 2 times rule.

Response: We do not agree that we should establish a new APC for every group that violates the 2 times rule. We believe that excepting certain APCs from the 2 times rule is necessary, especially for procedures assigned to the same APC based on clinical homogeneity. As we have seen throughout the years since the implementation of the OPPS on August 1, 2000, APCs excepted in one year are usually resolved the following year based on our analysis of the latest claims data used for ratesetting. For example, we listed C–APC 5165 (Level 5 ENT Procedures) in Table 19 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70374) as one of the APCs that violated the 2 times rule for CY 2016. However, this same APC no longer appeared in Table 9 of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79614) as excepted from the 2 times rule. We believe that the anomalies seen in one year but not the next year for a given APC are the result of more accurate coding and charge master identification by HOPDs.

After considering the public comments we received on APC assignments and our analysis of the CY 2016 costs from hospital claims and cost report data available for this CY 2018 final rule with comment period, we are finalizing our proposals with some modifications. Specifically, we are finalizing our proposal to except 6 of the 12 proposed APCs from the 2 times rule for CY 2018 (APCs 5112, 5521, 5691, 5731, 5771, and 5823), and also excepting 5 additional APCs (APCs 5522, 5524, 5571, 5721, and 5732). As noted above, we were able to remedy the other 6 of the proposed rule 2 time violations in this final rule with comment period.

Table 14 below lists the 11 APCs that we are excepting from the 2 times rule for CY 2018 based on the criteria described earlier and a review of updated claims data for dates of service between January 1, 2016 and December 31, 2016, that were processed on or before June 30, 2017, and updated CCRs, if available. We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we generally accept the HOP Panel's recommendation because those recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates. The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found on the CMS Web site at: *http://www.cms.gov*.

TABLE 14—APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2018

APC	CY 2018 APC title
5112	Level 2 Musculoskeletal Procedures.
5521	Level 1 Imaging without Contrast.
5522	Level 2 Imaging without Contrast.
5524	Level 4 Imaging without Contrast.
5571	Level 1 Imaging with Contrast.
5691	Level 1 Drug Administration.
5721	Level 1 Diagnostic Tests and Related. Services
5731	Level 1 Minor Procedures.
5732	Level 2 Minor Procedures.
5771	Cardiac Rehabilitation.
5823	Level 3 Health and Behavior Services.

C. New Technology APCs

1. Background

In the November 30, 2001 final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

For CY 2017, there are 51 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) through the highest cost band assigned to APC 1906 (New Technology—Level 51 ($140,001-$160,000)). In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1906, vary with increments ranging from $10 to $19,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level 7 ($501–$600)) is made at $550.50.

Every year, we receive several requests for higher payment amounts under the New Technology APCs for specific procedures paid under the OPPS because they require the use of expensive equipment. As we did in the CY 2018 OPPS/ASC proposed rule, we are taking this opportunity to reiterate our response, in general, to the issue of hospitals' capital expenditures as they relate to the OPPS and Medicare, as specified in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70374).

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital inpatient market basket increase. We believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries. Furthermore, we believe that our payment rates are adequate to ensure access to services (80 FR 70374).

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the techniques and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for

expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. (We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.)

We note that, in a budget neutral environment, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314).

2. Revised and Additional New Technology APC Groups

As stated earlier, for CY 2017, there are currently 51 levels of New Technology APCs. To improve our ability to have payments for services over $100,000 more closely match the cost of the service, in the CY 2018 OPPS/ASC proposed rule (82 FR 33606), for CY 2018, we proposed to narrow the increments for New Technology APCs 1901–1906 from $19,999 cost bands to $14,999 cost bands. We also proposed to add New Technology APCs 1907 and 1908 (New Technology Level 52 ($145,001–$160,000), which would allow for an appropriate payment of retinal prosthesis implantation procedures, which is discussed later in this section. Table 17 of the proposed rule included the complete list of the proposed modified and additional New Technology APC groups for CY 2018.

We did not receive any public comments on our proposal. Therefore, we are finalizing the proposal, without modification. Table 15 below includes the complete list of the final modified and additional New Technology APC groups for CY 2018.

TABLE 15—CY 2018 ADDITIONAL NEW TECHNOLOGY APC GROUPS

CY 2018 APC	CY 2018 APC title	CY 2018 SI	Updated or new APC
1901	New Technology—Level 49 ($100,001–$115,000)	S	Updated.
1902	New Technology—Level 49 ($100,001–$115,000)	T	Updated.
1903	New Technology—Level 50 ($115,001–$130,000)	S	Updated.
1904	New Technology—Level 50 ($115,001–$130,000)	T	Updated.
1905	New Technology—Level 51 ($130,001–$145,000)	S	Updated.
1906	New Technology—Level 51 ($130,001–$145,000)	T	Updated.
1907	New Technology—Level 52 ($145,001–$160,000)	S	New.
1908	New Technology—Level 52 ($145,001–$160,000)	T	New.

The final payment rates for New Technology APCs 1901 through 1908 are included in Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site).

3. Procedures Assigned to New Technology APC Groups for CY 2018

As we explained in the CY 2002 OPPS final rule with comment period (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC.

In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2018, in the CY 2018 OPPS/ASC proposed rule (82 FR 33606), we proposed to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been obtained (66 FR 59902).

a. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114, and 5414)

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33607), currently, there are four CPT/HCPCS codes that describe magnetic resonance image guided high intensity focused ultrasound (MRgFUS) procedures, three of which we proposed to continue to assign to standard APCs and one of which we proposed to continue to assign to a New Technology APC for CY 2018. These codes include CPT codes 0071T, 0072T, and 0398T, and HCPCS code C9734. CPT codes 0071T and 0072T are used for the treatment of uterine fibroids, CPT code 0398T is used for the treatment of essential

tremor, and HCPCS code C9734 is used for pain palliation for metastatic bone cancer.

As shown in Table 18 of the proposed rule, and as listed in Addendum B of the CY 2018 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 0071T and 0072T to APC 5414 (Level 4 Gynecologic Procedures), with a proposed payment rate of approximately $2,189 for CY 2018. We also proposed to continue to assign the APC to status indicator ''J1'' (Hospital Part B services paid through a comprehensive APC) to indicate that all covered Part B services on the claim are packaged with the payment for the primary ''J1'' service for the claim, except for services assigned to OPPS status indicator ''F'', ''G'', ''H'', ''L'', and ''U''; ambulance services; diagnostic and screening mammography; all preventive services; and certain Part B inpatient services. In addition, we proposed to continue to assign HCPCS code C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance) to APC 5114 (Level 4 Musculoskeletal Procedures), with a proposed payment rate of approximately $5,385 for CY 2018. We also proposed to continue to assign HCPCS code C9734 to status indicator ''J1''.

Further, we proposed to continue to assign CPT code 0398T to APC 1537 (New Technology—Level 37 ($9,501–$10,000)), with a proposed payment rate of $9,750.50 for CY 2018. At the time the proposed rule was developed, there was only one claim for CPT code 0398T with a geometric mean cost of $27,516. We referred readers to Addendum B to the proposed rule for the proposed payment rates for all codes reportable under the OPPS. Addendum B is available via the Internet on the CMS Web site.

Comment: Several commenters stated that the proposed payment rate for CPT code 0398T is too low and recommended that CPT code 0398T be assigned to either New Technology APC 1578 (New Technology—Level 41 ($25,001–$30,000)) or APC 5464 (Level 4 Neurostimulator and Related Procedures), which have payment rates closer to the reported cost of the procedure of $27,500 based on the one claim available at the time of the development of the proposed rule. Commenters also noted that the resources required for the procedure described by CPT code 0398T are substantially more than the resources required for the procedure described by CPT code C9734, which had been used by CMS to attempt to model the cost of the procedure described by CPT code 0398T.

Response: We appreciate the concerns of the commenters and, for the reasons set forth below, agree that the proposed payment rate for CPT code 0398T may be too low and the procedure should be reassigned to a different APC. The proposed payment rate for CPT code 0398T was based on the payment rate for HCPCS code C9734 because the MRgFUS equipment used in the performance of the procedure described by CPT code 0398T is very similar to the MRgFUS equipment used in the performance of the procedure described by HCPCS code C9734. Both machines are made by the same manufacturer (81 FR 79642). However, based on information from the manufacturer, resources involved for the procedure described by CPT code 0398T appear to be higher than those involved for the procedure described by HCPCS code C9734. In addition, we still have concerns that the costs reported from the one claim for the procedure described by CPT code 0398T may not accurately reflect the geometric mean costs of the procedure. However, the geometric mean cost of $29,254 for the one claim means the cost of CPT code 0398T is substantially higher than the proposed payment rate of $9,750.50. We note that, for CY 2017, the manufacturer indicated that an appropriate payment for the procedure described by CPT code 0398T would be approximately $18,000 and that either a New Technology APC paying that amount or assignment to clinical APC 5463 (Level 3 Neurostimulator and Related Procedures) would be appropriate. Based on the presence of only one claim along with the reported costs associated with the procedure described by CPT code 0398T presented to us last year by the manufacturer, we believe that it is appropriate to assign the procedure described by CPT code 0398T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)), with a payment rate of $17,500.50 for CY 2018. The continued New Technology APC assignment will allow time to collect more claims data before assigning CPT code 0398T to a clinical APC.

Comment: One commenter supported the proposal to assign CPT code C9734 to APC 5114.

Response: We appreciate the commenter's support.

In summary, after consideration of the public comments we received, we are modifying our proposal for the APC assignment of CPT code 0398T. Instead of continuing to assign this code to New Technology APC 1537 (New Technology—Level 37 ($9,501–$10,000)), with a payment rate of $9,750.50, for CY 2018, we are reassigning CPT code 0398T to New Technology APC 1576 (New Technology—Level 39 ($15,001–$20,000)), with a payment rate of $17,500.50. In addition, we are finalizing our proposal, without modification, to reassign HCPCS code C9734 to APC 5114. We did not receive any public comments related to our proposal for CPT codes 0071T and 0072T. Therefore, we are finalizing our proposal to continue to assign these CPT codes to APC 5414 without modification. Table 16 below lists the final CY 2018 status indicator and APC assignments for the magnetic resonance image guided high intensity focused ultrasound (MRgFUS) procedures. We refer readers to Addendum B of this final rule with comment period for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the Internet on the CMS Web site.

TABLE 16—CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRGFUS) PROCEDURES

CPT/HCPCS code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
0071T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue.	J1	5414	$2,084.59	J1	5414	Refer to OPPS Addendum B.

TABLE 16—CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRgFUS) PROCEDURES—Continued

CPT/HCPCS code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
0072T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue.	J1	5414	2,084.59	J1	5414	Refer to OPPS Addendum B.
0398T	Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed.	S	1537	9,750.50	S	1576	Refer to OPPS Addendum B.
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	J1	5114	5,219.36	J1	5114	Refer to OPPS Addendum B.

c. Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving the use of the Argus® II Retinal Prosthesis System. This first retinal prosthesis was approved by the FDA in 2013 for adult patients diagnosed with advanced retinitis pigmentosa. Pass-through payment status was granted for the Argus® II device under HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) beginning October 1, 2013, and this status expired on December 31, 2015. We note that after pass-through payment status expires for a medical device, the payment for the device is packaged into the payment for the associated surgical procedure. Consequently, for CY 2016, the device described by HCPCS code C1841 was assigned to OPPS status indicator ''N'' to indicate that payment for the device is packaged and included in the payment rate for the surgical procedure described by CPT code 0100T. For CY 2016, CPT code 0100T was assigned to New Technology APC 1599 with a payment rate of $95,000, which was the highest paying New Technology APC for that year. This payment includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). However, stakeholders (including the device manufacturer and hospitals) believed that the CY 2016 payment rate for the procedure involving the Argus® II System was insufficient to cover the hospital cost of performing the procedure, which includes the cost of the retinal prosthesis with a retail price of approximately $145,000.

For CY 2017, analysis of the CY 2015 OPPS claims data used for the CY 2017 final rule with comment period showed 9 single claims (out of 13 total claims) for CPT code 0100T, with a geometric mean cost of approximately $142,003 based on claims submitted between January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on the CY 2015 OPPS claims data available for the final rule with comment period and our understanding of the Argus® II procedure, we reassigned CPT code 0100T from New Technology APC 1599 to New Technology APC 1906, with a final payment rate of $150,000.50 for CY 2017. We noted that this payment rate included the cost of both the surgical procedure (CPT code 0100T) and the retinal prosthesis device (HCPCS code C1841).

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33607 through 33608), for the CY 2018 update, analysis of the CY 2016 OPPS claims data used for the CY 2018 proposed rule showed 3 single claims (out of 3 total claims) for CPT code 0100T, with a geometric mean cost of approximately $116,239 based on the claims submitted between January 1, 2016 through December 31, 2016, and processed through December 31, 2016. We stated in the proposed rule that, for the CY 2018 OPPS/ASC final rule with comment period, the final payment rate would be based on claims submitted between January 1, 2016 and December 31, 2016, and processed through June 30, 2017.

In the proposed rule, based on the CY 2016 OPPS claims data available, which showed a geometric mean cost of approximately $116,239, we proposed to reassign the Argus® II procedure to a New Technology APC with a payment band that covers the geometric mean cost of the procedure. Therefore, we proposed to reassign CPT code 0100T to APC 1904 (New Technology—Level 50 ($115,001–$130,000)), with a proposed payment of $122,500.50 for CY 2018. We invited public comments on this proposal.

Comment: One commenter, the manufacturer, opposed the proposal to reassign CPT code 0100T to APC 1904, with a proposed payment of $122,500.50 for CY 2018. Instead, the commenter requested that CMS reassign CPT code 0100T to a New Technology APC that would establish a payment rate near the CY 2017 payment rate of $150,000.50. The commenter stated that the estimated cost of the service generated from 3 claims reported in CY 2016 is much lower than the actual cost of the procedure. The commenter believed the lower cost of the procedure described by CPT code 0100T is a result of CMS' decision to set the payment rate of the procedure at $95,000 for CY 2016 based on 2 claims, for which the submitting hospital stated the charges reported were mistakenly low. The commenter asserted that the lower

payment rate forced the manufacturer of the Argus® II to provide a substantial discount for the device, which is reflected in the lower reported cost for the Argus® II procedure in CY 2016. This commenter and a second commenter were concerned with the high level of variation in payment for a low volume service like the Argus® II procedure from year to year. The commenters requested payment of approximately $150,000 for CPT code 0100T in CY 2018 to break the cycle of extremely volatile year-to-year shifts of the payment for the procedure described by this CPT code and noted its expectation that claims for CY 2017 (which would be used for the CY 2019 rulemaking) would reflect a significantly higher average cost than those for CY 2016.

Response: We understand the concerns of the commenters. The reported cost of the Argus® II procedure based on the updated CY 2016 hospital outpatient claims data, which include additional claims received after issuance of the CY 2018 proposed rule and finalized as of June 30, 2017, is approximately $94,455, which is more than $55,000 less than the payment rate for the procedure in CY 2017. We note that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS. In addition, the number of claims submitted has, to date, been very low and has not exceeded 10 claims. We believe it is important to mitigate significant payment differences, especially shifts of several tens of thousands of dollars, while also basing payment rates on available costs information and claims data. In CY 2016, the payment rate for the Argus® II procedure was $95,000.50. The payment rate increased to $150,000.50 in CY 2017. For CY 2018, we proposed a payment rate of $122,500.50 based on the most recent claims data available at the time of the development of the proposed rule. However, if we were to assign the payment rate based on updated final rule claims data, the payment rate would decrease, to $95,000.50 for CY 2018, a decrease of $55,000 relative to CY 2017. We are concerned that these large changes in payment could potentially create an access to care issue for the Argus® II procedure. While we believe that the proposed payment rate of $122,500.50 is a significant decrease, we believe that it would be appropriate to finalize the proposed rate to mitigate a much sharper decline in payment from one year to the next (as well as from the proposed rule to the final rule).

In accordance with section 1833(t)(2)(B) of the Act, we must establish that services classified within each APC are comparable clinically and with respect to the use of resources. Accordingly, we are using our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the proposed rate for this procedure, despite the lower geometric mean costs available in the claims data used for this final rule with comment period. As stated earlier, we believe that this situation is unique, given the high cost and very limited number of claims for the procedure. Therefore, for CY 2018, we are reassigning the Argus® II procedure to APC 1904 (New Technology—Level 50 ($115,001–$130,000)). This APC assignment will establish a payment rate for the Argus® II procedure of $122,500.50, which is the arithmetic mean of the payment rates for the service for CY 2016 and CY 2017. As we do each year, we acquire claims data regarding hospital costs associated with new procedures. We regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures like the Argus® II procedure as they transition into mainstream medical practice (77 FR 68314).

After consideration of the public comments we received, we are finalizing our proposal to reassign CPT code 0100T to APC 1904 through use of our equitable adjustment authority. We are reassigning CPT code 0100T from APC 1906 (New Technology—Level 51 ($140,001–$160,000)), which has a final payment rate of $150,000.50 for CY 2017, to APC 1904 (New Technology—Level 50 $115,001–$130,000)), which has a final payment rate of $122,500.50 for CY 2018. We note this payment includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841).

d. Pathogen Test for Platelets

As stated in the CY 2018 OPPS/ASC proposed rule (82 FR 33608), the CMS HCPCS Workgroup established HCPCS code Q9987 (Pathogen(s) test for platelets), effective July 1, 2017. HCPCS code Q9987 will be used to report any test used to identify bacterial or other pathogen contamination in blood platelets. Currently, there is one test approved by the FDA that is described by HCPCS code Q9987. The test is a rapid bacterial test, and the manufacturer estimates the cost of the test to be between $26 and $35. HCPCS code Q9987 was established after concerns from blood and blood product stakeholders that the previous CPT code used to describe pathogen tests for platelets, CPT code P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit), inappropriately described rapid bacterial testing by combining the test with the pathogen reduction of platelets. CPT code P9072 is inactive effective on July 1, 2017.

In the CY 2018 OPPS/ASC proposed rule, we sought more information on the actual costs of pathogen tests for platelets before assigning HCPCS code Q9987 to a clinical APC. Effective July 1, 2017, HCPCS code Q9987 is assigned to New Technology APC 1493 (New Technology—Level 1C ($21–$30)), with a payment rate of $25.50. We proposed to continue to assign HCPCS code Q9987 to New Technology APC 1493, with a proposed payment rate of $25.50, until such time as claims data are available to support the assignment to a clinical APC. We invited public comments on this proposal.

Comment: Two commenters supported the proposal to continue to provide separate payment for HCPCS code Q9987.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to continue separate payment for HCPCS code Q9987 for CY 2018, with a modification that HCPCS code Q9987 will be replaced by HCPCS code P9100 (Pathogen(s) test for platelets). Table 17 below contains more information on the coding change.

TABLE 17—REPLACEMENT CODE FOR HCPCS CODE Q9987 AS OF JANUARY 1, 2018

CY 2017 HCPCS code	CY 2018 HCPCS code	CY 2018 long descriptor	Final CY 2018 SI	Final CY 2018 APC
Q9987	P9100	Pathogen(s) test for platelets	S	1493

e. Fractional Flow Reserve Derived From Computed Tomography (FFR_{CT})

For CY 2018, the AMA CPT Editorial Panel established four new CPT codes for fractional flow reserve derived from computed tomography (FFR_{CT}). Table 18 below lists the new CPT codes along with their complete descriptors. These codes were listed in Addendum B and Addendum O to the CY 2018 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site). Addendum B included the proposed status indicator assignments for the new codes and their assignment to comment indicator ''NP'' (New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code). Addendum O included the proposed/placeholder CY 2018 CPT codes and the long descriptors.

We note that the CPT code descriptors that appeared in Addendum B were short descriptors and did not fully describe the complete procedure, service, or item identified for the CPT codes. Therefore, we included the 5-digit placeholder codes and their long descriptors in Addendum O to the proposed rule, specifically under the column labeled ''CY 2018 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code,'' so that the public could adequately comment on our proposed APC and status indicator assignments. We also indicated that the final CPT code numbers would be included in this CY 2018 OPPS/ASC final rule with comment period. The final CPT code numbers, along with their corresponding 5-digit placeholder codes, can be found in Table 19 below.

As displayed in Table 18 and in Addendum B of the CY 2018 OPPS/ASC proposed rule, we proposed to assign CPT codes 0501T and 0504T to status indicator ''M'' (Not paid under OPPS; Items and Services Not Billable to the MAC) to indicate that these services are not paid under the OPPS, and to assign CPT codes 0502T and 0503T to status indicator ''N'' (packaged) to indicate that the payment for these services is packaged into the primary service or procedure that is reported with the codes.

TABLE 18—PROPOSED CY 2018 STATUS INDICATOR (SI) ASSIGNMENT FOR THE NEW FFR_{CT} CPT CODES EFFECTIVE JANUARY 1, 2018

CPT code	CY 2018 OPPS/ASC proposed rule placeholder code	Long descriptor	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment
0501T	02X4T	Non-invasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission, analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model, with anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report.	M	N/A	N/A
0502T	02X5T	Non-invasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission.	N	N/A	N/A
0503T	02X6T	Non-invasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model.	N	N/A	N/A
0504T	02X7T	Non-invasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report.	M	N/A	N/A

According to the FDA, FFR_{CT} uses post-processing software to create ''a mathematically derived quantity, computed from simulated pressure, velocity and blood flow information obtained from a 3D computer model generated from static coronary CT images.'' [1] FFR_{CT} is performed outside the outpatient hospital setting by HeartFlow, which uses proprietary software to conduct the analysis. Hospital outpatient providers use industry-leading protocols and technologies at every step to ensure protection of patient data and that the CT images are securely transferred to HeartFlow.[2] After FFR_{CT} is performed, a report is generated that provides fractional flow reserve values throughout the coronary blood vessels, which allows providers to determine treatment strategies based on the findings of the report while considering the patient's medical history, symptoms, and results of other diagnostic tests.

The developer of FFR_{CT} first submitted an application for the procedure to be given a temporary

[1] Available at: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN130045.pdf*, page 1.

[2] Available at: *http://www.heartflow.com/*.

procedure code and assigned to a New Technology APC in March 2016. CMS denied the developer's application because we considered the FFR_{CT} procedure to be an image guidance, processing, supervision, or interpretation service whose payment should be packaged into the payment for the related computed tomography service, in accordance with our regulations at 42 CFR 419.2(b)(13). The developer then filed a New Technology APC reconsideration request in March 2017 asking that CMS reverse its denial of the developer's application to have the FFR_{CT} assigned to a New Technology APC. We reviewed the reconsideration request and denied the request for the same reason as we did in March 2016.

In a New Technology APC application for HeartFlow for CY 2018, the developer of the FFR_{CT} service proposed that the service be reported with CPT code 0503T (Non-invasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model) and requested that the service be assigned to APC 1517 (New Technology—Level 17 ($1,501–$1,600)), with a payment rate of $1,550.50. Because both the initial New Technology APC application and the reconsideration request were denied, we did not describe the associated New Technology APC application for HeartFlow in the CY 2018 OPPS/ASC proposed rule.

Comment: Several commenters, including the developer of HeartFlow and some clinicians who have experience with it, supported having a FFR_{CT} service paid as a separate service and not packaged into the payment for the coronary computed tomography angiography. The commenters stated that FFR_{CT} is performed separately from a coronary computed tomography angiography by an independent testing company that is not affiliated with any outpatient hospital provider and is performed at locations owned by the testing company. These commenters noted that the service may be performed several days or weeks after the original coronary computed tomography angiography is performed. Also, commenters noted that several physician societies involved in cardiac care recognize FFR_{CT} as a separate service from a coronary computed tomography angiography and requested that new CPT codes 0501T, 0502T, 0503T, and 0504T be established for FFR_{CT} services, effective January 1, 2018. The commenters stated that the physician societies and the AMA determined that a coronary computed tomography angiography and a FFR_{CT} service are not connected services.

Commenters asserted that a FFR_{CT} service provides information that cannot be obtained from standard analysis of a coronary computed tomography angiography image. Several commenters stated that FFR_{CT} services can improve the quality of screening for coronary artery disease (CAD) while reducing costs. That is, the commenters stated that, unlike a coronary computed tomography angiography service, which merely produces images, the FFR_{CT} service is able to directly produce FFR_{CT} values by creating a 3-D model of the patient's coronary arteries using the previously acquired image. Moreover, the commenters contended that, because the FFR_{CT} service does not produce images, it is improper to package the costs of FFR_{CT} into the payment for the associated coronary computed tomography angiography service.

Commenters stated that, many times, a coronary computed tomography angiography indicates that a beneficiary may potentially have CAD and that without FFR_{CT}, providers will often request an invasive coronary angiogram to verify the presence of CAD. In many cases, the invasive coronary angiogram finds no occurrence of CAD. FFR_{CT} services can provide analytic services not otherwise available to determine fractional flow rates in coronary arteries using the original coronary computed tomography angiography image and show whether a beneficiary has CAD without performing a coronary procedure.

The developer also stated that hospitals incur a cost charged by HeartFlow of $1,500 to perform the FFR_{CT} analysis, and certain other modest costs (for example, overhead for interpretation and entering results into medical record). Therefore, the commenters stated that bundling the payment for FFR_{CT} with the payment for the coronary computed tomography angiography imaging service would prevent hospitals from using FFR_{CT} because the payment rate for the bundled coronary computed tomography angiography service would be less than $300. One commenter (the developer) requested that the service be assigned to APC 1517 (New Technology—Level 17 ($1,501–$1,600)), with a payment rate of $1,550.50.

Some commenters, including the developer, stated that CMS did not properly interpret the regulation at 42 CFR 419.2(b)(13) in its previous decisions to deny the FFR_{CT} application and reconsideration request to receive separate payment in a New Technology APC. Specifically, the FFR_{CT} developer and other commenters stated that the FFR_{CT} service was not an image guidance service because CMS stated in prior preamble language that an image guidance service must produce images. The commenters stated that a FFR_{CT} service does not produce images, but instead produces FFR values. They stated that the FFR_{CT} service is also not an image processing service because such processing services help to compile diagnostic data to create an image, and noted that, although the FFR_{CT} service analyzes image data, it is not used to construct an anatomic image. In addition, the commenters asserted that the FFR_{CT} service is not an imaging supervision or interpretation service. The commenters believed that imaging supervision and interpretation services should be performed on the same day and at the provider location as the independent imaging service; whereas the FFR_{CT} service can be performed days or weeks after the original coronary computed tomography angiography service is performed and is performed in a specialized location outside of hospital. In addition, the commenters stated that imaging supervision and interpretation services are for radiological services that are mostly billed with the CPT radiological code set (CPT codes 70000–79999) and the FFR_{CT} service is not a radiological service and does not involve supervision or interpretation.

Response: We appreciate the comments we have received about the FFR_{CT} service. We have reviewed our image packaging regulations under 42 CFR 419.2(b)(13). This regulation states, in relevant part, that in determining the packaged costs for hospital outpatient prospective payment rates, the prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are integral, ancillary, supportive, dependent, or adjunctive to performing a procedure or furnishing a service on an outpatient basis. In general, these packaged costs may include, but are not limited to, among other items and services, image guidance, processing, supervision, and interpretation services, the payment for which are packaged or conditionally packaged into the payment for the related procedures or services.

After reviewing the public comments, we agree with the commenters that the

FFR_{CT} service is not image guidance or supervision because FFR_{CT} does not produce images, does not appear to be a supportive guidance service that aids in the performance of an independent procedure, and, unlike typical supervision services, is not generally reported when the initial image is acquired. However, we are concerned that it may be image processing and/or interpretation. We discuss these concerns below.

With respect to image processing, in the CY 2008 OPPS/ASC interim and final rule with comment period, we stated that an ''image processing service processes and integrates diagnostic test data that were captured during another independent procedure, usually one that is separately payable under the OPPS. The image processing service is not necessarily provided on the same date of service as the independent procedure. In fact, several of the image processing services that we proposed to package for CY 2008 do not need to be provided face-to-face with the patient in the same encounter as the independent service'' (72 FR 66625). In addition, we stated that we believed it was important to package payment for supportive dependent services that accompany independent services but that may not need to be provided face-to-face with the patient in the same encounter because the supportive services utilize data that were collected during the preceding independent services and packaging their payment encourages the most efficient use of hospital resources. We noted that we were particularly concerned with any OPPS payment policies that could encourage certain inefficient and more costly service patterns. In addition, we stated that packaging encourages hospitals to establish protocols that ensure that services are furnished only when they are medically necessary and to carefully scrutinize the services ordered by practitioners to minimize unnecessary use of hospital resources (72 FR 66625).

FFR_{CT} services necessarily require the use of the prior coronary computed tomography angiography image; the fact that the FFR_{CT} service is done on a different date, at a different site, and by nonhospital staff does not, in and of itself, mean that the service is separate and distinct, from the CCTA. This is especially true because it is using a prior image acquired by the hospital for the patient and is used for the same purpose to diagnose CAD.

With respect to imaging interpretation, as stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66630), we define ''imaging supervision and interpretation codes'' as HCPCS codes for services that are defined as ''radiological supervision and interpretation'' in the radiology series, codes 70000 through 79999 of the book of AMA CPT codes, with the addition of some services in other code ranges of CPT, Category III CPT tracking codes, or Level II HCPCS codes that are clinically similar or directly crosswalk to codes defined as radiological supervision and interpretation services in the CPT radiology range. The current CPT FFR_{CT} codes are Category III codes, and we believe they may be clinically similar to codes in the 70000 through 79999 range of the AMA book of CPT codes.

Nonetheless, we were persuaded by the commenters that the FFR_{CT} service is a separate and distinct service from the original coronary computed tomography angiography service and should receive separate payment. Specifically, the commenters provided additional details since the denial of the new technology reconsideration request that FFR_{CT} is not covered by the image packaging regulations under 42 CFR 419.2(b)(13). Most of the additional detail focuses on whether FFR_{CT} is an image processing service. In particular, the FFR_{CT} service generates data on FFR values that can only be obtained by performing the FFR_{CT} service. Accordingly, we now believe that the FFR_{CT} service should not be considered to be an image processing service because the diagnostic output of the FFR_{CT} service yields functional values (that is, FFR values), which reflect the drop in pressure across a narrowing in a coronary artery as opposed to anatomic images. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66625) states that image processing covers ''supportive dependent services to process and integrate diagnostic test data in the development of images, indicating that an image processing service must help develop or otherwise visually enhance an image and the FFR_{CT} service does neither. Further, we agree that the quantitative diagnostic information about the function of the coronary arteries produced by the FFR_{CT} service is not possible to derive from examining anatomic images of the arteries. Additionally, we agree with the commenters that the FFR_{CT} service does not support the diagnostic output of CCTA. Notably, CPT code 0503T does not mention processing, interpretation, or supervision. Further, the FDA clearance refers to the FFR_{CT} service as ''post-processing image analysis software . . . using graphics and text [FFR_{CT}] to aid the clinician in the assessment of coronary artery disease.''

Therefore, we conclude, based on the information available to us at this time, that the costs of the FFR_{CT} service, as described by CPT code 0503T, should not be a packaged service under the regulation at 42 CFR 419.2(b)(13). Accordingly, we are assigning CPT code 0503T to a New Technology APC for CY 2018. We remind hospitals that, according to the Medicare statute, this service should only be furnished when reasonable and medically necessary for the purposes of diagnosis of and treatment a Medicare beneficiary.

In summary, after consideration of the public comments we received, we are finalizing our proposal for CPT codes 0501T, 0502T, and 0504T without modification. However, for CPT code 0503T, we are finalizing our proposal with modification. Specifically, we are reassigning CPT code 0503T from packaged status (status indicator ''N'') to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50 for CY 2018. We note our belief that CPT code 0503T covers payment for the majority of hospital resources involved in the HeartFlow service, and that CPT 0502T, which reflects data preparation and transmission, will be packaged under the OPPS.

Table 19 lists the final status indicator assignments for CPT codes 0501T, 0502T, 0503T, and 0504T. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and B are available via the Internet on the CMS Web site.

TABLE 19—FINAL CY 2018 STATUS INDICATOR (SI) ASSIGNMENT FOR THE NEW FFR_{CT} CPT CODES EFFECTIVE JANUARY 1, 2018

CPT code	CY 2018 OPPS/ASC proposed rule placeholder code	Long descriptor	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment
0501T	02X4T	Non-invasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission, analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model, with anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report.	M	N/A	N/A.
0502T	02X5T	Non-invasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission.	N	N/A	N/A.
0503T	02X6T	Non-invasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model.	S	1516	Refer to OPPS Addendum B.
0504T	02X7T	Non-invasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report.	M	N/A	N/A.

D. OPPS APC-Specific Policies

1. Blood-Derived Hematopoietic Cell Harvesting

HCPCS code 38205 describes blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic. This code represents a donor acquisition cost for an allogeneic hematopoietic stem cell transplant (HSCT). In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60575), we assigned HCPCS code 38205 to status indicator ''B'', which indicates that this code is not recognized by the OPPS when submitted on an outpatient hospital Part B bill (type 12x and 13x).

In CY 2017, we finalized a C–APC for HSCT (81 FR 79586 through 79587). Payment for donor acquisition services for HSCT is included in the C–APC payment for the allogeneic stem cell transplant when the transplant occurs in the hospital outpatient setting. All donor acquisition costs, including the costs for HCPCS code 38205, should be reported on the same date of service as the transplant procedure (HCPCS code 38240 (Hematopoietic progenitor (HPC); allogeneic transplantation per donor)) in order to be appropriately packaged for payment purposes. Hospitals are instructed to identify services required to acquire stem cells from a donor for allogeneic HSCT separately in Field 42 on Form CMS–1450 (or UB–04), with revenue code 0815 when an allogeneic stem cell transplant occurs. (We refer readers to the Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 231.11, and Chapter 3, Section 90.3.1.)

There are other donor acquisition costs, namely those costs for the procedure described by HCPCS code 38230 (Bone marrow harvesting for transplantation; allogeneic), that are assigned to status indicator ''S''. For consistency and to ensure that the donor acquisition costs are captured accurately, in the CY 2018 OPPS/ASC proposed rule (82 FR 33608), for CY 2018, we proposed to change the status indicator assignment for the procedure described by HCPCS code 38205 from ''B'' to ''S'', which indicates that the procedure is paid under the OPPS and receives separate payment.

The CY 2016 claims data used for the proposed rule, which included claims submitted between January 1, 2016, and December 31, 2016, and processed on or before December 31, 2016, showed a geometric mean cost of approximately $580 for HCPCS code 38205 based on 2 single claims (out of 8 total claims). The procedure described by HCPCS code 38205 has resource and clinical similarities to procedures assigned to APC 5242 (Level 2 Blood Product Exchange and Related Services). Therefore, we proposed to assign HCPCS code 38205 to APC 5242. We invited public comments on these proposals.

Comment: Several commenters opposed the proposal to change the status indicator assignment for the procedure described by HCPCS code 38205 from ''B'' to ''S''. The commenters stated that this procedure represents a donor acquisition cost for allogeneic hematopoietic stem cell transplants for

which Medicare does not make separate payment because hospitals may bill and receive payment only for services provided to the Medicare beneficiary who is the recipient of the stem cell transplant and whose illness is being treated with the stem cell transplant. The commenters believed that a change from status indicator ''B'' to ''S'' may indicate to providers that they can bill donors for these services and lead to potential for erroneous separate payments if this code is billed with status indicator ''S''. In addition, the HOP Panel recommended that CMS retain status indicator ''B'' for HCPCS code 38205. The commenters also encouraged CMS to look at the entire series of bone marrow and stem cell transplant-related CPT codes to ensure consistency in terms of coding, billing guidance, appropriate APC assignment, and payment.

Response: We appreciate the commenters' responses. We believed that changing the status indicator assignment from ''B'' to ''S'' for HCPCS code 38205 would be consistent with other donor acquisition costs and ensure that the donor acquisition costs for allogeneic HSCT are captured accurately. However, we agree with the commenters that this change could result in erroneous billing or misinterpretations by providers.

After consideration of the public comments we received, we are not finalizing our proposal to change the status indicator assignment for the procedure described by HCPCS code 38205 from ''B'' to ''S'' and to assign HCPCS code 38205 to APC 5242.

2. Brachytherapy Insertion Procedures (C–APCs 5341 and 5092)

a. C–APC 5341 (Abdominal/Peritoneal/Biliary and Related Procedures)

For CY 2018, as displayed in Table 20 below and in Addendum B to the CY 2018 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 55920 to C–APC 5341 (Abdominal/Peritoneal/Biliary and Related Procedures), with a proposed payment rate of $2,788.26.

TABLE 20—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODE 55920

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
55920	Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application.	J1	5341	$2,861.53	J1	5341	$2,788.26

Comment: Commenters disagreed with the proposed APC assignment for CPT code 55920 and recommended that this code be reassigned to an APC that includes gynecologic procedures, specifically C–APC 5415 (Level 5 Gynecologic Procedures). The commenters noted that radiation therapy is an important adjuvant treatment for gynecological malignancies and the vignette for the procedure described by CPT 55920 describes a gynecological implant with a Syed-type intracavitary applicator insertion to the vagina, cervix, or female urethra. The commenters stated that the procedure described by CPT code 55920 was similar, from a clinical and resource perspective, to procedures assigned to C–APC 5415.

Response: Our analysis of the final rule updated claims data revealed a geometric mean cost of approximately $4,791 for CPT code 55920 based on 134 single claims (out of 135 total claims), which is comparable to the geometric mean cost of approximately $4,109 for C–APC 5415. The geometric mean cost for C–APC 5341 is approximately $2,909. After reviewing the procedures assigned to C–APC 5415, we agree with the commenters that CPT code 55920 would be more appropriately reassigned to C–APC 5415 based on its clinical homogeneity and resource costs.

After consideration of the public comments we received, we are finalizing our CY 2018 proposal with modification. Specifically, we are reassigning CPT code 55920 from C–APC 5341 to C–APC 5415 for CY 2018. We refer readers to Addendum B to this final rule with comment period for the final CY 2018 payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS for CY 2018. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

b. C–APC 5092 (Level 2 Breast/Lymphatic Surgery and Related Procedures)

For CY 2018, as displayed in Table 21 below and in Addendum B to the CY 2018 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 19298 to C–APC 5092 (Level 2 Breast/Lymphatic Surgery and Related Procedures), with a proposed payment rate of $4,616.48.

TABLE 21—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODE 19298

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
19298	Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into breast for interstitial; radioelement application following (at the time of or subsequent to) partial mastectomy, includes image guidance).	J1	5092	$4,417.60	J1	5092	$4,616.48

Comment: Commenters disagreed with the proposed continued APC assignment for CPT code 19298 to C–APC 5092. These commenters stated that the CY 2018 proposed payment is inadequate and does not cover the costs associated with the surgical placement of the breast brachytherapy catheter or the brachytherapy treatment delivery and related planning and preparation codes included on the claim. The commenters also stated that, previously, both breast brachytherapy catheter placement codes 19296 (Breast interstitial radiation treatment, delayed (expandable) and 19298 have been assigned to the same APC as they are similar clinically and with regard to resource cost. The commenters requested that CPT code 19298 be assigned to the same C–APC as CPT code 19296 proposed for CY 2018; that is, C–APC 5093 (Level 3 Breast/Lymphatic Surgery and Related Procedures).

Response: Our analysis of the final rule updated claims data revealed a geometric mean cost of approximately $5,944 for CPT code 19298 based on 68 single claims (out of 69 total claims). Based on our updated analysis, we believe that CPT code 19298 is appropriately assigned to C–APC 5092, which has a geometric mean cost of approximately $4,809, rather than to C–APC 5093, which has a geometric mean cost of approximately $7,383 as suggested by the commenters. In addition, our updated analysis showed that the geometric mean cost of approximately $5,944 for CPT code 19298 is within the range of the significant procedures assigned to C–APC 5092, which is between $4,276 (for CPT code 19380) and $6,134 (for CPT code 19340).

After consideration of the public comments we received and based on updated claims data, we are finalizing our proposal to continue to assign CPT code 19298 to C–APC 5092 for CY 2018.

3. Care Management Coding Changes Effective January 1, 2018 (APCs 5821 and 5822)

As noted in the CY 2018 MPFS proposed rule (82 FR 34079), we continue to be interested in the ongoing work of the medical community to refine the set of codes used to describe care management services, including chronic care management. In the CY 2018 OPPS/ASC proposed rule (82 FR 33603 and 33604), we proposed to adopt CPT replacement codes for CY 2018 for several of the care management services finalized last year and sought public comment on ways we might further reduce the burden on reporting providers, including through stronger alignment between CMS requirements and CPT guidance for existing and potential new codes. Table 15 of the CY 2018 OPP/ASC proposed rule detailed the proposed care management coding changes. We referred readers to Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2018 payment rates for the replacement codes.

Comment: Commenters supported CMS' proposed replacement codes for CY 2018 for several of the care management services finalized for CY 2017. One commenter recommended that the new chronic care management codes be removed from the financial settlement of accountable care organizations (ACOs). This commenter also recommended that CMS develop documentation and billing workflow to reduce administrative burden on providers billing transitional care management and chronic care management codes.

Response: We appreciate the commenters' support. We also appreciate the suggestion for reducing provider burden with respect to billing and documentation requirements for chronic care management and will consider these suggestions in future rulemaking. However, we note that ACOs are outside the scope of this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposal to adopt CPT replacement codes for CY 2018 for several of the care management services finalized last year. Table 22 below details the final care management coding changes. We refer readers to Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site) for the final CY 2018 payment rates for the replacement codes.

TABLE 22—CARE MANAGEMENT CODING CHANGES EFFECTIVE JANUARY 1, 2018

CY 2017 HCPCS code	CY 2017 HCPCS code short descriptor	CY 2017 OPPS SI	CY 2017 OPPS ASC	CY 2018 replacement CPT code	CY 2018 replacement HCPCS code short descriptor *	CY 2018 OPPS SI	CY 2018 OPPS APC
G0502	Init psych care Manag, 70min.	S	5822	99492	1st Psyc collab care mgmt.	S	5822
G0503	Subseq psych care man, 60mi.	S	5822	99493	Sbsg psyc collab care mgmt.	S	5822

TABLE 22—CARE MANAGEMENT CODING CHANGES EFFECTIVE JANUARY 1, 2018—Continued

CY 2017 HCPCS code	CY 2017 HCPCS code short descriptor	CY 2017 OPPS SI	CY 2017 OPPS ASC	CY 2018 replacement CPT code	CY 2018 replacement HCPCS code short descriptor *	CY 2018 OPPS SI	CY 2018 OPPS APC
G0504	Init/sub psych Care add 30 m.	N	N/A	99494	1st/sbsq psyc collab care	N	N/A
G0505	Cog/func assessment outpt.	S	5822	99483	Assmt & care pln pt cog imp.	S	5822
G0507	Care manage serv minimum 20.	S	5821	99484	Care mgmt. svc bhvl hlth cond.	S	5821

* The long descriptors for the final CPT codes can be found in Addendum O (New Category I and Category III CPT Codes Effective January 1, 2018) to this final rule with comment period, which is available via the Internet on the CMS Web site.

4. Cardiac Telemetry (APC 5721)

For CY 2018, as noted in Table 23 below and in Addendum B to the CY 2018 OPPS/ASC proposed rule, we proposed to reassign CPT code 93229 from APC 5733 (Level 3 Minor Procedures) to APC 5734 (Level 4 Minor Procedures), with a proposed payment rate of $94.27.

TABLE 23—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODE 93229

CPT Code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
93229	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ecg data storage (retrievable with query) with ecg triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional.	S	5733	$54.55	S	5734	$94.27

We proposed to revise the APC assignment for CPT code 93229 based on claims data used for the CY 2018 OPPS/ASC proposed rule. We note that the proposed rule data were based on claims data submitted between January 1, 2016, and December 31, 2016, that were processed on or before December 31, 2016. Our analysis of the claims data revealed a geometric mean cost of approximately $156 for CPT code 93229 based on 1,518 single claims (out of 3,370 total claims). Our analysis further revealed a geometric mean cost of approximately $98 for APC 5734. Based on the geometric mean cost, we believed that it was necessary to revise the APC assignment for CPT code 93229 from APC 5733 to APC 5734 to pay appropriately for the service.

Comment: Some commenters disagreed with the proposed reassignment of CPT code 93229 to APC 5734, and instead requested a reassignment to APC 5722 (Level 2 Diagnostic Tests and Related Services), which had a proposed payment rate of $242.21 and which is the same APC assignment for CPT code 93229 as in CY 2016. The commenters believed that the cost data used to set the payment rate for the CY 2017 OPPS update was based on miscoding of the service because mobile outpatient telemetry is a low-volume service in the HOPD setting that is performed by a small number of hospitals. The commenters indicated that since the publication of a 2016 coding guidance in the AHA Coding Clinic for HCPCS on the proper coding of remote cardiac monitoring services, they have noticed that the top billers of this service from prior years are no longer inappropriately reporting the service. In addition, the commenters believed that APC 5734 is an inappropriate assignment both from the clinical and resource cost perspectives. The commenters further indicated that the service is not a minor procedure, as described by the group description for APC 5734, and added that CPT code 93229 is the only code in APC 5734 with a status indicator assignment of ''S'' (Procedure or Service, Not Discounted When Multiple), while all the other codes in the APC are assigned to status indicator ''Q1'' (conditionally packaged).

Response: Although CPT code 93229 was assigned to status indicator ''S'' in APC 5734, it was not the only status indicator assigned to the codes in this APC. As indicated in OPPS Addendum B that was released with the CY 2018 OPPS/ASC proposed rule, three separate status indicators were assigned to the codes in APC 5734. Specifically, CPT code 93229 was assigned to status indicator ''S'', CPT codes 30903 and 30905 were assigned to status indicator ''T'' (Procedure or Service, Discounted

When Multiple), and the remaining codes were assigned to status indicator ''Q1''. We note that a specific status indicator assignment does not preclude a code's assignment to a specific APC.

In addition, as we have stated since the implementation of the OPPS in August 2000, section 1833(t)(9) of the Act requires that we annually review all the items and services within an APC group and revise the APC structures accordingly. Included in this review is the identification of any 2 times rule violations as provided under section 1833(t)(2) of the Act and, to the extent possible, rectification of these violations. We review the most recently available OPPS claims data every year and determine whether changes to the current APC assignment are necessary. Although CPT code 93229 was assigned to APC 5722 in CY 2016, we revised the APC assignment to APC 5733 for CY 2017 based on the latest claims data available at that time. The discussion related to this APC revision can be found in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79616 through 79617).

For this CY 2018 OPPS/ASC final rule with comment period, we again reviewed the claims data associated with CPT code 93229. We note that, for this final rule with comment period, we used claims data with dates of service between January 1, 2016, and December 31, 2016 that were processed on or before June 30, 2017. Our analysis revealed a geometric mean cost of approximately $160 for CPT code 93229 based on 1,750 single claims (out of 3,869 total claims). Based on our review of the four levels of Diagnostic Tests and Related Services APCs, we believe that CPT code 93229 appropriately fits in APC 5721 (Level 1 Diagnostic Tests and Related Services), which has a geometric mean cost of approximately $136, rather than in APC 5722, which has a geometric mean cost of approximately $249. In addition, our review shows that the geometric mean cost of approximately $160 for CPT code 93229 is within the range of the significant procedures in APC 5721, which is between $60 (for CPT code 93702) and $181 (for CPT code 94727). Consequently, we believe that a reassignment of CPT code 93229 to APC 5721 is more appropriate.

In summary, after consideration of the public comments we received, we are finalizing our CY 2018 proposal with modification. Specifically, we are revising the assignment for CPT code 93229 to APC 5721 for CY 2018 rather than the proposed APC 5734. Consistent with our policy of reviewing APC assignments annually, we will reevaluate the cost of CPT code 93229 and its APC assignment for the CY 2019 rulemaking. Table 24 below lists the final status indicator and APC assignment for CPT code 93229 for CY 2018. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addenda A and B are available via the Internet on the CMS Web site.

TABLE 24—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT CODE 93229

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
93229	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ecg data storage (retrievable with query) with ecg triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional.	S	5733	$54.55	S	5721	Refer to OPPS Addendum B.

5. Collagen Cross-Linking of Cornea (C–APC 5503)

For CY 2018, as noted in Addendum B to the CY 2018 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 0402T (Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)) to APC 5502 (Level 2 Extraocular, Repair, and Plastic Eye Procedures) for CY 2018.

Comment: One commenter requested that CMS reassign CPT code 0402T from APC 5502 to APC 5504 (Level 4 Extraocular, Repair, and Plastic Eye Procedures). The commenter recommended reassignment to APC 5504 because it believed that assignment to that APC would more accurately reflect the level of resource utilization (particularly labor time and capital equipment) involved in the corneal collagen cross-linking procedure. In addition, the commenter provided resource information on the supplies, equipment, and labor required to perform the procedure described by CPT code 0402T. According to the commenter, the capital equipment required for the procedure costs approximately $90,000, and disposable supplies and at least one technician or registered nurse are also required. In addition, the commenter stated that the average procedure time can last from 1.25 to 2 hours. The commenter acknowledged that there are no Medicare claims data for CPT code

0402T because it was established on January 1, 2016.

Response: We reviewed the updated CY 2016 claims data used for this final rule with comment period. Based on our review, and with consideration of the resource information provided by the commenter, in the absence of data and based on the resources and operating expenses to perform the procedure as described by the commenter, we disagree with the commenter's recommendation that CPT code 0402T should be reassigned to APC 5504, which has a geometric mean cost of approximately $3,000 in CY 2018. In the absence of claims data, we may use other data, such as invoices, to assign a new procedure to a clinical APC. In this case, the commenter did not provide invoices, but did supply some cost information in its comment. We note that the payment rate is not designed to pay for capital equipment costs on a per claim basis. However, taking into account the disposable costs as well as information from the commenter about the time to perform the procedure and the hospital staff involved, we are persuaded to modify our proposal. Given the resource cost and clinical congruence of CPT code 0402T with other procedures assigned to APC 5503 (approximate geometric mean cost of $1,800), such as CPT code 65436 (Removal of corneal epithelium; with application of chelating agent, *e.g.,* EDTA), we believe that the reassignment to APC 5503 is more appropriate for CY 2018. Therefore, we are modifying our proposal, and reassigning CPT code 0402T to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) for CY 2018. We will consider reassignment of CPT code 0402T to APC 5504 in the CY 2019 rulemaking.

6. Cryoablation Procedure for Lung Tumors (C–APC 5361)

For CY 2018, the AMA CPT Editorial Panel deleted CPT code 0340T and replaced the code with CPT code 32994, effective January 1, 2018. We note that CPT code 0340T was effective January 1, 2014, and deleted on December 31, 2017. Table 25 below lists the complete descriptors for the deleted and replacement code. We note that the deleted and replacement code were both listed in Addendum B and Addendum O to the CY 2018 OPPS/ASC proposed rule (which are available via the Internet on the CMS Web site). Addendum B listed the proposed status indicator assignment for the replacement code and assigned it to comment indicator ''NP'' (New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code), while Addendum O listed the proposed/placeholder CY 2018 CPT codes and the long descriptors.

TABLE 25—CODING CHANGES FOR CPT CODE 32994

CPT Code	CY 2018 OPPS/ASC proposed rule placeholder code	Long descriptor
0340T	.....	Ablation, pulmonary tumor(s), including pleura or chest wall when involved by tumor extension, percutaneous, cryoablation, unilateral, includes imaging guidance.
32994	32X99	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; cryoablation.

As noted in Table 26 below and in Addendum B to the CY 2018 OPPS/ASC proposed rule, we proposed to delete CPT code 0340T (status indicator ''D'') and assign its replacement code, CPT code 32994 (placeholder code 32X99), to C–APC 5361 (Level 1 Laparoscopy and Related Services), with a proposed payment rate of $4,340.65. As noted in Table 26, for CY 2017, CPT code 0340T was assigned to C–APC 5361, which is the same APC assignment for CPT code 32994.

TABLE 26—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODE 32994

CPT code	CY 2018 OPPS/ASC proposed rule placeholder code	Short descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
0340T	.....	Ablate pulm tumors + extnsn.	J1	5361	$4,199.13	D	N/A	N/A
32994	32X99	Ablate pulm tumor perq crybl.	N/A	N/A	N/A	J1	5361	$4,340.65

Comment: Commenters presented opposing recommendations on the proposed APC assignment for CPT code 32994. Some commenters supported the proposed APC assignment to C–APC 5361. One commenter stated that the APC assignment maintains clinical homogeneity for services within the APC and addresses resource cost fluctuation and volatility, and suggested that CMS finalize the proposal. However, other commenters disagreed with the proposed APC assignment and recommended that CPT code 32994 be assigned to C–APC 5362 (Level 2 Laparoscopy and Related Services), which had a proposed payment rate of $7,213.53. One commenter understood why CMS proposed to assign CPT code 32994 to C–APC 5361, which is the same APC to which its predecessor code was assigned. However, the commenter believed that the cost of the procedure will only increase as hospitals gain

experience with it. Consequently, the commenter suggested that CMS assign the CPT code to C–APC 5362. Another commenter recommended that CMS assign CPT code 32994 to C–APC 5362 and further noted the importance of new codes to be priced correctly before they are subject to APC placement based on their actual cost data.

Response: Because CPT code 0340T is a predecessor code to CPT code 32994, we have historical claims data on which to base the payment rate for CPT code 32994. Review of our claims data for this final rule with comment period shows a geometric mean cost of approximately $5,471 for CPT code 0340T based on 27 single claims (out of 27 total claims), which is more comparable to the geometric mean cost of approximately $4,486 for C–APC 5361 than to the geometric mean cost of approximately $7,591 for C–APC 5362. We do not agree that we should assign CPT code 32994 to C–APC 5362 because the geometric mean cost for this APC is significantly greater than that of CPT code 32994 (cross-walked from CPT code 0340T) as indicated in our claims data available for this final rule with comment period. In addition, if the cost of the procedure increases, this will be identified through our annual review of the claims data. Consistent with our policy of reviewing APC assignments annually, we will reevaluate the geometric mean cost of CPT code 32994 and its APC assignment in next year's rulemaking for the CY 2019 OPPS update.

In summary, after consideration of the public comments we received and our analysis of the updated claims data for this final rule with comment period, we are finalizing our CY 2018 proposal without modification, and assigning CPT code 32994 to C–APC 5361. The final CY 2018 geometric mean cost for C–APC 5361 is approximately $4,486. Table 27 below lists the final status indicator and APC assignment for CPT code 32994 for CY 2018. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addenda A and B are available via the Internet on the CMS Web site.

TABLE 27—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT CODE 32994

CPT code	CY 2018 OPPS/ASC proposed rule placeholder code	Short descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
0340T	N/A	Ablate pulm tumors + extnsn.	J1	5361	$4,199.13	D	N/A	N/A.
32994	32X99	Ablate pulm tumor perq crybl.	N/A	N/A	N/A	J1	5361	Refer to OPPS Addendum B.

7. Diagnostic Bone Marrow Aspiration and Biopsy (C–APC 5072)

For CY 2018, the AMA CPT Editorial Panel revised the bone marrow and aspiration CPT codes. Specifically, the descriptors for CPT codes 38220 and 38221 were revised and new CPT codes 20939 (placeholder code 2093X) and 38222 (placeholder code 382X3) were established, effective January 1, 2018. In addition, add-on HCPCS code G0364, which was effective January 1, 2005, will be deleted on December 31, 2017 and replaced with CPT codes 38220, 38221, and 38222, effective January 1, 2018. The deleted and replacement codes were listed in Addendum B and Addendum O to the CY 2018 OPPS/ASC proposed rule. Addendum B listed the proposed status indicator assignment for revised CPT codes 38220 and 38221 and new CPT code 38222, which was assigned to comment indicator ''NP'' (New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code), while Addendum O listed the proposed/placeholder CY 2018 CPT codes and the long descriptors.

Table 28 below lists the complete descriptors for the bone marrow aspiration and biopsy codes.

TABLE 28—CODING CHANGES FOR THE BONE MARROW ASPIRATION AND BIOPSY CODES

HCPCS code	CY 2018 OPPS/ASC proposed rule placeholder code	Long descriptor
20939	2093X	Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision (List separately in addition to code for primary procedure).
38220	N/A	Diagnostic bone marrow; aspiration.
38221	N/A	Diagnostic bone marrow; biopsy(ies).
38222	382X3	Diagnostic bone marrow; biopsy(ies) and aspiration(s).
G0364	N/A	Bone marrow aspiration performed with bone marrow biopsy through the same incision on the same date of service.

As noted in Table 29 below and in Addendum B of the CY 2018 OPPS/ASC proposed rule, we proposed to delete HCPCS code G0364 (status indicator ''D'') and assign revised CPT codes 38220 and 38221, as well as new CPT code 38222 (placeholder code 382X3) to C–APC 5072 (Level 2 Excision/Biopsy/Incision and Drainage), with a proposed payment rate of $1,268.53. We note that, under the OPPS, we packaged the payment for HCPCS code G0364 (status

indicator ''N'') into the primary service or procedure that is reported with the code because we considered the service to be an add-on furnished as part of a comprehensive service. In addition, we proposed to assign CPT code 20939 (placeholder 2093X) to status indicator ''N'' (Packaged status) because it is an add-on code. Under Medicare regulations at 42 CFR 419.2(b)(18), add-on codes are packaged under the OPPS. Further, we proposed to continue to assign revised CPT codes 38220 and 38221 to C–APC 5072 for CY 2018.

TABLE 29—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATES FOR THE BONE MARROW ASPIRATION AND BIOPSY CODES

HCPCS Code	CY 2018 OPPS/ASC proposed rule placeholder code	Short descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
20939	2093X	Bone marrow aspir bone grfg	N/A	N/A	N/A	N	N/A	N/A
38220	N/A	Dx bone marrow aspirations	J1	5072	$1,236.62	J1	5072	$1,268.53
38221	N/A	Dx bone marrow biopsies	J1	5072	1,236.62	J1	5072	1,268.53
38222	382X3	Dx bone marrow bx & aspir	N/A	N/A	N/A	J1	5072	1,268.53
G0364	N/A	Bone marrow aspirate &biopsy	N	N/A	N/A	D	N/A	N/A

Comment: One commenter disagreed with the proposed APC assignment of new CPT code 38222 to C–APC 5072 and recommended that the code be assigned to C–APC 5073 (Level 3 Excision/Biopsy/Incision and Drainage), which had a proposed payment rate of $2,222.47. This commenter further noted the importance of new codes being priced correctly before they are subject to APC assignment based on their actual cost data.

Response: As displayed in Table 29, we proposed to make no change to the APC assignments for CPT codes 38220 and 38221. Specifically, we proposed to continue to assign both codes to C–APC 5072 for CY 2018 based on claims data used for the CY 2018 OPPS/ASC proposed rule. We note that the proposed rule data was based on claims data submitted between January 1, 2016, and December 31, 2016, that were processed on or before December 31, 2016. For CPT code 38220, our examination of the claims data revealed a geometric mean cost of approximately $1,645 based on 5,361 single claims (out of 5,431 total claims). For CPT code 38221, our claims data showed a geometric mean cost of approximately $1,615 based on 53,789 single claims (out of 54,335 total claims). We believe that the geometric mean costs of approximately $1,645 for CPT code 38220 and $1,615 for CPT code 38221 are comparable to the geometric mean cost of approximately $1,319 for C–APC 5072. Consequently, we proposed to maintain both codes in C–APC 5072 for CY 2018. We note that we had no claims data for HCPCS code G0364 because this is an add-on code whose payment is packaged into the primary service that is reported with the code.

For this final rule with comment period, we again analyzed updated claims data associated with the four codes. We note that, for this final rule with comment period, we used claims data with dates of service between January 1, 2016, and December 31, 2016, that were processed on or before June 30, 2017. Our review of the final rule claims data revealed a similar pattern for both codes. For CPT code 38220, we found a geometric mean cost of approximately $1,787 based on 5,908 single claims (out of 5,993 total claims), and for CPT code 38221, our claims data revealed a geometric mean cost of approximately $1,799 based on 59,892 single claims (out of 60,467 total claims). Because the geometric mean costs of approximately $1,787 for CPT code 38220 and $1,799 for CPT code 38221 are similar to the geometric mean cost of approximately $1,347 for C–APC 5072, we continue to believe that C–APC 5072 is the most appropriate APC assignment for both codes for CY 2018.

In addition, based on input from our medical advisors, we believe that C–APC 5072 is the most appropriate APC assignment for new CPT code 38222, consistent with the APC assignment for similar diagnostic bone marrow aspiration and biopsy procedures. As noted in Table 29, CPT codes 38220 and 38221 are assigned to C–APC 5072, and we believe that the service described by new CPT code 38222 is similar to the existing bone marrow aspiration and biopsy codes. Consistent with the statutory requirement under section 1833(t)(9)(A) of the Act, we will reevaluate the APC groupings during the next rulemaking cycle.

After consideration of the public comment we received, we are finalizing our CY 2018 proposals, without modification, for the bone marrow aspiration and biopsy codes, specifically, CPT codes 20939, 38220, 38221, and 38222. Table 30 below lists the final APC and status indicator assignments for CPT codes 20939, 38220, 38221, and 38222 for CY 2018. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 30—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR THE BONE MARROW ASPIRATION AND BIOPSY CODES

HCPCS code	CY 2018 OPPS/ASC proposed rule placeholder code	Short descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
20939	2093X	Bone marrow aspir bone grfg.	N/A	N/A	N/A	N	N/A	N/A.
38220	N/A	Dx bone marrow aspirations	J1	5072	$1,236.62	J1	5072	Refer to OPPS Addendum B.

TABLE 30—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR THE BONE MARROW ASPIRATION AND BIOPSY CODES—Continued

HCPCS code	CY 2018 OPPS/ASC proposed rule placeholder code	Short descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
38221	N/A	Dx bone marrow biopsies	J1	5072	1,236.62	J1	5072	Refer to OPPS Addendum B.
38222	382X3	Dx bone marrow bx & aspir	N/A	N/A	N/A	J1	5072	Refer to OPPS Addendum B.
G0364		Bone marrow aspirate &biopsy.	N	N/A	N/A	D	N/A	N/A.

8. Discussion of Comment Solicitation in the Proposed Rule on Intraocular Procedure APCs

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33609 through 33610), as part of our CY 2018 comprehensive review of the structure of the APCs and procedure code assignments, we evaluated the intraocular procedure APCs with a particular focus on C–APC 5491 (Level 1 Intraocular Procedures) that contains cataract surgery procedures. We strive to maintain APCs that contain procedures that are relatively homogenous in resource costs and clinical characteristics. While it is impracticable and contrary to the principles of a prospective payment system to assign each procedure to its own APC, thus resulting in a cost-based, fee schedule payment system, we seek to ensure our clinical groupings appropriately group like items and services while maintaining the integrity of a prospective payment system under which bundled, encounter-based payments are essential.

For CY 2018, we considered proposing a new intraocular procedure APC that would further distinguish the resource costs and clinical characteristics between cataract surgery and complex cataract surgery. As listed in Addendum B of the CY 2018 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 66984 (Cataract surgery with IOL 1 stage procedure) and CPT code 66982 (Cataract surgery complex) to C–APC 5491. However, because the 2017 AMA CPT Code manual describes a complex cataract surgery case as ''requiring devices or techniques not generally used in routine cataract surgery (*e.g.,* iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis),'' we stated that we believe it may be more appropriate to assign CPT code 66982 to a C–APC that is separate from the C–APC assignment for CPT code 66984. However, because this potential APC grouping would assign CPT code 66982 to a higher paying C–APC than CPT code 66984, we indicated that we would monitor claims data for changes in the distribution of coding complex cataract surgery and routine cataract surgery if we were to adopt this change. In the proposed rule, we sought public comments from stakeholders, including ophthalmologists, organizations representing ophthalmologists, beneficiaries, hospitals, and all other interested parties on whether we should create a new C–APC that includes complex cataract surgeries identified by CPT code 66982 (along with other intraocular procedures that are similar in resources) in a newly created C–APC that is separate from those identified by CPT code 66984. That is, we are considering whether to establish a new Level 2 Intraocular Procedures C–APC in between existing C–APCs 5491 and 5492.

Comment: Commenters, including several ophthalmologists and organizations representing ophthalmologists, did not support separation of complex cataract surgery identified by CPT code 66982 and simple cataract surgery identified by CPT code 66984 into separate APCs. Commenters recommended that CMS maintain the current assignment of CPT code 66982 and 66984 in the same APC (APC 5491) because the procedures are similar clinically and the modest variation in cost between the two procedures does not warrant reassignment of CPT code 66982 into a higher payment APC. However, commenters supported CMS' intent to monitor the data for these procedures and make future changes, if needed. In addition, one commenter indicated that variations in payment between simple and complex cataract surgery should be reflected in the physician payment rather than the facility fee.

Response: We thank the commenters for providing detailed responses to the comment solicitation on whether to separate simple and complex cataract surgery into separate APCs. Based on the points raised in response to the comment solicitation with respect to the facility resource costs and clinical similarity between simple and complex cataract surgery, it does not appear necessary to separate these procedures into separate APCs.

After consideration of the public comments we received, we are continuing the assignment of simple and complex cataract surgery procedures (described by CPT codes 66984 and 66982, respectively) to the same APC for CY 2018. We appreciate the commenters' support of CMS' continuing efforts to monitor both the cost and utilization of simple and complex cataract surgery to determine if an APC reassignment or other change may be needed in the future.

9. Endovascular APCs (C–APCs 5191 through 5194)

For CY 2018, we proposed to continue the existing four levels of Endovascular C–APCs (C–APCs 5191 through 5194) as displayed in Table 31 below and in Addendum B to the CY 2018 OPPS/ASC proposed rule.

TABLE 31—PROPOSED CY 2018 GEOMETRIC MEAN COST AND PAYMENT FOR ENDOVASCULAR C–APCS

C–APC	CY 2018 geometric mean cost	Proposed CY 2018 OPPS payment
5191—Level 1 Endovascular Procedures	$2,958.89	$2,844

TABLE 31—PROPOSED CY 2018 GEOMETRIC MEAN COST AND PAYMENT FOR ENDOVASCULAR C–APCS—Continued

C–APC	CY 2018 geometric mean cost	Proposed CY 2018 OPPS payment
5192—Level 2 Endovascular Procedures	5,199.87	4,999
5193—Level 3 Endovascular Procedures	10,627.86	10,218
5194—Level 4 Endovascular Procedures	16,197.55	15,572

Comment: Commenters disagreed with the proposal to continue the four levels of the endovascular C–APCs and requested that CMS create more levels within the endovascular C–APCs to improve resource homogeneity within these C–APCs. Specifically, the commenters requested that CMS create a six-level endovascular C–APC family by reassigning endovascular procedures with costs greater than approximately $7,000 up one level, from the current C–APC 5192 (Level 2 Endovascular Procedures) to a new Level 3 Endovascular Procedures C–APC (519X), and reassigning procedures with costs less than approximately $9,000 down one level, from the current C–APC 5193 (Level 3 Endovascular Procedures) to the new requested Level 3 Endovascular Procedures C–APC. Commenters also requested that procedures with costs greater than approximately $12,000 in the current C–APC 5193 be moved up one level to a new Level 5 Endovascular Procedures C–APC (519Y), and those procedures with costs greater than approximately $13,000 to be moved down one level from current C–APC 5194 (Level 4 Endovascular Procedures) to the new requested Level 5 C–APC (519Y). The commenters' requested the C–APC structure and estimated payment amount for each C–APC as listed in Table 32 below.

TABLE 32—CY 2018 STRUCTURE FOR ENDOVASCULAR C–APCS REQUESTED BY COMMENTERS

C–APC	Estimated CY 2018 OPPS payment
5191—Level 1 Endovascular Procedures	$2,845
5192—Level 2 Endovascular Procedures	4,875
519X—New Level 3 Endovascular Procedures	8,042
5193—Current Level 3 Endovascular Procedures/New Level 4 Endovascular Procedures	10,084
519Y—New Level 5 Endovascular Procedures	12,149
5194—Current Level 4 Endovascular Procedures/New Level 6 Endovascular Procedures	15,713

At the annual meeting for the HOP Panel held on August 21, 2017, the HOP Panel recommended that, for CY 2018, CMS examine the number of APCs for endovascular procedures. The HOP Panel also recommended that the appropriate Panel subcommittee review the APCs for endovascular procedures to determine whether more granularity (that is, more APCs) is warranted.

Other commenters opposed a reorganization of the endovascular C–APCs for CY 2018 and expressed concerns regarding changing the number of C–APCs in this family without a chance for the public to comment. These commenters encouraged CMS to consider the impact that adding APCs for the endovascular procedures may have on other procedures in existing APCs and recommended that, if CMS plans to make a change to the endovascular APCs, it include a proposal in the CY 2019 OPPS/ASC proposed rule to allow the opportunity for the public to comment.

Response: We thank the commenters for their input. At this time, we continue to believe that the current C–APC levels for the endovascular C–APC family provide an appropriate distinction between the resource costs at each level and provide clinical homogeneity. We will continue to review this C–APC structure, including consultation with the appropriate HOP Panel subcommittee, to determine if additional granularity is necessary for this C–APC family.

10. Esophagogastroduodenoscopy (EGD) (C–APC 5362)

For CY 2018, as displayed in Table 33 below and in Addendum B to the CY 2018 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 43210 to APC 5331 (Complex GI Procedures), with a proposed payment rate of $4,119.27.

TABLE 33—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODE 43210

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
43210	Esophagogastroduo-denoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed.	J1	5331	$3,940.61	J1	5331	$4,119.27

Comment: One commenter disagreed with the proposed APC assignment for CPT code 43210 and stated that that the proposed payment is inadequate to cover the cost of the procedure. The commenter stated that the device associated with the procedure costs approximately $4,100. The commenter elaborated that because of the inadequate payment for the procedure, providers are reluctant to perform the procedure, and instead are opting to perform the higher paying procedures for the treatment of gastroesophageal reflux disease (GERD). The commenter also stated that, based on the geometric mean cost of $7,013 for CPT code 43210, the code is inappropriately assigned to APC 5331, which has a geometric mean cost of approximately $4,284. To correct the inadequate payment for the procedure, the commenter suggested that CMS either reassign CPT code 43210 to C–APC 5362 (Level 2 Laparoscopy and Related Services), which had a proposed payment rate of $7,214, or establish a new Level 2 Complex GI Procedures APC that contains only the surgical procedures described by the following CPT codes:

- 43210 (Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed);
- 43257 (Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease);
- 43280 (Laparoscopy, surgical, esophagogastric fundoplasty (*e.g.,* nissen, toupet procedures));
- 43281 (Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh);
- 43284 (Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (*i.e.,* magnetic band), including cruroplasty when performed);
- 43770 (Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (*e.g.,* gastric band and subcutaneous port components)); and
- 46762 (Sphincteroplasty, anal, for incontinence, adult; implantation artificial sphincter).

Response: For the second suggestion, we believe the grouping of procedures in the suggested APC may be inappropriate based on lack of clinical homogeneity. Specifically, CPT code 46762 describes a sphincteroplasty procedure, which is unlike that of the other GERD-related procedures in the suggested APC. However, for the first suggestion, based on our analysis of the final rule claims data, we believe that it would be appropriate to reassign CPT code 43210 to C–APC 5362. We note that, for this final rule with comment period, we used claims data with dates of service between January 1, 2016, and December 31, 2016, that were processed on or before June 30, 2017. Our analysis of the final rule claims data revealed a geometric mean cost of approximately $6,759 for CPT code 43210 based on 91 single claims (out of 92 total claims), which is comparable to the geometric mean cost of approximately $7,591 for C–APC 5362. Compared to the geometric mean cost of approximately $4,291 for C–APC 5331, we agree with the commenter that C–APC 5362 is the more appropriate C–APC assignment for CPT code 43210 based on its clinical homogeneity and resource costs.

In summary, after consideration of the public comment we received, we are finalizing our CY 2018 proposal with modification. Specifically, we are reassigning CPT code 43210 from C–APC 5331 to C–APC 5362 for CY 2018. As we do every year under the OPPS, we will reevaluate the cost of the procedure and its APC assignment for next year's OPPS rulemaking. Table 34 below lists the final status indicator and APC assignments for CPT code 43210. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 34—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT CODE 43210

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
43210	Esophagogastroduo-denoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed.	J1	5331	$3,940.61	J1	5362	Refer to OPPS Addendum B.

11. Hemorrhoid Treatment by Thermal Energy (APC 5312)

For CY 2018, as displayed in Table 35 below and in Addendum B to the CY 2018 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 46930 to APC 5311 (Level 1 Lower GI Procedures), with a proposed payment rate of $690.37.

TABLE 35—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODE 46930

HCPCS code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
46930	Destruction of internal hemorrhoid(s) by thermal energy (*e.g.,* infrared coagulation, cautery, radiofrequency).	T	5311	$667.67	T	5311	$690.37

Comment: One commenter requested a reassignment of CPT code 46930 to APC 5312 (Level 2 Lower GI Procedures), which had a CY 2018 proposed payment rate of $907.04. The commenter indicated that review of the geometric mean cost of approximately $879 for CPT code 46930 from the CY 2018 proposed rule claims data is more in line with the geometric mean cost for APC 5312. Specifically, the commenter noted that the geometric mean cost for APC 5312 is approximately $943, which is comparable to the geometric cost of $879 for CPT code 46930, rather than the geometric mean cost of approximately $718 for APC 5311.

Response: For this final rule with comment period, we reviewed the claims data associated with CPT codes 46930. We used claims data for this final rule with comment period with dates of service between January 1, 2016, and December 31, 2016 that were processed on or before June 30, 2017. Our analysis of the final rule claims data revealed that a change in the APC assignment to APC 5312 for CPT code 46930 is appropriate. Specifically, we found a geometric mean cost of approximately $858 for CPT code 46930 based on 363 single claims (out of 970 total claims), which is similar to the geometric mean cost of approximately $936 for APC 5312 rather than the geometric mean cost of approximately $710 for APC 5311. In addition, our analysis of the range of geometric mean costs for the significant procedures within APCs 5311 and 5312 shows that the geometric mean cost for CPT code 46930 is comparable to the costs of procedures assigned to APC 5312. Specifically, the geometric mean costs of the significant procedures assigned to APC 5311 range between approximately $382 (for CPT code 46221) and $750 (for CPT code 45378), while the range for procedures assigned to APC 5312 is between approximately $824 (for CPT code 45341) and $1,579 (for CPT 45390). Consequently, we agree that a reassignment of CPT code 46930 to APC 5312 is more appropriate.

Therefore, after consideration of the public comment we received, we are finalizing our CY 2018 proposal with modification to the APC assignment for CPT code 46930. Specifically, we are reassigning CPT code 46930 from C–APC 5311 to C–APC 5312 for CY 2018. Table 36 below lists the final status indicator and APC assignments for CPT code 49630. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 36—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT CODE 46930

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
46930	Destruction of internal hemorrhoid(s) by thermal energy (*e.g.,* infrared coagulation, cautery, radiofrequency).	T	5311	$667.67	T	5312	Refer to OPPS Addendum B.

12. Ileoscopy Through Stoma With Stent Placement (C–APC 5303)

For CY 2018, as displayed in Table 37 below and in Addendum B to the CY 2018 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 44384 to C–APC 5303 (Level 3 Upper GI Procedures).

TABLE 37—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODE 44384

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	J1	5303	$2,510.70	J1	5303	$2,630.93

Comment: Several commenters opposed the proposed continued assignment of CPT code 44384 to C–APC 5303. The commenters stated that the procedure includes the use of a stent that costs approximately $1,500, and that the resources required to perform the procedure are similar to those other small and large bowel procedures that require stent placement in C–APC 5331 (Complex GI Procedures), which had a CY 2018 proposed payment rate of $4,119.27. The commenters further added that because C–APC 5303 is not a device-dependent designated APC, the continued assignment of CPT code 44384 to C–APC 5303 results in an ASC payment that is below the cost of performing the procedure. Consequently, the commenters urged CMS to revise the APC assignment for CPT code 44384 back to its CY 2016 APC assignment, specifically, C–APC 5331.

Response: We proposed to continue the APC assignment for CPT code 44384 based on claims data used for the CY 2018 OPPS/ASC proposed rule. We note that the proposed rule data was based on claims data submitted between January 1, 2016, and December 31, 2016, that were processed on or before December 31, 2016. For CPT code 44384, our analysis of the claims data revealed a geometric mean cost of approximately $2,404 for the CPT code based on 25 single claims (out of 26 total claims), which is similar to the geometric mean cost of approximately $2,736 for C–APC 5303 rather than the geometric mean cost of approximately $4,284 for C–APC 5331. Consequently, we proposed to continue the APC assignment for CPT code 44384 to C–APC 5303 for CY 2018.

For this final rule with comment period, we again examined updated claims data associated with CPT code 44384. We note that for this final rule with comment period we used claims data with dates of service between January 1, 2016, and December 31, 2016, that were processed on or before June 30, 2017. Our examination of the final rule claims data revealed a similar pattern for CPT code 44384. Specifically, we found a geometric mean cost of approximately $2,492 for CPT code 44384 based on 32 single claims (out of 33 total claims), which is similar to the geometric mean cost of approximately $2,742 for C–APC 5303 rather than the geometric mean cost of approximately $4,291 for C–APC 5331. Assigning CPT code 43384 to C–APC 5331 would result in an overpayment for the procedure. C–APC 5303 contains several GI-related procedures, which are similar to those procedures described by CPT code 44384, based on clinical homogeneity and resource costs.

In response to the comment related to device-dependent APCs, we note that device-dependent APCs are no longer recognized under the OPPS as of CY 2015 and that, effective January 1, 2017, device-intensive status is assigned at the HCPCS code level, not at the APC level. We note that when we implemented the C–APC policy in CY 2015, we eliminated the device-dependent APC policy and replaced it with the device-intensive policy, effective January 1, 2015. For more information on this change, we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66793 through 66795), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70422), and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79657 through 79659). In addition, we refer readers to section IV.B. of this final rule with comment period for the discussion related to the device-intensive policy under the OPPS. For a discussion of ASC procedures designated as device-intensive, we refer readers to section XII.C.1.c. of this final rule with comment period.

Finally, we remind readers that, as we have stated since the implementation of the OPPS in August 2000, section 1833(t)(9) of the Act requires that we annually review all the items and services within an APC group and revise the APC structures accordingly. Included in this review is the identification of any 2 times rule violations as provided under section 1833(t)(2) of the Act and, to the extent possible, rectification of these violations. We review our claims data every year and determine whether we need to make changes to the current APC assignment for the following year. Although CPT code 44384 was assigned to C–APC 5331 in CY 2016, we revised the assignment to C–APC 5303 for CY 2017 based on the latest claims data.

In summary, after consideration of the public comments we received, we are finalizing our CY 2018 proposal without modification to continue the assignment of CPT code 44384 to C–APC 5303. Table 38 below lists the final status indicator and APC assignments for CY 2018. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 38—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT CODE 44384

CPT code	Long descriptors	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	J1	5303	$2,510.70	J1	5303	Refer to OPPS Addendum B.

13. Laparoscopic Nephrectomy (C–APC 5362)

For CY 2018, as displayed in Table 39 below and in Addendum B to the CY 2018 OPPS/ASC proposed rule, we proposed to reassign CPT code 50543 from C–APC 5377 (Level 7 Urology and Related Services), which had a proposed payment rate of $15,220.83 to C–APC 5362 (Level 2 Laparoscopy and Related Services), which had a proposed payment rate of $7,213.53.

TABLE 39—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODE 50543

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment
50543	Laparoscopy, surgical; partial nephrectomy.	J1	5377	$14,363.61	J1	5362	$7,213.53

Comment: One commenter applauded CMS' proposal to remove CPT code 50543 from C–APC 5377. The commenter indicated that the code was inappropriately placed in C–APC 5377 because the procedure involves no implantable device, which is in contrast to the device-related procedures in C–APC 5377. The commenter believed that the addition of this CPT code to C–APC 5377 for CY 2017 was an error that disrupted the clinical homogeneity of the APC. The commenter suggested that CMS finalize the proposal to reassign CPT code 50543 from C–APC 5377 to APC 5362.

Response: We appreciate the commenter's support. For this final rule with comment period, we again reviewed the updated claims data associated with CPT code 50543 and continue to believe that C–APC 5362 is the more appropriate assignment for the CPT code based on its clinical coherence and resource similarity to the other procedures in the APC. Although our analysis showed a geometric mean cost of approximately $7,591 for C–APC 5362, which is lower than the geometric mean cost of approximately $10,247 for CPT code 50543 based on 1,008 single claims (out of 1,016 total claims), we found that the geometric mean cost for the CPT code falls within the range of costs for significant procedures assigned to C–APC 5362. Specifically, the cost range for procedures assigned to C–APC 5362 is between approximately $5,997 (for CPT code 50593) and $10,247 (for CPT code 50543). Based on the final rule claims data, we believe that CPT code 50543 is more appropriately assigned to C–APC 5362 based on its clinical coherence and resource similarity to the other procedures assigned to C–APC 5362.

Therefore, after consideration of the public comment we received, we are finalizing our proposal, without modification, to reassign CPT code 50543 to C–APC 5362 for CY 2018. As we do every year, we will review our claims data for the procedure for the CY 2019 OPPS rulemaking. Table 40 below lists the final CY 2018 status indicator and APC assignments for CPT code 50543. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 40—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT CODE 50543

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
50543	Laparoscopy, surgical; partial nephrectomy.	J1	5377	$14,363.61	J1	5362	Refer to OPPS Addendum B.

14. Multianalyte Assays With Algorithmic Analyses (MAAA)

For CY 2018, as displayed in Table 41 below and as listed in Addendum B to the CY 2018 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 81490, 81503, 81535, 81536, 81538, and 81539, to status indicator ''Q4'' to indicate that the codes are conditionally packaged. Specifically, as defined in Addendum D1 to the CY 2018 OPPS/ASC proposed rule, an

assignment to status indicator ''Q4'' indicates that payment for the laboratory test is either packaged if billed on the same claim as a HCPCS code assigned to status indicator ''J1'', ''J2'', ''S'', ''T'', ''V'', ''Q1'', ''Q2'', or ''Q3'', or in other circumstances, is paid through the CLFS.

TABLE 41—PROPOSED CY 2018 STATUS INDICATOR (SI) FOR CPT CODES 81490, 81503, 81535, 81536, 81538, AND 81539

CPT code	Long descriptor	CY 2017 OPPS SI	Proposed CY 2018 OPPS SI
81490	Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score.	Q4	Q4
81503	Oncology (ovarian), biochemical assays of five proteins (ca-125, apolipoprotein a1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score.	Q4	Q4
81535	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by dapi stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination.	Q4	Q4
81536	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by dapi stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (list separately in addition to code for primary procedure).	Q4	Q4
81538	Oncology (lung), mass spectrometric 8-protein signature, including amyloid a, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival.	Q4	Q4
81539	Oncology (high-grade prostate cancer), biochemical assay of four proteins (total psa, free psa, intact psa, and human kallikrein-2 [hk2]), utilizing plasma or serum, prognostic algorithm reported as a probability score.	Q4	Q4

Comment: Some commenters requested a revision to the status indicator assignment for the six MAAA codes (CPT codes 81490, 81503, 81535, 81536, 81538, and 81539) from ''Q4'' to ''A'' (Not paid under the OPPS but may be paid under a different Medicare payment system), consistent with the status indicator assignment for the DNA and RNA-based MAAA tests. The commenters stated that these tests are generally not performed in the HOPD setting. Also, the commenters indicated that all of the Category I CPT MAAA codes are already assigned to status indicator ''A'' except for CPT codes 81490, 81503, 81535, 81536, 81538, and 81539, which are protein-based MAAA codes. The commenters asserted that, based on the June 23, 2016 CLFS final rule entitled ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System,'' CMS defined an ADLT under section 1834A(d)(5)(A) of the Act to include DNA, RNA, and protein-based tests, and, as such, the six protein-based MAAA codes should be reassigned to status indicator ''A''.

Response: As we stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79594), we will assign status indicator ''A'' (Separate payment under the CLFS) to ADLTs once a laboratory test is designated as an ADLT under the CLFS. Before a test can be designated as an ADLT, applicants must submit an application for successful designation as an ADLT by CMS. These 6 codes (CPT codes 81490, 81503, 81535, 81536, 81538, and 81539) have not been designated as ADLTs by CMS at this time, and therefore we do not believe they should be reassigned to status indicator ''A''. However, once a code has been designated under the CLFS as an ADLT that meets the criteria of section 1834A(d)(5)(A) of the Act, we will update the OPPS payment file (Addendum B) on a quarterly basis to reflect the appropriate status indicator assignment.

Therefore, after consideration of the public comments, we are finalizing our proposal, without modification, for CPT codes 81490, 81503, 81535, 81536, 81538, and 81539. As stated earlier, we will update the OPPS payment file (Addendum B) to appropriately reflect the status indicator assignment once a CPT code has been designated under the CLFS as an ADLT that meets the criteria of section 1834A(d)(5)(A) of the Act. Table 42 below lists the final status indicator for the CPT codes. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 42—FINAL CY 2018 STATUS INDICATOR (SI) FOR CPT CODES 81490, 81503, 81535, 81536, 81538, AND 81539

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2018 OPPS SI
81490	Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score.	Q4	Q4
81503	Oncology (ovarian), biochemical assays of five proteins (ca-125, apolipoprotein a1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score.	Q4	Q4
81535	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by dapi stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination.	Q4	Q4
81536	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by dapi stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (list separately in addition to code for primary procedure).	Q4	Q4
81538	Oncology (lung), mass spectrometric 8-protein signature, including amyloid a, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival.	Q4	Q4

TABLE 42—FINAL CY 2018 STATUS INDICATOR (SI) FOR CPT CODES 81490, 81503, 81535, 81536, 81538, AND 81539—Continued

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2018 OPPS SI
81539	Oncology (high-grade prostate cancer), biochemical assay of four proteins (total psa, free psa, intact psa, and human kallikrein-2 [hk2]), utilizing plasma or serum, prognostic algorithm reported as a probability score.	Q4	Q4

15. Musculoskeletal APCs (APC 5111 Through 5116)

For CY 2018, we proposed to continue the existing C–APCs for the six levels of musculoskeletal procedures (C–APCs 5111 through 5116), as displayed in Table 43 below and in Addendum B to the CY 2018 OPPS/ASC proposed rule.

TABLE 43—PROPOSED CY 2018 GEOMETRIC MEAN COST AND PAYMENT FOR MUSCULOSKELETAL C–APCS

C–APC	CY 2018 geometric mean cost	Proposed CY 2018 OPPS payment
5111—Level 1 Musculoskeletal Procedures	$222.10	$214
5112—Level 2 Musculoskeletal Procedures	1,311.47	1,261
5113—Level 3 Musculoskeletal Procedures	2,600.94	2,501
5114—Level 4 Musculoskeletal Procedures	5,602.87	5,385
5115—Level 5 Musculoskeletal Procedures	10,310.27	9,913
5116—Level 6 Musculoskeletal Procedures	15,783.57	15,175

Comment: Commenters disagreed with the proposal for six levels of the musculoskeletal C–APCs and requested that CMS create two additional levels within the musculoskeletal C–APCs. The commenters stated concerns about the range of costs of procedures assigned to Level 4, Level 5, and Level 6. The commenters believed that the gap between the musculoskeletal procedure levels and payments is too large and results in APCs that include disparate procedures in terms of clinical complexity and resource use.

Response: At this time, we continue to believe that the proposed C–APC levels for the musculoskeletal procedures C–APC family provide an appropriate distinction between the resource costs at each level and provide clinical homogeneity. We will continue to review this C–APC structure to determine if additional granularity is necessary for this C–APC family.

16. Nasal/Sinus Endscopy Procedures (C–APC 5155)

For CY 2018, the AMA CPT Editorial Panel established several new bundled nasal/sinus endoscopy CPT codes. Table 44 below lists the complete descriptors for the new CPT codes. These codes were listed in Addendum B and Addendum O to the CY 2018 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site). Addendum B listed the proposed status indicator assignments for the new codes and assigned them to comment indicator ''NP'' (New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code), while Addendum O listed the proposed/placeholder CY 2018 CPT codes and the long descriptors. We note that the CPT code descriptors that appeared in the OPPS Addendum B were short descriptors and did not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors in Addendum O to the proposed rule, specifically under the column labeled ''CY 2018 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code'' so that the public could adequately comment on our proposed APC and status indicator assignments. We also indicated that the final CPT code numbers would be included in this CY 2018 OPPS/ASC final rule with comment period. The final CPT code numbers, along with their corresponding 5-digit placeholder codes, can be found in Table 45 below.

As displayed in Table 44 below and in Addendum B of the CY 2018 OPPS/ASC proposed rule, we proposed to assign CPT code 31241 to status indicator ''C'' to indicate that this is an inpatient only procedure, and to assign CPT codes 31253, 31257, 31259, and 31298 to C–APC 5155 (Level 5 Airway Endoscopy), with a proposed payment rate of $4,628.89.

TABLE 44—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATES FOR THE NEW NASAL/SINUS ENDOSCOPY CPT CODES EFFECTIVE JANUARY 1, 2018

CPT code	CY 2018 OPPS/ASC proposed rule placeholder code	Long descriptor	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
31241	31XX1	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery.	C	N/A	N/A
31253	31XX2	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including frontal sinus exploration, with removal of tissue from frontal sinus, when performed.	J1	5155	$4,628.89
31257	31XX3	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy.	J1	5155	4,628.89
31259	31XX4	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy, with removal of tissue from the sphenoid sinus.	J1	5155	4,628.89
31298	31XX5	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (*e.g.,* balloon dilation).	J1	5155	4,628.89

Comment: Several commenters expressed concern with the APC placement and indicated that assignment to C–APC 5155 in the OPPS would reduce the ASC payment for the procedures by 32 percent. The commenters requested that CMS assign the new bundled codes to a higher paying APC to provide appropriate payment in the ASC setting. Some commenters clarified that, in CY 2017, these bundled procedures were reported under two separate codes that were separately payable. Because of the effect on the ASC payment, the commenters recommended that CMS establish a new APC for multiple (five or more) sinus procedures, reconfigure the airway APCs to better recognize the complexity associated with performing multiple sinus procedures in a single surgery, or create a complexity adjustment for sinus procedures billed with a device or drug HCPCS C-code or J-code.

Response: C–APC 5155 contains several endoscopic sinus procedures, including the single endoscopic sinus surgeries. Based on input from our medical advisors, we believe this APC is the most appropriate assignment for CPT codes 31253, 31257, 31259, and 31298. C–APC 5155, which has a final rule geometric mean cost of approximately $4,861, is currently the highest paying APC within the airway endoscopy APC series. Because CPT codes 31253, 31257, 31259, and 31298 are new codes for CY 2018, we believe that we should assign these codes to C–APC 5155 where similar endoscopic sinus procedures are assigned.

With regards to the comment recommending separate payment for the single endoscopic sinus procedures performed in 2017, because the codes describing single endoscopic sinus surgery are assigned to status indicator ''J1'', HOPDs receive one payment for the multiple surgeries, regardless of the number of endoscopic sinus procedures performed in a day. The status indicator assignment of ''J1'' to C–APC 5155 indicates that the APC is designated as a comprehensive APC (C–APC) under the OPPS. C–APCs provide a single payment for a primary service, and payment for all adjunctive services reported on the same claim is packaged into payment for the primary service. With few exceptions, all other services reported on a hospital outpatient claim in combination with the primary service are considered to be related to the delivery of the primary service and packaged into the single payment for the primary service and, therefore, separate payment is not available. We note that C–APCs do not apply to ASCs; consequently, the procedures would not be packaged. Instead, the procedures would be separately payable in the ASC setting. As we stated in the CY 2017 OPPS/ASC final rule with comment period, we did not implement C–APCs in the ASC payment system, and consequently, procedures paid separately through the ASC payment system are paid based on the standard ASC methodology (81 FR 79738). We refer readers to section II.A.2.b. (Comprehensive APCs) of this final rule with comment period for the discussion on the payment methodology for C–APCs and to section XII. (ASC Payment System) of this final rule with comment period for the discussion on the ASC Payment System. For the history on the establishment of C–APCs under the OPPS, we refer readers to the CY 2014 OPPS/ASC final rule (78 FR 74861–4910).

In summary, after consideration of the public comments we received, we are finalizing our proposal for CPT codes 31241, 31253, 31257, 31259, and 31298 without modification. Consistent with the statutory requirement under section 1833(t)(9)(A) of the Act, we will reevaluate the APC assignment for these codes in the next rulemaking cycle. Table 45 below lists the final status indicator and APC assignments for CPT codes 31241, 31253, 31257, 31259, and 31298 for CY 2018. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 45—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR THE NEW NASAL/SINUS ENDOSCOPY CPT CODES EFFECTIVE JANUARY 1, 2018

CPT code	CY 2018 OPPS/ASC proposed rule placeholder code	Long descriptor	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
31241	31XX1	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery.	C	N/A	Refer to OPPS Addendum B.
31253	31XX2	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including frontal sinus exploration, with removal of tissue from frontal sinus, when performed.	J1	5155	Refer to OPPS Addendum B.
31257	31XX3	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy.	J1	5155	Refer to OPPS Addendum B.
31259	31XX4	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy, with removal of tissue from the sphenoid sinus.	J1	5155	Refer to OPPS Addendum B.
31298	31XX5	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation).	J1	5155	Refer to OPPS Addendum B.

17. Nuclear Medicine Services (APCs 5592 and 5593)

For CY 2018, as illustrated in Table 46 below, we proposed to continue to assign CPT codes 78018 and 78121 to APC 5592 (Level 2 Nuclear Medicine and Related Services) and to also continue to assign CPT codes 78110 and 78111 to APC 5593 (Level 3 Nuclear Medicine and Related Services).

TABLE 46—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODES 78018, 78110, 78111, AND 78121

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment Rate
78018	Thyroid carcinoma metastases imaging; whole body.	S	5592	$429.13	S	5592	$439.56
78110	Plasma volume, radiopharmaceutical volume-dilution technique (separate procedure); single sampling.	S	5593	1,138.94	S	5593	1,163.30
78111	Plasma volume, radiopharmaceutical volume-dilution technique (separate procedure); multiple samplings.	S	5593	1,138.94	S	5593	1,163.30
78121	Red cell volume determination (separate procedure); multiple samplings.	S	5592	429.13	S	5592	439.56

Comment: One commenter stated that CMS proposed to reassign CPT codes 78018, 78110, 78111 and 78121 to new APC groups, and recommended that CMS maintain the CPT codes in the ''new APC groups'' to ensure stability within the coding structure. The commenter added that CMS has moved these codes several times over the years and believed they are currently assigned to appropriate APC groups. This commenter noted that the codes are low volume with high costs, and recommended that CMS defer to the specialty societies for appropriate APC assignment.

Response: For the CY 2017 update, as indicated in the OPPS Addendum B that was released with the CY 2017 OPPS/ASC final rule with comment period, we assigned CPT codes 78018, 78110, 78111 and 78121 to comment indicator ''CH'' to indicate that their APC assignments were revised. However, as displayed in Table 46, we proposed to make no change to the APC assignments for all four codes for the CY 2018 OPPS update. Specifically, we proposed to continue to assign CPT codes 78018, 78110, 78111, and 78121 to the same CY 2017 APCs for CY 2018 based on claims data used for the CY 2018 OPPS/ASC proposed rule. We note that the proposed rule data was based on claims data submitted between January 1, 2016, and December 31, 2016, that were processed on or before December 31, 2016. For CPT code 78018, our examination of the claims data revealed a geometric mean cost of approximately $418 based on 5,604 single claims (out of 6,327 total claims). Because the geometric mean cost of $418 is similar to the geometric mean cost of approximately $457 for APC 5592, we proposed to maintain the assignment of this code to APC 5592. For CPT code 78110, our claims data showed a geometric mean cost of approximately $1,046 based on 12 single claims (out of 14 total claims). We believe that the geometric mean cost of $1,046 for CPT code 78110 is comparable to the geometric mean cost of approximately $1,210 for APC 5593. Consequently, we proposed to maintain the assignment of this code to APC 5593. For CPT code 78111, we had no claims data. However, based on its clinical similarity to CPT code 78110, we proposed to continue to assign the CPT code to APC 5593. For CPT code 78121, our analysis revealed a geometric mean cost of approximately $807 based on 3 single claims (out of 3 total claims). Based on the low volume and because revising the assignment to

APC 5593, which had a proposed geometric mean cost of approximately $1,210 would result in an overpayment for the test, we proposed to continue to assign CPT code 78121 to APC 5592, and to review the claims data for the final rule to determine whether a revision to the APC assignment would be necessary.

For this final rule with comment period, we again analyzed updated claims data associated with the four codes. We note that, for this final rule with comment period, we used claims data with dates of service between January 1, 2016, and December 31, 2016, that were processed on or before June 30, 2017. Our review of the final rule claims data revealed a similar pattern for all four codes. For CPT code 78018, we found a geometric mean cost of approximately $418 based on 6,113 single claims (out of 6,923 total claims), which is similar to the geometric mean cost of approximately $453 for APC 5592. Consequently, we believe that it continues to be appropriate to assign CPT code 78018 to APC 5592. For CPT code 78110, our claims data revealed a geometric mean cost of approximately $1,037 based on 12 single claims (out of 14 total claims), which is similar to the geometric mean cost of approximately $1,202 for APC 5593.

Consequently, we are maintaining CPT code 78110 in APC 5593. For CPT code 78111, we again had no claims data. However, because of its clinical similarity to CPT code 78110, we will maintain the assignment to APC 5593. For CPT code 78121, we found a geometric mean cost of approximately $808 based on 3 single claims (out of 3 total claims). Based on the comment received that the APC assignment is appropriate, we will retain CPT code 78121 in APC 5592, whose geometric mean cost is approximately $453, for CY 2018. In addition, given the low volume for the CPT code, we do not believe that we should reassign CPT code 78121 to APC 5593, whose geometric mean cost is approximately $1,202 for CY 2018. To reassign CPT code 78121 to APC 5593 would result in an overpayment for CPT code 78121.

Further, we remind the commenter, that as we do every year, we review the latest OPPS claims data to set the payment rates for the following year. Section 1833(t)(9) of the Act requires that we annually review all the items and services within an APC group and revise the APC structures accordingly. Included in this review is the identification of any 2 times rule violations as provided under section 1833(t)(2) of the Act and, to the extent possible, rectification of these violations.

With regard to the comment of deferring to specialty societies for appropriate APC placement for designated codes, while we rely on our latest claims data to appropriately set payment rates under the OPPS, we welcome and appreciate comments from all stakeholders on our proposals. We note that every year we publish the OPPS/ASC proposed rules with requests for public comments on the OPPS and ASC payment assignments from interested parties, including hospitals, specialty societies, physicians, nurses, health care technicians, other health care professionals, interested individuals, patients, and any other stakeholders interested on commenting on our proposed payment assignments.

In summary, after consideration of the public comment we received, we are finalizing our CY 2018 proposals, without modification, for CPT codes 78018, 78110, 78111, and 78121. Table 47 below lists the final status indicator and APC assignments for the CPT codes. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 47—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT CODES 78018, 78110, 78111, AND 78121

CPT code	Long descriptors	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
78018	Thyroid carcinoma metastases imaging; whole body.	S	5592	$429.13	S	5592	Refer to OPPS Addendum B.
78110	Plasma volume, radiopharmaceutical volume-dilution technique (separate procedure); single sampling.	S	5593	1,138.94	S	5593	Refer to OPPS Addendum B.
78111	Plasma volume, radiopharmaceutical volume-dilution technique (separate procedure); multiple samplings.	S	5593	1,138.94	S	5593	Refer to OPPS Addendum B.
78121	Red cell volume determination (separate procedure); multiple samplings.	S	5592	429.13	S	5592	Refer to OPPS Addendum B.

18. Percutaneous Transluminal Mechanical Thrombectomy (C–APC 5192)

For CY 2018, as noted in Table 48 below and in Addendum B to the CY 2018 OPPS/ASC proposed rule, we proposed to revise the APC assignment for the percutaneous transluminal mechanical thrombectomy procedures, specifically, CPT codes 37184 and 37187. Specifically, we proposed to reassign CPT codes 37184 and 37187 from APC 5183 (Level 3 Vascular Procedures) to APC 5184 (Level 4 Vascular Procedures), with a proposed payment rate of $4,084.25.

TABLE 48—PROPOSED CY 2018 U (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODES 37184 AND 37187

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
37184	Primary percutaneous transluminal mechanical thrombectomy, noncoronary, non-intracranial, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); initial vessel.	T	5183	$3,924.28	T	5184	$4,084.25
37187	Percutaneous transluminal mechanical thrombectomy, vein(s), including intraprocedural pharmacological thrombolytic injections and fluoroscopic guidance.	T	5183	3,924.28	T	5184	4,084.25

Comment: One commenter requested that CMS revise the proposed APC assignment for CPT codes 37184 and 37187 from APC 5184 to C–APC 5192 based on their clinical and resource homogeneity to the procedures assigned to C–APC 5192 (Level 2 Endovascular Procedures). The commenter indicated that both procedures are clinically similar to other percutaneous transluminal procedures assigned to C–APC 5192, including CPT code 36904 (Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s)), which CMS proposed to assign to C–APC 5192 for CY 2018, with a proposed payment of $4,999.36. This commenter added that the geometric mean costs associated with the procedures described by CPT codes 37184 and 37187 are similar to the geometric mean costs of other procedures currently assigned to C–APC 5192.

Response: For this final rule with comment period, we reviewed the updated CY 2016 claims data associated with CPT codes 37184 and 37187. We note that, for this final rule with comment period, we used claims data with dates of service between January 1, 2016, and December 31, 2016, that were processed on or before June 30, 2017. Our analysis of the final rule claims data revealed that a change in the APC assignment for CPT codes 37184 and 37187 to C–APC 5192 (rather than proposed APC 5184) is appropriate. Specifically, we found a geometric mean cost of approximately $8,459 for CPT code 37184 based on 149 single claims (out of 150 total claims), and a geometric mean cost of approximately $6,343 for CPT code 37187 based on 188 single claims (out of 190 total claims). We believe that the geometric mean costs for CPT codes 37184 and 37187 are more similar to the geometric mean costs of other procedures assigned to C–APC 5192, whose geometric mean cost is approximately $5,082, rather than the geometric mean costs of procedures assigned to APC 5184, whose geometric mean cost is approximately $4,262. We note that we also considered whether we should reassign CPT codes 37184 and 37187 to C–APC 5193 (Level 3 Endovascular Procedures), which has a geometric mean cost of approximately $10,504. However, based on our review, we believe that C–APC 5192 is more appropriate. Therefore, based on their clinical homogeneity and resource costs in relation to the other procedures assigned to C–APC 5192, we agree with the commenter that C–APC 5192 is the most appropriate APC assignment for CPT codes 37184 and 37187.

After consideration of the public comment we received, we are finalizing our CY 2018 proposal, with modification, for CPT codes 37184 and 37187. Specifically, we are reassigning CPT codes 37184 and 37187 from APC 5183 to C–APC 5192 for CY 2018. As we do every year under the OPPS, we will reevaluate the cost of CPT codes 37184, and 37187 and their APC assignment for next year's OPPS update. Table 49 below lists the final status indicator and APC assignments for both CPT codes. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 49—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT CODES 37184 AND 37187

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
37184	Primary percutaneous transluminal mechanical thrombectomy, noncoronary, non-intracranial, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); initial vessel.	T	5183	$3,924.28	J1	5192	Refer to OPPS Addendum B.
37187	Percutaneous transluminal mechanical thrombectomy, vein(s), including intraprocedural pharmacological thrombolytic injections and fluoroscopic guidance.	T	5183	3,924.28	J1	5192	Refer to OPPS Addendum B.

19. Peripherally Inserted Central Venous Catheter (PICC) (APC 5182)

For CY 2018, as noted in Table 50 below, we proposed to reassign CPT code 36569 from APC 5181 (Level 1 Vascular Procedures) to APC 5182 (Level 2 Vascular Procedures), with a proposed payment rate of $945.33.

TABLE 50—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODE 36569

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
36569	Insertion of peripherally inserted central venous catheter (picc), without subcutaneous port or pump; age 5 years or older.	T	5181	$684.13	T	5182	$945.33

We proposed to revise the APC assignment for CPT code 36569 based on claims data used for the CY 2018 OPPS/ASC proposed rule. We note that the proposed rule data was based on claims data submitted between January 1, 2016, and December 31, 2016, that were processed on or before December 31, 2016. Our analysis of the proposed rule claims data revealed a geometric mean cost of approximately $934 for CPT code 36569 based on 29,514 single claims (out of 52,035 total claims). Our analysis further revealed a geometric mean cost of approximately $983 for APC 5182 and $610 for APC 5181. Based on the geometric mean costs of APCs 5181 and 5182, we believed it was necessary to revise the APC assignment for CPT code 36569 from APC 5181 to APC 5182 to pay appropriately for the procedure. Consequently, we proposed to revise the APC assignment for CPT code 36569, whose geometric mean cost of approximately $934 is comparable to the geometric mean cost of approximately $983 for APC 5182.

For this final rule with comment period, we again reviewed the updated claims data associated with CPT code 36569. We note that, for this final rule with comment period, we used claims data with dates of service between January 1, 2016, and December 31, 2016, that were processed on or before June 30, 2017. Our analysis of the final rule claims data revealed a similar pattern for CPT code 36569. Specifically, we found a geometric mean cost of approximately $929 for CPT code 36569 based on 31,559 single claims (out of 56,891 total claims). We also found the geometric mean cost of approximately $982 for APC 5182 to be similar to the geometric mean cost of CPT code 36569 compared to the geometric mean cost of approximately $612 for APC 5181.

Comment: One commenter supported the proposed APC reassignment for CPT code 36569 and stated that APC 5182 more appropriately reflects the resources to perform the procedure.

Response: We appreciate the commenter's support. Based on our latest analysis of the final rule claims data, we are finalizing our proposal to reassign CPT code 36569 from APC 5181 to APC 5182.

In summary, after consideration of the public comment we received, we are finalizing our CY 2018 proposal, without modification, to reassign CPT code 36569 to APC 5182. Table 51 below lists the final status indicator and APC assignments for CPT code 36569 for CY 2018. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 51—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT CODE 36569

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
36569	Insertion of peripherally inserted central venous catheter (picc), without subcutaneous port or pump; age 5 years or older.	T	5181	$684.13	T	5182	Refer to OPPS Addendum B.

20. Pulmonary Rehabilitation Services (APCs 5732 and 5733) and Cardiac Rehabilitation Services (APC 5771)

For CY 2018, as displayed in Table 52 below, and as listed in Addendum B of the CY 2018 OPPS/ASC proposed rule, we did not propose to make any change to the APC assignments for the pulmonary rehabilitation services and cardiac rehabilitation services codes. Currently, there are four HCPCS codes that describe pulmonary rehabilitation services, specifically, HCPCS codes G0237, G0238, G0239, and G0424. For CY 2018, we proposed to continue to assign HCPCS codes G0237, G0238, and G0239 to APC 5732 (Level 2 Minor Procedures) and to continue to assign HCPCS code G0424 to APC 5733 (Level 3 Minor Procedures) for CY 2018. In addition, there are currently four HCPCS codes that describe the cardiac rehabilitation services, specifically, HCPCS codes 93797, 93798, G0422, and G0423. For CY 2018, we proposed to continue to assign the cardiac rehabilitation services codes to APC 5771 (Cardiac Rehabilitation) for CY 2018.

TABLE 52—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE PULMONARY REHABILITATION SERVICES AND CARDIAC REHABILITATION SERVICES HCPCS CODES

HCPCS code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
Pulmonary Rehabilitation Services							
G0237	Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring).	S	5732	$28.38	S	5732	$29.65
G0238	Therapeutic procedures to improve respiratory function, other than described by g0237, one on one, face to face, per 15 minutes (includes monitoring).	S	5732	28.38	S	5732	29.65
G0239	Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring).	S	5732	28.38	S	5732	29.65
G0424	Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day.	S	5733	54.55	S	5733	53.22
Cardiac Rehabilitation Services							
93797	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ecg monitoring (per session).	S	5771	$110.22	S	5771	$113.71
93798	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ecg monitoring (per session).	S	5771	110.22	S	5771	113.71
G0422	Intensive cardiac rehabilitation; with or without continuous ecg monitoring with exercise, per session.	S	5771	110.22	S	5771	113.71
G0423	Intensive cardiac rehabilitation; with or without continuous ecg monitoring; without exercise, per session.	S	5771	110.22	S	5771	113.71

Comment: Several commenters expressed concern that the payment rates for the pulmonary rehabilitation services are significantly less than those for the cardiac rehabilitation services. The commenters stated that, despite the legislative and clinical similarity between both services, CMS has taken different approaches to implementing the services, with pulmonary rehabilitation services paid less than cardiac rehabilitation services. One commenter indicated that, since 2010, the code describing pulmonary rehabilitation services has had three different status indicator assignments and payment volatility. This commenter recommended that CMS reassign the pulmonary rehabilitation HCPCS code G0464 from APC 5733 to the cardiac rehabilitation APC group, specifically, APC 5771. Another commenter recommended that CMS revisit its approach to payment for pulmonary rehabilitation services to improve access to care. One commenter recommended that both types of services be placed in one composite APC under the OPPS.

Response: The payment rates for both the pulmonary and cardiac rehabilitation services are based on claims data that are analyzed each year. As we do every year, we review the latest OPPS claims data to set the payment rates for the following year. We note that section 1833(t)(9) of the Act requires that we annually review all the items and services within an APC group and revise the APC structures accordingly. Included in this review is the identification of any 2 times rule violations as provided under section 1833(t)(2) of the Act and, to the extent possible, rectification of these violations.

For the proposed rule, we based the proposed payment rates on claims data submitted between January 1, 2016, and December 31, 2016, that were processed on or before December 31, 2016. Based on our analysis, we found the costs for both types of services to be significantly different.

For the pulmonary rehabilitation services, our analysis revealed a geometric mean cost of approximately $26 for HCPCS code G0237 (based on 19,925 single claims), $22 for HCPCS code G0238 (based on 17,361 single claims), and $33 for HCPCS code G0239 (based on 168,295 single claims). We note that the range of costs (between $26 and $33) for HCPCS codes G0237, G0238, and G0239 are similar to the geometric mean cost of approximately $31 for APC 5732. Consequently, we proposed to continue to assign all three pulmonary rehabilitation services HCPCS codes to APC 5732 for CY 2018. In addition, we found a geometric mean cost of approximately $45 for HCPCS code G0424 (based on 468,571 single claims) that is comparable to the geometric mean cost of approximately $55 for APC 5733. Therefore, we proposed to continue to assign HCPCS code G0424 to APC 5733.

For the cardiac rehabilitation services, our analysis revealed a geometric mean cost of approximately $101 for HCPCS code 93797 (based on 129,124 single claims), $118 for HCPCS code 93798 (based on 2,698,534 single claims), $212 for HCPCS code G0422 (based on 38,094 single claims), and $174 for HCPCS code G0423 (based on 18,001 single claims). Because the range of costs (between $101 and $212) for the cardiac rehabilitation services are comparable to the geometric mean cost of approximately $118 for APC 5771, we proposed to continue to assign the cardiac rehabilitation HCPCS codes to APC 5771 for CY 2018.

For this final rule with comment period, we again analyzed the updated claims data associated with the pulmonary and cardiac rehabilitation services. We note that, for this final rule with comment period, we used claims data with dates of service between January 1, 2016, and December 31, 2016, that were processed on or before June 30, 2017. Similar to our proposed rule findings, we found the costs to be different for both services.

For the pulmonary rehabilitation services, our final rule claims data revealed a geometric mean cost of approximately $25 for HCPCS code G0237 (based on 22,097 single claims), $22 for HCPCS code G0238 (based on 18,900 single claims), and $33 for HCPCS code G0239 (based on 187,134 single claims). Based on the range of costs (between $22 and $33), we believe that HCPCS codes G0237, G0238, and G0239 are appropriately assigned to APC 5732, whose geometric mean cost is approximately $32. Similarly, we believe that the geometric mean cost of approximately $44 (based on 514,478 single claims) for HCPCS code G0424 is comparable to the geometric mean costs of those services assigned to APC 5733, whose geometric mean cost is approximately $56 for CY 2018.

For the cardiac rehabilitation services, our final rule claims data revealed a geometric mean cost of approximately $224 for HCPCS code G0422 (based on 44,754 single claims), $186 for HCPCS code G0423 (based on 22,188 single claims), $101 for HCPCS code 93797 (based on 143,507 single claims), and $116 for HCPCS code 93798 (based on 2,991,759 single claims). Based on the costs for the cardiac rehabilitation HCPCS codes (between $101 to $224), we believe that the geometric mean cost of approximately $117 for APC 5771 appropriately reflects the resources in providing cardiac rehabilitation services.

In addition, while the commenters believed that pulmonary and cardiac rehabilitation services are similar, our analysis of the available OPPS data reveals that their costs are significantly different. Consequently, we do not agree that we should assign both services to one APC, or even assign the pulmonary rehabilitation HCPCS code G0424 to the cardiac rehabilitation services group (APC 5771). We note that the commenters did not provide data to suggest that the hospital reported costs in our data are incorrect or that the resources (costs) incurred to furnish these two types of services are equal. Accordingly, we have no reason to believe that the data reported to us by hospitals are incorrect.

Moreover, we do not agree that we should create a composite APC for the pulmonary and cardiac rehabilitation services. Composite APCs provide a single payment for groups of services that are typically performed together during a single clinical encounter that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. Establishing a composite APC for these services would not be appropriate because pulmonary and cardiac rehabilitation services are generally not performed on the same day. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for a full discussion of the development of the composite APC methodology (72 FR 66611 through 66614 and 66650 through 66652) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) for more recent background.

Comment: Some commenters stated that, despite evidence that pulmonary rehabilitation is a valuable service, few patients with chronic obstructive pulmonary disease (COPD) are able to access this treatment. The commenters further indicated that a study of Medicare beneficiaries revealed that only 3.7 percent of COPD patients received pulmonary rehabilitation in 2012, and believe this number may be higher for non-Medicare beneficiaries. The commenters noted that payment for pulmonary rehabilitation is lower than cardiac rehabilitation (a similar service) in the Medicare program, and believed

this difference is based on idiosyncratic hospital billing and OPPS rules, not based on rational policy or evidence. Specifically, the commenter indicated that, for CY 2017, payment for 1 hour of pulmonary rehabilitation is $54.55 under the OPPS. These commenters suggested that the payment discrepancy between cardiac services and pulmonary rehabilitation services may be a contributing factor to inadequate access of the pulmonary rehabilitation services.

Response: As stated in section III.B. of this final rule with comment period, payments for OPPS services and procedures are based on our analysis of the latest claims data. Under the OPPS, we pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. Under the Medicare program, we pay separately for both cardiac and pulmonary rehabilitation services. We have not found evidence that there is an access to care issue for pulmonary rehabilitation services compared to cardiac rehabilitation services. We note that there are a variety of treatment options for patients with COPD and pulmonary rehabilitation remains a covered service for those beneficiaries for whom physicians order this service. We note that, under the Medicare program, when the service is provided in the hospital outpatient setting, we make two payments, one to the hospital outpatient department under the OPPS and another for the professional services under the MPFS.

In addition, as illustrated in Table 52–1 below, the number of services paid by Medicare for both cardiac rehabilitation and pulmonary rehabilitation has grown in the last several years. For the CY 2018 OPPS update, our claims data reveal over 514,000 single claims for pulmonary rehabilitation services as described by HCPCS code G0424 alone. Accordingly, we do not believe that beneficiary access to pulmonary rehabilitation services is inadequate. Details pertaining to the volume of these services furnished in the physician office setting can be derived from the CY 2018 MPFS final rule and associated public use files.

TABLE 52–1—OPPS CLAIMS DATA FOR THE PULMONARY AND CARDIAC (INCLUDING INTENSIVE CARDIAC) REHABILITATION HCPCS CODES FOR THE CY 2014 THROUGH CY 2018 OPPS UPDATES

HCPCS code	Short descriptor	2014 OPPS single claims data	2015 OPPS single claims data	2016 OPPS single claims data	2017 OPPS single claims data	2018 OPPS single claims data
Cardiac Rehabilitation Services						
93797	Cardiac rehab	87,689	94,769	109,420	120,821	143,507
93798	Cardiac rehab/monitor	2,428,984	2,481,175	2,581,446	2,761,806	2,991,759
G0422	Intens cardiac rehab w/exerc	12,060	12,043	17,646	30,165	44,754
G0423	Intens cardiac rehab no exer	703	1,325	6,654	11,979	22,188
Pulmonary Rehabilitation Services						
G0237	Therapeutic procd strg endur	15,337	43,591	47,046	19,098	22,097
G0238	Oth resp proc, indiv	14,437	22,736	23,960	18,482	18,900
G0239	Oth resp proc, group	132,475	111,755	127,425	165,799	187,134
G0424	Pulmonary rehab w exer	457,226	459,572	454,121	443,777	514,478

In summary, after consideration of the public comments we received and after our analysis of the updated claims data for this final rule with comment period, we believe that the current APC assignments for the pulmonary and cardiac rehabilitation services appropriately reflects their clinical coherence and resource costs. Consequently, we are finalizing our proposal to continue the current APC assignment of the pulmonary and cardiac rehabilitation HCPCS codes, without modification, for CY 2018. As we do every year, we will review our claims data for these services for the CY 2019 OPPS rulemaking. Table 53 below lists the final status indicator and APC assignments for the codes for pulmonary and cardiac rehabilitation services. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 53—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR THE PULMONARY REHABILITATION SERVICES AND CARDIAC REHABILITATION SERVICES

HCPCS code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
Pulmonary Rehabilitation Services							
G0237	Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring).	S	5732	$28.38	S	5732	Refer to OPPS Addendum B.

TABLE 53—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR THE PULMONARY REHABILITATION SERVICES AND CARDIAC REHABILITATION SERVICES—Continued

HCPCS code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
G0238	Therapeutic procedures to improve respiratory function, other than described by g0237, one on one, face to face, per 15 minutes (includes monitoring).	S	5732	28.38	S	5732	Refer to OPPS Addendum B.
G0239	Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring).	S	5732	28.38	S	5732	Refer to OPPS Addendum B.
G0424	Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day.	S	5733	54.55	S	5733	Refer to OPPS Addendum B.
	Cardiac Rehabilitation Services						
93797	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ecg monitoring (per session).	S	5771	$110.22	S	5771	Refer to OPPS Addendum B.
93798	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ecg monitoring (per session).	S	5771	110.22	S	5771	Refer to OPPS Addendum B.
G0422	Intensive cardiac rehabilitation; with or without continuous ecg monitoring with exercise, per session.	S	5771	110.22	S	5771	Refer to OPPS Addendum B.
G0423	Intensive cardiac rehabilitation; with or without continuous ecg monitoring; without exercise, per session.	S	5771	110.22	S	5771	Refer to OPPS Addendum B.

21. Radiology and Imaging Procedures and Services

a. Imaging APCs

Section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually, and revise the APC group assignments, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. In addition, section 1833(t)(2)(G) of the Act requires the Secretary to create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those procedures that do not utilize contrast agents.

In CY 2016, as a part of our comprehensive review of the structure of the APCs and procedure code assignments, we restructured the APCs that contain imaging services (80 FR 70392). The purpose of this restructuring was to more appropriately reflect the resource costs and clinical characteristics of the services classified within the imaging APCs. The restructuring of the imaging APCs resulted in broader groupings that removed the excessive granularity of grouping imaging services according to organ or physiologic system, which did not necessarily reflect either significant differences in resources or how these services are delivered in the hospital outpatient setting. In CY 2017, in response to public comments on the CY 2017 OPPS/ASC proposed rule, we further consolidated the imaging APCs from 17 APCs in CY 2016 to 7 APCs in CY 2017 (81 FR 79633). These included four imaging APCs without contrast and three imaging APCs with contrast.

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33608), for CY 2018, we reviewed the services assigned to the imaging without contrast APCs and imaging with contrast APCs. Specifically, we evaluated the resource costs and clinical coherence of the procedures associated with the four levels of imaging without contrast APCs and the three levels of imaging with contrast APCs, as well as identified and corrected any 2 times rule violations as discussed in section III.B.2. of the CY 2018 OPPS/ASC proposed rule. In addition, we reviewed and considered stakeholder recommendations to make additional refinements to the structure of the APC groupings of the imaging procedures classified within the imaging APCs that would maintain clinical homogeneity while more appropriately addressing resource cost fluctuation and volatility. As a result of our analysis and review of the claims data used for CY 2018 ratesetting, we stated in the proposed rule that we believed a Level 5 Imaging without Contrast APC was needed to more appropriately group certain imaging services with higher resource costs. Specifically, we stated our belief that

the data supported splitting the current (CY 2017) Level 4 Imaging without Contrast APC into two APCs such that the Level 4 Imaging without Contrast APC would include high frequency, low-cost services and the proposed Level 5 Imaging without Contrast APC would include low frequency high-cost services. Therefore, for CY 2018, we proposed to add a fifth level within the Imaging without Contrast APCs. In Table 19 of the proposed rule, we listed the CY 2017 imaging APCs, and in Table 20 of the proposed rule, we listed the proposed CY 2018 imaging APCs with the addition of a fifth level within the Imaging without Contrast APCs. The specific APC assignments for each service grouping were listed in Addendum B to the proposed rule, which is available via the Internet on the CMS Web site. We stated that this proposal would increase the imaging APCs from 7 APCs in CY 2017 to 8 in CY 2018. The specific APC assignments for each imaging service HCPCS code were listed in Addendum B to the proposed rule, which is available via the Internet on the CMS Web site. We noted that some of the imaging procedures are assigned to APCs that are not listed in the tables (for example, the vascular procedures APCs). Also, the nuclear medicine services APCs were not included in this proposal. These imaging services were not included in this proposal because we did not propose changes to their APC structure.

We invited public comments on our proposal to add a Level 5 Imaging without Contrast APC in CY 2018.

Comment: Commenters generally disagreed with CMS' proposal to add a fifth level within the Imaging without Contrast APC series. These commenters represented various imaging specialty societies and individual practitioners who utilize various imaging modalities. Many of the commenters opposed adding a fifth level because of the proposed resultant reduction in payment to several vascular ultrasound procedures. The commenters urged CMS to not finalize the proposal because it would destabilize and drastically decrease payments for certain imaging services compared to CY 2017 rates. The commenters noted that the proposed rate for certain imaging services would cause certain providers to no longer be able to furnish these services, thereby impeding access to these important services for Medicare beneficiaries. However, some commenters recommended various alternative HCPCS code placements within the Imaging without Contrast APC series if CMS finalized its proposal to add a fifth level. Some of these same commenters suggested that maintaining the CY 2017 APC groupings and payment rates, to the extent possible, would address their concerns.

Response: We appreciate these comments and recommendations on how to structure and assign HCPCS codes to the Imaging without Contrast APC series. We analyzed the various alternative suggestions for the various recommended HCPCS code placements, including maintaining the CY 2017 APC groupings. After consideration of the public comments and suggestions we received, we are not finalizing our proposal to add a fifth level to the Imaging without Contrast APC series. Instead, we are maintaining the CY 2017 APC structure of four levels of Imaging Without Contrast APCs and making minor reassignments to the HCPCS codes within this series to resolve or mitigate any violations of the 2 times rule or both. We understand the importance of payment stability for providers and believe that continuation of the four levels of Imaging without Contrast APCs would minimize fluctuation in payment rates from CY 2017 to CY 2018. As displayed in the ''2 Times Rule'' for this final rule with comment period, which is available via the Internet on the CMS Web site, the APC geometric mean costs for APCs 5521 through 5524 are consistent with the CY 2017 APC geometric mean costs for the same APCs, indicating the cost-based relative weights that are used to calculate payment are stable.

Comment: A few commenters objected to the proposed exception to the violation of the 2 times rule for APC 5573 (Level 3 Imaging With Contrast) and recommended alternative approaches to resolving the violation, such as the creation of a Level 4 Imaging With Contrast or maintaining the CY 2017 APC groupings. Commenters stated that the proposed reassignment of nine high-volume contrast magnetic resonance imaging (MRI) procedures from Level 2 (CY 2017 placement) to Level 3 (proposed CY 2018 placement) would result in a significant reduction and underpayment for contrast echocardiography procedures and would significantly lower the payment rate for contrast echocardiography procedures, which has been relatively stable for the past several years, consistent with the procedure costs. These nine high-volume contrast MRI procedures are described by the following CPT codes:

- CPT code 70543 (Magnetic resonance imaging, orbit, face, and/or neck; without contrast material(s) and further sequences);
- CPT code 70553 (Magnetic resonance imaging, brain (including brain stem); without contrast material, followed by contrast material(s) and further sequences);
- CPT code 71552 (Magnetic resonance imaging, chest; without contrast material(s), followed by contrast material(s) and further sequences);
- CPT code 72156 (Magnetic resonance imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; cervical);
- CPT code 72157 (Magnetic resonance imaging spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; thoracic);
- CPT code 72158 (Magnetic resonance imaging spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; lumbar);
- CPT code 72197 (Magnetic resonance imaging pelvis; without contrast material(s), followed by contrast material(s) and further sequences);
- CPT code 73223 (Magnetic resonance imaging, any joint of upper extremity; without contrast material(s), followed by contrast material(s) and further sequences); and
- CPT code 74183 (Magnetic resonance imaging abdomen; without contrast material(s), followed by with contrast material(s) and further sequences).

Response: We were persuaded by the points raised by the commenters and agree that continuation of the CY 2017 groupings is appropriate to maintain payment stability for imaging services assigned to APC 5572 and APC 5573. Although the proposed grouping for APC 5573 achieved clinical similarity, based on analysis of the claims data used for this final rule with comment period, we believe we should take a deliberate approach to maintain consistency in payment assignment by not adopting the proposals to reassign the nine high-volume contrast MRI procedures from APC 5572 to APC 5573 and to allow for an exception for APC 5573 from the 2 times rule. Therefore, we are modifying our proposed grouping for APC 5573 by moving the nine high-volume contrast MRI procedures from Level 3 (Imaging with Contrast) to Level 2 (Imaging with Contrast), which is consistent with their CY 2017 APC assignment. In addition, we are making a few other code reassignments to resolve the 2 times rule violation in APC 5573.

In summary, after consideration of the public comments we received and for the reasons discussed above, we are not finalizing the proposal to create a Level 5 (Imaging without Contrast) APC or the proposal to assign nine high-volume contrast MRI procedures to Level 3 (Imaging with Contrast) for CY 2018. Table 54 below compares the CY 2017 and 2018 APC geometric mean costs for the imaging APCs.

TABLE 54—COMPARISON OF CY 2017 AND CY 2018 GEOMETRIC MEAN COSTS FOR THE IMAGING APCS

APC	APC group title	CY 2017 APC geometric mean cost	CY 2018 APC geometric mean cost
5521	Level 1 Imaging without Contrast	$61.53	$62.08
5522	Level 2 Imaging without Contrast	115.88	118.68
5523	Level 3 Imaging without Contrast	232.21	245.08
5524	Level 4 Imaging without Contrast	462.23	486.38
5571	Level 1 Imaging with Contrast	272.40	252.58
5572	Level 2 Imaging with Contrast	438.42	456.08
5573	Level 3 Imaging with Contrast	675.23	681.45

The specific APC assignments for each imaging procedure grouping are listed in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

b. Non-Ophthalmic Fluorescent Vascular Angiography (APC 5523)

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33609), for the CY 2018 OPPS update, we proposed to reassign HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography) from APC 5523 (Level 3 Imaging without Contrast) to APC 5524 (Level 4 Imaging without Contrast) based on the latest claims data available for the proposed rule. We proposed to maintain the status indicator assignment of ''Q2'' (T-packaged) to indicate that the service is conditionally packaged when performed in conjunction with other procedures on the same day but paid separately when performed as a stand-alone service.

Our claims data used for the proposed rule, which included claims submitted between January 1, 2016, and December 31, 2016, and processed on or before December 31, 2016, showed a geometric mean cost of approximately $236 for HCPCS code C9733 based on 216 single claims (out of 953 total claims), which is closely aligned with the geometric mean cost of approximately $275 for APC 5524. Because HCPCS code C9733 is an imaging service which is similar to the codes assigned to APC 5524, we proposed to reassign HCPCS code C9733 from APC 5523 to APC 5524. We stated that we believe this proposed reassignment would improve the clinical homogeneity of APC 5524 and appropriately align the resource costs of HCPCS code C9733 to the resource costs of those procedures assigned to APC 5524.

As we have stated in previous OPPS/ASC final rules, specifically, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68345 through 68346), the CY 2014 OPPS/ASC final rule with comment period (78 FR 74976 through 74977), and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79632), the service described by HCPCS code C9733 is primarily an intraoperative imaging service that is performed in combination with a number of primary procedures, including facial reconstruction and reanimation, muscle flaps, trauma reconstruction, digital and limb reattachment, and breast reconstruction. Therefore, payment for the service described by HCPCS code C9733 is conditionally packaged under 42 CFR 419.2(b)(14), which contains the policies governing packaging of intraoperative items and services. Consequently, we proposed to maintain the status indicator assignment of ''Q2'' to indicate that the payment for the service will be packaged in the APC payment if billed on the same date of service as a HCPCS code assigned to status indicator ''T'', but in all other circumstances, a separate APC payment for the service will be made. We believe that the OPPS payments, separate or packaged, for surgical procedures with which this service is performed are more than adequate to cover the cost of the service described by HCPCS code C9733 for Medicare beneficiaries in need of this service.

Comment: Several commenters supported the proposed APC reassignment for HCPCS code C9733 to APC 5524. A few commenters also suggested assignment of HCPCS code C9733 in a higher payment APC (compared to the CY 2017 payment rate) that would cover the cost of the service, but did not recommend a specific APC. In addition, commenters requested that CMS change the status indicator assignment from ''Q2'' to a separately payable status indicator ''S''. The commenters noted that status indicator ''Q2'' indicates that payment for the procedure described by HCPCS code C9733 is conditionally packaged when provided in conjunction with other procedures assigned to status indicator ''T,'' which are primarily surgical procedures.

Response: Regarding the status indicator assignment of HCPCS code C9733, we have addressed this comment in prior rules (81 FR 79632). The service described by HCPCS code C9733 is primarily an intraoperative imaging service. Therefore, payment for the service is conditionally packaged under § 419.2(b)(14), which packages intraoperative items and services. When the procedure described by HCPCS code C9733 is not furnished in conjunction with a surgical procedure, the service is paid separately. We believe that the OPPS payments, separate or packaged, for surgical procedures with which this test is performed (for example, breast reconstruction) are more than adequate to cover the cost of the service described by HCPCS code C9733 for Medicare beneficiaries in need of this service. With respect to the APC reassignment for APC 5524, because we are maintaining the CY 2017 APC group assignments for imaging services, we are not finalizing our proposal to reassign HCPCS code C9733 from APC 5523 to APC 5524. Rather, we are maintaining the assignment of the procedure described by HCPCS code C9733 to APC 5523 for CY 2018. Based on our review of the CY 2018 final rule claims data, the procedure described by HCPCS code C9733 has a geometric mean unit cost of approximately $237 and the geometric mean cost of APC 5523 is approximately $245 for CY 2018. Therefore, it is not necessary to reassign the procedure described by HCPCS code C9733 to APC 5524, which has a geometric mean unit cost of about $486. It is more appropriate to maintain the assignment

of the procedure described by HCPCS code C9733 to APC 5523 because of the similarity in clinical characteristics and resource use for this procedure and other imaging procedures assigned to APC 5523.

After consideration of the public comments we received, we are not finalizing our proposal to reassign HCPCS code C9733 from APC 5523 to APC 5524 for CY 2018. Instead, for CY 2018, we are continuing to assign HCPCS code C9733 to APC 5523 and continuing to assign the code to status indicator ''Q2'' to indicate that the service is conditionally packaged. The final CY 2018 OPPS payment rate for HCPCS code C9733 can be found in OPPS Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

22. Sclerotherapy (APC 5054)

For CY 2018, the AMA CPT Editorial Panel established two new codes to describe the injection of a noncompounded foam sclerosant for treatment of incompetent veins. Table 55 below lists the complete descriptors for the new CPT codes. These codes were listed in Addendum B and Addendum O to the CY 2018 OPPS/ASC proposed rule (which are available via the Internet on the CMS Web site). Addendum B listed the proposed status indicator assignments for the new codes and assigned them to comment indicator ''NP'' (New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code), while Addendum O listed the proposed/placeholder CY 2018 CPT codes and the long descriptors. We note that the CPT code descriptors that appeared in Addendum B to the CY 2018 proposed rule were short descriptors and did not accurately describe the complete procedure, service, or item described of the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors in Addendum O to the proposed rule, specifically under the column labeled ''CY 2018 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code'' so that the public could adequately comment on our proposed APC and status indicator assignments. We also indicated that the final CPT code numbers would be included in this CY 2018 OPPS/ASC final rule with comment period. The final CPT code numbers, along with their corresponding 5-digit placeholder codes, can be found in Table 55 below.

As displayed in Table 55 below and in Addendum B of the CY 2018 OPPS/ASC proposed rule, we proposed to assign CPT codes 36465 and 36466 to APC 5053 (Level 3 Skin Procedures), with a proposed payment rate of $468.82.

TABLE 55—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATES FOR CPT CODES 36465 AND 36466

CPT code	CY 2018 OPPS/ASC proposed rule placeholder code	Long descriptor	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
36465	364X5	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (*e.g.,* great saphenous vein, accessory saphenous vein).	T	5053	$468.82
36466	364X6	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (*e.g.,* great saphenous vein, accessory saphenous vein), same leg.	T	5053	468.82

Comment: Several commenters opposed the proposed assignment of new CPT codes 36465 and 36466 to APC 5053 and requested the assignment to APC 5183 (Level 3 Vascular Procedures), which had a proposed payment rate of $2,409.72. The commenters stated that CMS inappropriately proposed to assign these codes to APC 5053 based on a comparison to CPT codes 36470 (Injection of sclerosing solution; single vein) and 36471 (Injection of sclerosing solution; multiple veins, same leg). However, the commenters indicated that CPT codes 36465 and 36466 are dissimilar to the procedures assigned to APC 5053, which describe simple skin procedures (for example, debridement, Moh's surgery, and skin lesion destruction). They stated that the procedures assigned to APC 5053 are not comparable to the procedures described by new CPT codes 36465 and 36466 based on complexity, staff type, staff time, and use of ultrasound guidance. The commenters further added that the two procedures are most similar to the endovenous ablative procedures that treat incompetent veins in APC 5183, specifically, the procedures described by the following CPT codes:

- CPT code 36473 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated);
- CPT code 36474 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure));
- CPT code 36475 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated);
- CPT code 36476 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure))
- CPT code 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated); and

• CPT code 36479 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure)).

One commenter stated that the procedures described by CPT codes 36465 and 36466 share similar characteristics and comparable anticipated costs as the procedures assigned to APC 5183, and consequently, requested an assignment to APC 5183 for the two new CPT codes. Another commenter noted that CPT codes 36473, 36475, and 36478 are currently assigned to APC 5183, and requested that CMS also assign new CPT codes 36465 and 36466 to APC 5183. One commenter reported that, in the CY 2018 MPFS proposed rule, CMS proposed a nonfacility payment of $1,605.17 for new CPT code 36465 and $1,678.23 for new CPT code 36466 for CY 2018. This commenter also listed a practice expense input price of $1,054 for the Varithena (foam) used in the procedures.

Response: Because CPT codes 36465 and 36466 are new codes for CY 2018, we have no claims data on which to base our payment rate. However, in the absence of claims data, we reviewed the clinical characteristics of the procedures to determine whether they are similar to existing procedures. After reviewing information from the public commenters and input from our clinical advisors, we believe that new CPT codes 36465 and 36466 are clinically similar to those procedures assigned to APC 5053. However, in light of the commenter's reported supply expense of $1,054 for the Varithena (foam), we believe that an assignment to APC 5054 is necessary. We note that the final CY 2018 geometric mean cost for APC 5054 is approximately $1,567. Therefore, we believe that APC 5054 is a more appropriate APC assignment for the new CPT codes. Consistent with the statutory requirement under section 1833(t)(9)(A) of the Act, we will reevaluate the APC assignment for CPT codes 36465 and 36466 in the next rulemaking cycle.

In summary, after consideration of the public comments we received, we are finalizing our proposal for the APC assignment of the procedures described by new CPT codes 36465 and 36466, with modification. Specifically, we are assigning both codes to APC 5054, instead of proposed APC 5053, for CY 2018. Table 56 below lists the final status indicator and APC assignments for CPT codes 36465 and 36466 for CY 2018. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 56—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT CODES 36465 AND 36466

CPT code	CY 2018 OPPS/ASC proposed rule placeholder code	Long descriptor	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	CY 2018 OPPS payment rate
36465	364X5	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (*e.g.,* great saphenous vein, accessory saphenous vein).	T	5054	Refer to OPPS Addendum B.
36466	364X6	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (*e.g.,* great saphenous vein, accessory saphenous vein), same leg.	T	5054	Refer to OPPS Addendum B.

23. Skin Substitutes (APCs 5053, 5054, and 5055)

For CY 2018, we proposed to assign skin substitute procedures to APCs 5053 through 5055 (Level 3 through 5 Skin Procedures). The cost of the procedures is affected by whether the skin substitute product is low cost or high cost, the surface area of the wound, and the location of the wound.

Comment: Commenters requested that CPT codes for large wounds be assigned to higher paying APCs. One commenter asked that HCPCS code C5277 (Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children) be moved from APC 5053 (Level 3 Skin Procedures) to APC 5054 (Level 4 Skin Procedures) and that CPT code 15277 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children) be moved from APC 5054 (Level 4 Skin Procedures) to APC 5055 (Level 5 Skin Procedures). Another commenter focused on the payment for large venous leg ulcers that are over 100 cm^2. This commenter requested that the skin substitute procedures used to treat large venous leg ulcers and other large wounds be moved to a higher paying APC.

Response: We reviewed the procedures assigned to both APC 5053 and APC 5054 and continue to believe that the procedures described by HCPCS code C5277 and CPT code 15277 are appropriately assigned to APCs 5053 and 5054, respectively. While the geometric mean cost of the procedure described by HCPCS code C5277 ($2,187) is higher than the geometric mean cost of other procedures assigned to APC 5053 ($488), there are fewer than 25 single claims billed for the procedure described by HCPCS code C5277. Therefore, HCPCS code C5277 is not a significant procedure code and does not create a 2 times rule violation in APC 5053. Likewise, while the geometric mean cost of the procedure described by CPT code 15277 ($2,464) is higher than the geometric mean cost for all procedures assigned to APC 5054 ($1,567), there are fewer than 80 single claims billed for the procedure described by CPT code 15277.

Therefore, CPT code 15277 is not a significant procedure and does not create a 2 times violation in APC 5054. Accordingly, we continue to believe that both HCPCS code C5277 and CPT code 15277 are appropriately assigned to APCs 5053 and 5054, respectively. As we do every year, we will evaluate the costs and APC assignment of both of these codes in the next annual rulemaking cycle.

After consideration of the public comments we received, we are finalizing our proposal for CY 2018 for assignment of skin substitute procedures to APCs 5053 through 5055, including the assignment of HCPCS code C5277 to APC 5053 and CPT code 15277 to APC 5054.

24. Subdermal Drug Implants for the Treatment of Opioid Addiction (APC 5735)

In the CY 2018 MPFS proposed rule (82 FR 34011 through 34012), CMS proposed to establish three G-codes to appropriately report the insertion and removal of buprenorphine hydrochloride, formulated as a 4-rod, 80 mg, long-acting subdermal drug implant for the treatment of opioid addiction (82 FR 34011 through 34012). Specifically, we proposed to establish the following HCPCS G-codes:

- Placeholder HCPCS Code GDDD1 (Insertion, non-biodegradable drug delivery implants, 4 or more);
- Placeholder HCPCS Code GDDD2 (Removal, non-biodegradable drug delivery implants, 4 or more); and
- Placeholder HCPCS code GDDD3 (Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more).

We did not make any proposal related to HCPCS codes GDDD1 through GDDD3 in the CY 2018 OPPS/ASC proposed rule because there are existing codes that can be used to report the insertion and removal of buprenorphine hydrochloride, as well as a HCPCS J-code to report use of the buprenorphine hydrochloride drug. Listed below in Table 57 are the specific CPT and HCPCS codes for the buprenorphine hydrochloride subdermal drug and its administration, and the proposed OPPS payment rates for CY 2018.

TABLE 57—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODES 11981, 11982, AND 11983 AND HCPCS CODE J0570

HCPCS code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
11981	Insertion, non-biodegradable drug delivery implant.	Q1	5734	$100.02	Q1	5734	$94.27
11982	Removal, non-biodegradable drug delivery implant.	Q1	5735	263.61	Q1	5735	265.20
11983	Removal with reinsertion, non-biodegradable drug delivery implant.	Q1	5735	263.61	Q1	5735	265.20
J0570	Buprenorphine implant, 74.2 mg	G	9058	* 1,260.59	G	9058	** 1,261.31

* The proposed payment rate of $1,260.59 was based on the April 1, 2017 OPPS update.
** The payment rate of $1,261.31 was based on the October 1, 2017 OPPS update. Payments for the HCPCS drug codes are updated on a quarterly basis, and this payment rate will be updated for the January 2018 OPPS update. Refer to the January 2018 OPPS Addendum B payment file for the payment rate.

Comment: Some commenters requested that the MPFS proposal for establishment of HCPCS G-codes for insertion and removal of buprenorphine hydrochloride also apply to the OPPS and ASC payment systems. In addition, the commenters recommended that CMS assign the HCPCS G-codes to APC 5735 (Level 5 Minor Procedures), which had a proposed payment rate of $265.20, for CY 2018.

Response: We agree with the commenters that the HCPCS G-codes GDDD1 through GDDD3 (now HCPCS codes G0516, G0517, and G0518 in this final rule with comment period) should also be recognized under the OPPS because the service associated with the insertion and removal of buprenorphine hydrochloride can be performed in the hospital outpatient department. However, because these services are conditionally packaged under the OPPS, they will be packaged when performed in the ASC and, therefore, not separately paid. Accordingly, to adequately track and improve data collection and analysis associated with subdermal buprenorphine implants, we are recognizing these HCPCS G-codes in the OPPS.

In summary, after consideration of the public comments we received, we are establishing HCPCS G-codes G0516, G0517, and G0518 under the OPPS, effective January 1, 2018. Table 58 below lists the final status indicator and APC assignments for HCPCS G-codes G0516, G0517, G0518, and HCPCS code J0570 for CY 2018. We remind hospitals that the HCPCS drug code for buprenorphine hydrochloride (HCPCS code J0570) should also be reported when billing for the subdermal administration of the drug. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 58—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR HCPCS CODES G0516, G0517, G0518 AND HCPCS CODE J0570

HCPCS code	CY 2018 MPFS proposed rule placeholder code	Long descriptor	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
G0516	GDDD1	Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants).	Q1	5735	Refer to OPPS Addendum B.
G0517	GDDD2	Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants).	Q1	5735	Refer to OPPS Addendum B.
G0518	GDDD3	Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants).	Q1	5735	Refer to OPPS Addendum B.
J0570	N/A	Buprenorphine implant, 74.2 mg	G	9058	Refer to OPPS Addendum B.

25. Suprachoroidal Delivery of Pharmacologic Agent (APC 5694)

For CY 2018, as noted in Table 59 below, we proposed to continue to assign CPT codes 67028 and 0465T to APC 5694 (Level 4 Drug Administration), with a proposed payment rate of $286.62. We also proposed to continue to assign CPT code 67028 to status indicator ''S'' (Procedure or Service, Not Discounted When Multiple) and to continue to assign CPT code 0465T to status indicator ''T'' (Procedure or Service, Multiple Procedure Reduction Applies).

TABLE 59—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODES 67028 AND 0465T

CPT code	Long descriptors	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
67028	Intravitreal injection of a pharmacologic agent (separate procedure).	S	5694	$279.45	S	5694	$286.62
0465T	Suprachoroidal injection of a pharmacologic agent (does not include supply of medication).	T	5694	279.45	T	5694	286.62

Comment: Some commenters stated that the different status indicator assignment for both CPT codes 67028 and 0465T appears to be an error and contradicts CMS' decision in the CY 2017 OPPS/ASC final rule with comment period where CMS indicated that both procedures are similar from a clinical and resource consideration (81 FR 79617). The commenters reported that the different status indicators suggest that the procedures are not similar. Consequently, the commenters requested the reassignment of CPT code 0465T from status indicator ''T'' to ''S''.

Response: We note that while many HCPCS codes within a given APC may have the same status indicator, having an identical status indicator is not a prerequisite for APC assignment. That is, assignment of a HCPCS code to an APC is based on the resource and clinical similarity of the service described by the HCPCS code, while assignment of a status indicator is based on service-specific characteristics. Status indicator ''T'' is used to denote that the procedure is subject to the multiple procedure reduction under the OPPS, while status indicator ''S'' describes a procedure or service that is not discounted. Within APC 5694, there are four CPT codes that are assigned to status indicator ''T''. These include the following procedures:

- CPT code 0465T (Suprachoroidal injection of a pharmacologic agent (does not include supply of medication));
- CPT code 36593 (Declotting by thrombolytic agent of implanted vascular access device or catheter);
- CPT code 37195 (Thrombolysis, cerebral, by intravenous infusion); and
- CPT code 92977 (Thrombolysis, coronary; by intravenous infusion).

As stated earlier, status indicator ''T'' indicates that the service will be reduced by 50 percent if it is the lower priced service on the same claim with another procedure that is also assigned to a status indicator ''T''. For CPT code 0465T, we expect this reduction to occur when there is a separate procedure performed on the same day as the suprachoroidal injection due to significant efficiencies in administering the pharmacologic agent. If the suprachoroidal injection is performed by itself or with a visit, or with a service or procedure assigned to status indicator ''S'', the multiple procedure reduction will not apply. We remind hospitals that, when reporting CPT code 0465T, the appropriate HCPCS drug code should also be reported on the claim.

Therefore, after consideration of the public comments we received, we are finalizing our CY 2018 proposal, without modification, to continue to assign CPT codes 67028 and 0465T to status indicator ''S'' and ''T'' respectively, and to continue to assign the CPT codes to APC 5694. Table 60 below lists the final status indicator and APC assignments for both codes for CY 2018. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 60—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT CODES 67028 AND 0465T

HCPCS code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
67028	Intravitreal injection of a pharmacologic agent (separate procedure).	S	5694	$279.45	S	5694	Refer to OPPS Addendum B.
0465T	Suprachoroidal injection of a pharmacologic agent (does not include supply of medication).	T	5694	279.45	T	5694	Refer to OPPS Addendum B.

26. Transperineal Placement of Biodegradeable Material (C–APC 5375)

For CY 2018, the AMA CPT Editorial Panel deleted CPT code 0438T and replaced the code with CPT code 55874, effective January 1, 2018. CPT code 0438T was effective July 1, 2016 and will be deleted on December 31, 2017. Prior to July 2016, the transperineal placement of biodegradable material procedure was described by HCPCS code C9743 (Injection/implantation of bulking or spacer material (any type) with or without image guidance (not to be used if a more specific code applies)), which was effective October 1, 2015 and was deleted on June 30, 2016, when it was replaced with CPT code 0438T, effective July 1, 2016.

Table 61 below lists the complete descriptors for the deleted and replacement CPT codes. We note that the deleted and replacement CPT codes were both listed in Addendum B and Addendum O to the CY 2018 OPPS/ASC proposed rule (which are available via the Internet on the CMs Web site). Addendum B listed the proposed status indicator assignment for the replacement code and assigned it to comment indicator ''NP'' (New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code), while Addendum O listed the proposed/placeholder CY 2018 CPT codes and the long descriptors.

TABLE 61—CODING CHANGES FOR CPT CODE 55874

CPT code	CY 2018 OPPS/ASC proposed rule placeholder code	Long descriptor
0438T	N/A	Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance.
55874	55X87	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed.

As listed in Table 63 below and in Addendum B of the CY 2018 OPPS/ASC proposed rule, we proposed to delete CPT code 0438T (status indicator ''D'') and assign its replacement code, CPT code 55874 (placeholder code 55X87), to C–APC 5375 (Level 5 Urology and Related Services) with a proposed payment rate of $3,597.65. As noted in Table 62, the predecessor code 0438T was assigned to C–APC 5374 (Level 4 Urology and Related Services), while this replacement code is proposed to be reassigned to C–APC 5375. We proposed to revise the APC assignment for CPT code 55874 based on claims data used for the CY 2018 OPPS/ASC proposed rule. We note that the proposed rule claims data was based on claims data submitted between January 1, 2016, and December 31, 2016, that were processed on or before December 31, 2016. For the predecessor codes HCPCS codes C9743 and 0438T that were in effect during CY 2016, our analysis of the proposed rule claims data revealed a geometric mean cost of approximately $4,504 based on 157 single claims (out of 159 total claims), which is similar to the geometric mean cost of approximately $3,742 for C–APC 5375 rather than the geometric mean cost of approximately $2,714 for C–APC 5374 or the geometric mean cost of approximately $7,747 for C–APC 5376 (Level 6 Urology and Related Services). Based on its clinical homogeneity and resource similarity to the other procedures assigned to C–APC 5375, we proposed to reassign replacement CPT code 55874 from C–APC 5374 to C–APC 5375 for CY 2018.

TABLE 62—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR CPT CODE 55874

CPT code	CY 2018 OPPS/ASC proposed rule placeholder code	Short descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
0438T		Tprnl plmt biodegrdabl matrl	T	5374	$2,542.56	D	N/A	N/A
55874	55X87	Tprnl plmt biodegrdabl matrl	N/A	N/A	N/A	T	5375	$3,597.65

Comment: One commenter supported the reassignment to C–APC 5375 for CPT code 55874 and urged CMS to finalize the proposal. The commenter further indicated that C–APC 5375 is the appropriate APC assignment for CPT code 55874 based on its clinical and resource coherence to the other procedures assigned to C–APC 5375. While supportive of the assignment to C–APC 5375, this same commenter expressed concern with the payment for the procedure under the ASC payment system. The commenter suggested that CPT code 55874 should be designated as a device-intensive procedure.

Response: We appreciate the commenter's support. For this final rule with comment period, we again reviewed the updated claims data associated with predecessor HCPCS codes C9743 and 0438T. We note that, for this final rule with comment period, we used claims data with dates of service between January 1, 2016, and December 31, 2016, that were processed on or before June 30, 2017. Our analysis of the final rule claims data shows a similar pattern for the predecessor codes. Specifically, we found a geometric mean cost of approximately $4,452 for the predecessor codes based on 157 single claims (out of 160 total claims), which is similar to the geometric mean cost of approximately $3,704 for C–APC 5375. In addition, our analysis of the significant procedures within C–APC 5375 shows that the geometric mean cost of $4,452 for the predecessor codes are similar to the costs of the procedures assigned to C–APC 5375. Specifically, our analysis revealed the range of the significant procedures assigned to C–APC 5375 is between $3,134 (for CPT code 52320) and $5,004 (for CPT code 55875). Consequently, we believe that C–APC 5375 is the most appropriate APC assignment for CPT code 55874.

With regards to the device-intensive designation for CPT code 55874, based on our analysis of the predecessor HCPCS code C9743, this code is not eligible for device-intensive status because it does not meet the criteria of a device offset that is greater than 40 percent. For more information on how codes are designated as device-intensive status, we refer readers to section IV.B. of this final rule with comment period.

In summary, after consideration of the public comments we received and our analysis of the updated claims data for this final rule with comment period, we are finalizing our CY 2018 proposal, without modification, and assigning CPT code 55874 to C–APC 5375. Table 63 below lists the final status indicator and APC assignments for CPT code 55874 for CY 2018. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 63—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT CODE 55874

CPT code	CY 2018 OPPS/ASC proposed rule placeholder code	Short descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
0438T		Tprnl plmt biodegrdabl matrl	T	5374	$2,542.56	D	N/A	N/A.
55874	55X87	Tprnl plmt biodegrdabl matrl	N/A	N/A	N/A	T	5375	Refer to OPPS Addendum B.

27. Transcranial Magnetic Stimulation (TMS) Therapy (APCs 5721 and 5722)

For CY 2018, as listed in Table 64 below, we proposed to continue to assign CPT code 90867 to APC 5722 (Level 2 Diagnostic Tests and Related Services) and to also continue to assign CPT code 90869 to APC 5721 (Level 1 Diagnostic Tests and Related Services). However, we proposed to reassign CPT code 90868 from APC 5722 to APC 5721.

TABLE 64—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE TRANSCRANIAL MAGNETIC STIMULATION (TMS) THERAPY CPT CODES

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
90867	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; initial, including cortical mapping, motor threshold determination, delivery and management.	S	5722	$232.31	S	5722	$242.21
90868	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent delivery and management, per session.	S	5722	232.31	S	5721	129.59
90869	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent motor threshold re-determination with delivery and management.	S	5721	127.10	S	5721	129.59

Comment: Several commenters disagreed with CMS' proposal to reassign CPT code 90868 to APC 5721 and stated that the proposed payment rate does not cover the cost of providing the service. One commenter stated that

transcranial magnetic stimulation (TMS) therapy requires the use of an expensive machine, technicians to assist with the service, staff to work on insurance approvals, and significant time with physicians. Another commenter stated that the proposed payment rate for CPT codes 90868 and 90869 is insufficient, and that the cost of providing the service exceeds the payment rate. Several commenters requested that CMS reconsider and increase the payment rates for CPT codes 90868 and 90869.

Response: We proposed to revise the APC assignment for CPT code 90868 and to continue the APC assignment for CPT code 90869 based on CY 2016 claims data used for the CY 2018 OPPS/ASC proposed rule. We note that the proposed rule data was based on claims data submitted between January 1, 2016, and December 31, 2016, that were processed on or before December 31, 2016. For CPT code 90868, our analysis of the claims data showed a geometric mean cost of approximately $152 for the code based on 6,433 single claims (out of 6,493 total claims), which is similar to the geometric mean cost of approximately $135 for APC 5721 rather than the geometric mean cost of approximately $252 for APC 5722. Consequently, we proposed to revise the APC assignment for CPT code 90868 to APC 5721 rather than continue to assign it to APC 5722. For CPT code 90869, our claims data showed a geometric mean cost of approximately $119 for CPT code 90869 based on 95 single claims (out of 96 total claims), which is similar to the geometric mean cost of approximately $135 for APC 5721. Consequently, we proposed to continue to assign CPT code 90869 to APC 5721.

For this final rule with comment period, we again reviewed the updated claims data associated with CPT codes 90868 and 90869. We note that, for this final rule with comment period, we used claims data with dates of service between January 1, 2016, and December 31, 2016, that were processed on or before June 30, 2017. Our analysis of the final rule claims data revealed a similar pattern for both codes. Specifically, we found a geometric mean cost of approximately $148 for CPT code 90868 based on 7,258 single claims (out of 7,312 total claims), which is similar to the geometric mean cost of approximately $136 for APC 5721, rather than the geometric mean cost of approximately $249 for APC 5722. Our analysis also revealed a geometric mean cost of approximately $125 for CPT code 90869 based on 105 single claims (out of 106 total claims), which is comparable to the geometric mean cost of $136 for APC 5721. Based on our analysis of the final rule claims data, we believe that APC 5721 is the appropriate APC assignment for both CPT codes 90868 and 90869 based on their clinical homogeneity and resource costs to the other procedures in APC 5721.

With regards to the comment that TMS therapy requires significant time with physicians, we remind readers that payments under the OPPS are for services provided by hospital outpatient facilities, not physician services. We note that physician services are paid under the MPFS. Medicare payment rates for physician services can be found on the CMS Physician Fee Schedule Web site, specifically at: *https://www.cms.gov/apps/physician-fee-schedule/overview.aspx*.

In summary, after consideration of the public comments we received, we are finalizing our CY 2018 proposal, without modification, for CPT codes 90867, 90868, and 90869. Table 65 below lists the final status indicator and APC assignments for all three CPT codes. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 65—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR THE TRANSCRANIAL MAGNETIC STIMULATION (TMS) THERAPY CPT CODES

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
90867	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; initial, including cortical mapping, motor threshold determination, delivery and management.	S	5722	$232.31	S	5722	Refer to OPPS Addendum B.
90868	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent delivery and management, per session.	S	5722	232.31	S	5721	Refer to OPPS Addendum B.
90869	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent motor threshold re-determination with delivery and management.	S	5721	127.10	S	5721	Refer to OPPS Addendum B.

28. Transurethral Waterjet Ablation of the Prostate (C–APC 5375)

On June 5, 2017, the Category B Investigational Device Exemption (IDE) study associated with the ''Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue II (WATER)'' met CMS' standards for coverage. According to the National Institutes of Health (NIH) *clinicaltrials.gov* Web site, the estimated completion date of this study is August 2020. Under Medicare, studies with Category A designation are approved for coverage of routine services only, while studies with the Category B designation are approved for coverage of the Category B device and related services, and routine services. We note that the procedure associated with this study is currently described by CPT code 0421T. Based on the recent Medicare coverage of the IDE study, we revised the OPPS status indicator assignment for CPT

code 0421T from ''E1'' (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to ''J1'' (Hospital Part B services paid through a comprehensive APC) and assigned the code to C–APC 5374 (Level 4 Urology and Related Services) to indicate that the procedure would be paid separately under the OPPS. We announced this change through the October 2017 OPPS quarterly update CR (Transmittal 3864, Change Request 10236, dated September 15, 2017), and further stated in this same CR that the payment would be effective on June 5, 2017, which is the date of Medicare's approval for coverage.

In the CY 2018 OPPS/ASC proposed rule, we solicited public comments on the proposed APC and status indicator assignments for the code. Specifically, as listed in Table 66 below, we proposed to continue to assign CPT code 0421T to C–APC 5374 for CY 2018.

TABLE 66—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT FOR CPT CODE 0421T

CPT code	Long descriptor	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed CY 2018 OPPS payment rate
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed).	J1	5374	$2,542.56	J1	5374	$2,609.60

Comment: Several commenters expressed concern over the proposed payment rate for CPT code 0421T and requested a reassignment to either C–APC 5375 (Level 5 Urology and Related Services), which had a proposed payment rate of $3,597.65, or C–APC 5376 (Level 6 Urology and Related Services), which had a proposed payment rate of $7,448.11 for the Aquablation procedure. The commenters stated that the proposed payment rate for C–APC 5374 does not take into account the cost of the device, the overhead costs, and the personnel costs associated with providing the Aquablation procedure. One commenter stated that the Aquablation procedure is dissimilar to the other procedures assigned to C–APC 5374, some of which require the use of reusable equipment. This same commenter reported that the level of complexity in the performing the Aquablation procedure is comparable to those procedures in C–APC 5375 and C–APC 5376. Specifically, as indicated by the commenter, the Aquablation procedure is similar to implanting brachytherapy seeds into the prostate (CPT code 55875, proposed for assignment to C–APC 5375), cryoablation of the prostate (CPT code 55873, proposed for assignment to C–APC 5376), and high intensity focused ultrasound (HIFU) of the prostate (HCPCS code C9747, proposed for assignment to C–APC 5376). Another commenter believed the Aquablation procedure requires more effort than the traditional transurethral resection of the prostate (TURP) procedure (CPT code 52601, proposed for assignment to C–APC 5375) or the laser ablation of the prostate procedure (GreenLight Laser Therapy described by CPT code 52648, proposed for assignment to C–APC 5375), and added that the TURP and Aquablation each require general anesthesia and take approximately 1 hour to perform. Several commenters stated that the complexity of performing the Aquablation procedure is similar to the cryoablation of the prostate and HIFU procedures, of which both were proposed to be assigned to C–APC 5376. Consequently, these same commenters requested that CMS revisit the APC assignment for CPT code 0421T and consider a reassignment to C–APC 5376.

Response: Based on our review of the procedure and input from our clinical advisors, we believe that a reassignment from C–APC 5374 to C–APC 5375 for the Aquablation is appropriate. We note that this procedure is currently in clinical trial with an estimated study completion date of August 2020. We believe that the procedure is clinically similar to other procedures that are currently assigned to C–APC 5375. As we do every year under the OPPS, we will reevaluate the cost of the procedure described by CPT code 0421T and its APC assignment for next year's rulemaking update.

In summary, after consideration of the public comments, we are finalizing our CY 2018 proposal with modification. Specifically, we are revising the APC assignment for CPT code 0421T from proposed C–APC 5374 to C–APC 5375 for CY 2018. Table 67 below lists the final status indicator and APC assignments for CPT code 0421T for CY 2018. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 67—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR CPT U0421T

CPT code	Long descriptors	CY 2017 OPPS SI	CY 2017 OPPS APC	CY 2017 OPPS payment rate	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed).	J1	5374	$2,542.56	J1	5375	Refer to OPPS Addendum B.

29. Transurethral Water Vapor Thermal Therapy of the Prostate (C–APC 5373)

For CY 2018, CMS received a New Technology APC application requesting a new HCPCS code for the Rezūm therapy. The Rezūm procedure is a new treatment, and the Rezūm System associated with this procedure received a 510(k) FDA clearance on August 27, 2015. The procedure utilizes water vapor for the treatment of benign prostatic hypertrophy (BPH). The applicant maintained that there was coding confusion about whether the procedure could be described by existing CPT code 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy). We note that CPT code 53852 is assigned to C–APC 5375 (Level 5 Urology and Related Services), which has a geometric mean cost of approximately $3,704 for CY 2018.

Based on our review of the application, the procedure, and input from our clinical advisors, we agree that CPT code 53852 does not appropriately describe the Rezūm procedure. Consequently, we are establishing HCPCS code C9748 to appropriately describe the procedure. Effective January 1, 2018, HOPDs should report HCPCS code C9748 to report the use of the Rezūm procedure for the treatment of BPH. In addition, based on cost information submitted to CMS in the application, we believe that the procedure should appropriately be assigned to C–APC 5373 (Level 3 Urology and Related Services), which has a geometric mean cost of approximately $1,695. We believe the Rezūm procedure shares similar resource and clinical homogeneity to the other procedures currently assigned to C–APC 5373.

Table 68 below lists the final status indicator and APC assignments for HCPCS code C9748 for CY 2018. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the Internet on the CMS Web site.

TABLE 68—FINAL CY 2018 STATUS INDICATOR (SI) AND APC ASSIGNMENT FOR THE TRANSURETHRAL WATER VAPOR THERMAL THERAPY OF THE PROSTATE

HCPCS code	Long descriptor	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate
C9748	Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy.	J1	5373	Refer to OPPS Addendum B.

We note that HCPCS code C9748 is assigned to comment indicator ''NI'' in Addendum B to this CY 2018 OPPS/ASC final rule with comment period to indicate that we have assigned the code an interim OPPS payment status for CY 2018. We are inviting public comments on the interim status indicator and APC assignments that will be finalized in the CY 2019 OPPS/ASC final rule with comment period.

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

Under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at 42 CFR 419.66(g) provided that this pass-through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79654), in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update. This means that device pass-through status would expire

at the end of a calendar year when at least 2 years of pass-through payments have been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the changes to the device pass-through payment policy. We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. There currently are three device categories eligible for pass-through payment: (1) HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser), which was established effective April 1, 2015; (2) HCPCS code C2613 (Lung biopsy plug with delivery system), which was established effective July 1, 2015; and (3) HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), which was established effective January 1, 2016. The pass-through payment status of the device categories for HCPCS codes C2623, C2613, and C1822 will end on December 31, 2017. We note that our new policy adopted in the CY 2017 OPPS/ASC final rule with comment period to allow for quarterly expiration of pass-through payment status for devices applies to devices approved in CY 2017 and subsequent years. As all the devices in these three device categories were approved prior to CY 2017, we are applying our policy to expire them at the end of the calendar year when at least 2 years of pass-through payments have been made. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33610), we proposed, beginning in CY 2018, to package the costs of each of the devices described by HCPCS codes C2623, C2613, and C1822 into the costs related to the procedure with which each device is reported in the hospital claims data.

Comment: Various stakeholders, including physicians, device manufacturers, and professional societies, opposed the proposal to package the costs of the device described by HCPCS code C2623 into the costs related to the procedure(s) with which the device is reported. The commenters specifically opposed packaging of the cost of the drug-coated balloons into the procedure described by CPT code 37224 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty). These commenters stated concerns that the proposed payment rate for this procedure did not adequately reflect the additional costs of drug-coated balloons over non-drug-coated balloons, which could limit patient access to the technology. Several commenters described the clinical benefits provided by the drug-coated balloon in the treatment of peripheral arterial disease (PAD) and supported the continuation of the pass-through status of the device category for HCPCS code C2623 beyond December 31, 2017. At the August 21, 2017 meeting of the HOP Panel, the HOP Panel made a recommendation that CMS continue to track CPT code 37224 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty) with HCPCS code C2623, and that the appropriate HOP Panel subcommittee review the APCs for endovascular procedures to determine whether more granularity (that is, more APCs) is warranted. One commenter supported the proposal to package the costs of the device described by HCPCS code C2623 into the costs related to the procedure(s) with which the device is reported. The commenter stated that the proposed payment rate provided under the OPPS for procedures using drug-coated balloons was appropriate. This commenter also stated concerns over a lack of scientific evidence of the effectiveness of these devices outside of clinical trials.

Response: As mentioned earlier, under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Our policy for devices approved for pass-through payment status prior to CY 2017 is to propose and finalize the dates for expiration of pass-through payment status for device categories as part of the OPPS annual update. This means that device pass-through payment status would expire at the end of a calendar year when at least 2 years of pass-through payments had been made, regardless of the quarter in which the device was approved for pass-through payment status. According to our established policy (67 FR 66763), after this eligibility period expires, payments for the costs of the device(s) are packaged into payment for the procedures with which they are billed. The device category for HCPCS code C2623 was established effective April 1, 2015, and will have been in effect for a period of at least 2 years, but not more than 3 years, when its eligibility expires on December 31, 2017. Therefore, this category is no longer eligible for pass-through payments. In accordance with our established policy, we are finalizing our proposal to package payment for the costs of the device(s) described by this category into payment for the costs of the procedures with which they are reported. In response to the recommendation of the HOP Panel from the August 21, 2017 meeting, we will continue to track CPT code 37224 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty) with HCPCS code C2623. We will share information on all items and services paid under the OPPS, including endovascular procedures, so that the appropriate HOP Panel subcommittee may review the APCs for endovascular procedures and advise on whether more granularity (that is, more APCs) is warranted.

Comment: Some commenters, including device manufacturers and associations, stated that the geometric mean costs of the procedure described by CPT code 37224 involving a drug-coated balloon were higher than the geometric mean costs of the same angioplasty procedure when a drug-coated balloon was not used and a plain balloon angioplasty catheter was used instead. Specifically, these commenters presented their analysis of Medicare claims data which suggested that when CPT code 37224 is billed with HCPCS code C2623, the geometric mean cost of these claims is $8,483, while the geometric mean cost of claims including CPT code 37224 without HCPCS code C2623 is $6,396. The commenters also noted that the total geometric mean costs for CPT code 37224, regardless of whether HCPCS code C2623 is billed with CPT code 37224, is approximately $7,153. These commenters requested that CMS create a new procedural HCPCS C-code or G-code for hospitals to

use to differentiate procedures described by CPT code 37224 that use drug-coated balloons from procedures described by CPT code 37224 that use plain balloon angioplasty catheters, with a suggested descriptor of ''Revascularization, endovascular, open percutaneous, femoral, popliteal artery(s), unilateral; with transluminal drug-coated balloon angioplasty''.

One commenter also referenced the proposal in the CY 2018 OPPS/ASC proposed rule (82 FR 33579 and 33580) to establish a HCPCS C-code to describe blue light cystoscopy (HCPCS code C9738 (Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure)) and to apply the C–APC complexity adjustment policy when this C-code is billed with specific white light cystoscopy codes. The commenter pointed out that, in the proposed rule, CMS stated that establishment of this C-code was appropriate because CMS believed that blue light cystoscopy is a distinguishable service in comparison to white light cystoscopy alone. CMS further stated that, with the C–APC complexity adjustment, qualifying combinations of the blue light cystoscopy C-code and white light cystoscopy codes are paid at the next higher paying C–APC when billed together on the same claim. The commenter requested that CMS take comparable steps to separately identify and pay for angioplasty procedures involving drug-coated balloons.

Finally, several commenters referenced the HOP Panel's recommendation that CMS examine the number of APCs for endovascular procedures for CY 2018 and requested CMS create two new levels within the Endovascular C–APCs to provide higher payment for angioplasty procedures using a drug-coated balloon.

Response: We believe that procedures with which the drug-coated balloons are used, specifically the procedure described by CPT code 37224, are appropriately described by the existing procedure code and do not believe it is necessary at this time to establish a HCPCS C-code or G-code to distinguish an angioplasty procedure with a drug-coated balloon from an angioplasty procedure without a drug-coated balloon. The OPPS is a prospective payment system that relies on the principles of averaging, with some cases in an APC being more costly than others (and some cases being less costly). Although there is some evidence of higher geometric mean costs when a drug-coated balloon is used for certain angioplasty procedures versus a plain balloon angioplasty catheter, the higher costs of the procedures involving the drug-coated balloon are reflected in the claims data. Our analysis of the final rule claims data revealed a geometric mean cost of approximately $7,029 for CPT code 37224 based on 11,346 single claims (out of 11,437 total claims). CPT code 37224 is assigned to C–APC 5192 (Level 2 Endovascular Procedures), which has a geometric mean cost of approximately $5,081. There is no 2 times violation in this C–APC. We also do not believe a C–APC complexity adjustment would be applicable, based on existing criteria used to assign a complexity adjustment. We do not believe that the example the commenter raised is entirely analogous because the HCPCS C-code that the commenter referenced necessarily involves an additional procedure (blue light cystoscopy) in addition to white light cystoscopy and the administration of the fluorescent imaging agent is required, which adds additional procedure time. In contrast, the use of a drug coated balloon does not involve a separate procedure.

We note that stakeholders who are interested in the establishment of a CPT procedure code to describe angioplasty procedures involving the use of drug-coated balloons may request a new procedure code from the AMA CPT Editorial Panel.

With regard to the request to create additional levels within the Vascular C–APC clinical family, this issue is discussed in greater detail in section III.D. of this final rule with comment period. As we do every year, we will review and evaluate the APC groupings based on the latest available data in the next rulemaking cycle.

Comment: Several commenters requested that HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), otherwise known as the Senza SCS System, receive an additional year of pass-through payment status for CY 2018. Reasons stated by the commenters included: (1) A belief that CMS has the authority under current law to extend pass-through payment status for one more year, for a total of 3 years, and that, although CMS' policy to allow devices with transitional pass-through payment status as close to 3 years as possible was effective for device approvals on or after January 1, 2017, CMS has the authority to grant the third year of pass-through payment status on a case-by-case basis for devices that were granted pass-through payment status prior to CY 2017 based on specific characteristics of the device and procedure with which it is used; (2) the reported costs for devices described by HCPCS code C1822 in CY 2016 were lower than actual cost for the device due to hospital CCR ratios used to calculate device cost instead of implantable device CCRs, which were used for many hospitals to calculate device costs starting in CY 2017; (3) the reported costs for devices described by HCPCS C1822 in CY 2016 were lower than actual costs due to hospital cost reporting errors, billing of HCPCS code C1822 by hospitals that, according to the device manufacturer, had not purchased the device, hospitals not reporting use of the device, and other claims reporting problems; and (4) ending pass-through payment status would reduce access to the Senza SCS System. The commenters stated that the Senza SCS System helps beneficiaries manage chronic pain and reduces opioid usage among beneficiaries with the device.

Response: Historically, a device approved for pass-through payment status under the OPPS had an eligibility period of at least 2 years but no more than 3 years—with the pass-through payment period starting on the date when CMS established a particular transitional category of devices (80 FR 70415) and expiring at the end of a calendar year when at least 2 years but no more than 3 years have passed. Effective January 1, 2017, we revised our policy to allow for a quarterly expiration of pass-through payment status for devices to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices (81 FR 79655). HCPCS code C1822 was established as a pass-through payment category on January 1, 2016, and will have received 2 years of pass-through payment status on December 31, 2017, in accordance with the statutory requirement of receiving at least 2 years of pass-through payments, but not more than 3 years, and consistent with the policy in effect at the time the device pass-through payment period began for HCPCS code C1822. Accordingly, the policy adopted in CY 2017 does not apply to devices approved for pass-through payment status prior to that date. Likewise, the change in CY 2017 from using the average hospital-wide CCR to the implantable device CCR also was a prospective policy change to use the best available data in a given year to determine device pass-through payment.

With respect to comments expressing concerns that the reported costs for HCPCS code C1822 for CY 2016 were lower due to hospital cost reporting

errors, as we have stated in Section 20.5 (Clarification of HCPCS Code to Revenue Code Reporting) of Chapter 4 of the Medicare Claims Processing Manual, hospitals are responsible for reporting the correct revenue code on the claim form. Specifically, we state that we do not instruct hospitals on how to report the assignment of HCPCS codes to revenue codes for services provided under OPPS because hospitals' costs vary. Where explicit instructions are not provided, providers should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report. We note that the Medicare cost report form allows hospitals to report in a manner that is consistent with their own financial accounting systems and, therefore, should be accurate for each individual hospital. Moreover, we believe that the cost report data and their use in the OPPS cost estimation and payment rate development process, combined with potential penalties for inaccurate reporting, provide financial incentives for hospitals to report costs accurately. Furthermore, as we have stated repeatedly, beyond our standard OPPS trimming methodology that we apply to those claims that have passed various types of claims processing edits, it is not our general policy to judge the accuracy of hospital coding and charging for purposes of ratesetting. (We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 71838) for further discussion.)

Commenters writing in support of extending the pass-through payment period for HCPCS code C1822 also stated that access to the service covered by HCPCS code C1822 could be reduced if pass-through payment status for HCPCS code C1822 is removed. Because reported costs for CPT code 63685 appear to be consistent with or without being reported in combination with HCPCS code C1822, we do not anticipate a significant impact to the payment amount for CPT code 63685 once HCPCS code C1822 is removed from pass-through payment status. We anticipate that hospitals will be able to adjust to any possible changes to the payment for the service.

Comment: One commenter, another device manufacturer, agreed with CMS' proposal to end pass-through payment status of HCPCS code C1822 on December 31, 2017, stating that the decision to end pass-through payment status is consistent with CMS policy and there is no need to apply the policy established in CY 2017 retroactively.

Response: We appreciate the commenter's support.

We did not receive any public comments regarding the proposal to package the payment for the costs of the device described by HCPCS code C2623 into the payment for the costs related to the procedure with which the device is reported.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to package the payment for the costs of each of the devices described by HCPCS codes C2623, C2613, and C1822 into the payment for the costs related to the procedure with which each device is reported in the hospital claims data.

2. New Device Pass-Through Applications

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations might be most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at 42 CFR 419.66(b)(1) through (b)(3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria: (1) If required by FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability; (2) the device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and (3) the device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion. In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) The estimated average reasonable costs of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoblation, which are exempt from the cost

requirements as specified at §§ 419.66(c)(3) and (e)); and

• Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications will be subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

More details on the requirements for device pass-through payment applications are included on the CMS Web site in the application form itself at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*, in the ''Downloads'' section. In addition, CMS is amenable to meeting with applicants or potential applicants to discuss research trial design in advance of any device pass-through application or to discuss application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Payment for CY 2018

We received five applications by the March 1, 2017 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included for the CY 2018 OPPS/ASC proposed rule. All applications were received in the second quarter of 2016. None of the five applications were approved for device pass-through payment during the quarterly review process.

Applications received for the later deadlines for the remaining 2017 quarters (June 1, September 1, and December 1), if any, will be presented in the CY 2019 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed in light of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf*. A discussion of the five applications received by the March 1, 2017 deadline is presented below, as detailed in the CY 2018 OPPS/ASC proposed rule (82 FR 33611 through 33618).

(1) Architect® Px

Harbor MedTech, Inc. submitted an application for a new device category for transitional pass-through payment status for Architect® Px. Architect® Px is a collagen biomatrix comprised of a stabilized extracellular matrix derived from equine pericardium. The equine pericardium is stabilized to become a catalyst and scaffold for use by autologous tissue regeneration factors. Architect® Px is packaged as an individual unit in sizes ranging from 2 cm x 2 cm up to 10 cm x 15 cm and is approximately 0.75 mm thick. Architect® Px typically requires only one application. The applicant asserted that it is clinically superior to other skin substitutes that work by flooding the wound with nonautologous collagen and growth factors because Architect® Px attracts and concentrates the patient's own autologous collagen and growth factors to support healing.

With respect to the newness criterion at § 419.66(b)(1), the applicant received FDA clearance for Architect® Px on September 12, 2014, and its June 1, 2016 application was submitted within 3 years of FDA clearance. However, Unite BioMatrix, cleared by the FDA on June 20, 2007, is claimed as a predicate of Architect® Px. The Architect® Px application states that ''. . . while packaged differently, Architect® Px and Unite BioMatrix are identical . . . they are both stabilized equine pericardium manufactured using the same processes . . . .'' If the date for FDA clearance for Unite BioMatrix is used to evaluate the newness criterion, Architect® Px may not meet the newness criterion. We invited public comments on this issue.

Comment: One commenter, the manufacturer, stated that Architect® Px is substantially different than its predicate product, Unite Biomatrix, and should be considered to meet the newness criterion for device pass-through payment. The commenter pointed out the following: Architect® Px uses a different process from Unite Biomatrix to stabilize the equine pericardium. Architect® Px is dehydrated, packaged dry in a foil pouch, and is sterilized by radiation. Unite Biomatrix is packaged wet in a jar and is not sterilized using radiation. The new process that is used to manufacturer Architect® Px was found by researchers in 2016 to add key properties to the device that promote the use of endogenous collagen and growth factors to support healing. The commenter implied that Unite Biomatrix does not contain these key properties.

Response: The statements by the manufacturer about the differences in performance between Architect® Px and Unite Biomatrix appear to be different than what was stated in the device pass-through application. The application stated that, despite different packaging, the two products were identical. However, we acknowledge that the research cited by the manufacturer of substantial performance differences between Architect® Px and Unite Biomatrix is from 2016, and the findings may not have been available when the device pass-through payment application was submitted. For purposes of the device pass-through payment process, we are persuaded by this additional information and have determined that Architect® Px does meet the newness criterion based on the additional performance information supplied by the manufacturer.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Architect® Px is a skin substitute product that is integral to the service provided, is used for one patient only, comes in contact with human skin, and is surgically inserted into the patient. The applicant also claims Architect® Px meets the device eligibility requirements of § 419.66(b)(4) because Architect® Px is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS

determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through category that describes Architect® Px. Harbor MedTech, Inc. suggested a new device category descriptor of ''Stabilized Skin Substitute for Autologous Tissue Regeneration'' for Architect® Px. We invited public comments on this issue.

We did not receive any public comments on this issue. We are confirming that there is no existing pass-through category that describes Architect® Px and have determined that Architect® Px meets this eligibility criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With regard to the substantial clinical improvement criterion, the applicant only identified two references, neither of which we believe provide evidence of substantial clinical improvement. One reference is a 2012 summary report [3] of skin substitute products that can be used to treat chronic wounds that only describes characteristics of the predecessor product to Architect® Px with no efficacy or performance information. The second reference [4] is a small observational study of 34 subjects with no comparison group. We invited public comments on whether Architect® Px meets the substantial clinical improvement criterion.

Comment: One commenter, the manufacturer, stated that the inclusion of stabilized equine pericardium is an extremely important property of Architect® Px and Unite Biomatrix, and that this property allows these products to stay on a chronic wound, resist degradation, and remain on the wound until it heals. The commenter stated that Architect® Px is a nondegrading skin substitute that constantly supports healing and does not need to be reapplied. The commmenter also stated that skin substitutes that degrade need to be reapplied multiple times and there is the risk that reapplying the skin substitute may interrupt the wound healing process which drives up the costs of medical care. The commenter believed that Architect® Px is the first skin substitute that totally aligned with the Quality and Value of Care objectives of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Lastly, the commenter stated that other skin substitute products have previously received pass-through payment approval by presenting similar data as have been presented for Architect® Px.

Response: The commenter has provided additional information about the potential beneficial qualities of Architect® Px. However, the commenter has provided no additional studies that demonstrate that its use results in a substantial clinical improvement relative to other skin substitute and wound healing products available on the market. The commenter mentioned that skin substitutes had previously received pass-through payment status based on the same type of information the manufacturer provided in its device pass-through payment application and in its comments on the proposed rule. However, the commenter is referring to a previous process to evaluate skin substitutes for pass-through payment eligibility (the drugs and biological pass-through payment process), which did not require evidence of a substantial clinical improvement. Since CY 2015, skin substitutes have been evaluated using the medical device pass-through payment process (79 FR 66885 through 66888), which includes the criterion for substantial clinical improvement. Applicants must demonstrate that the device under consideration for pass-through payment status will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. The commenter has not provided additional information showing substantial clinical improvement. Therefore, we determine that Architect® Px does not meet the criterion for substantial clinical improvement.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements: Architect® Px would be reported with CPT codes 15271 through 15278, which cover the application of skin substitute grafts to different areas of the body for high-cost skin substitutes. To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criteria for at least one APC. CPT codes 15271 through 15278 are assigned to either APC 5054 (Level 4 Skin Procedures), with a CY 2016 payment rate of $1,411.21 and a device offset of $4.52, or APC 5055 (Level 5 Skin Procedures), with a CY 2016 payment rate of $2,137.49 and a device offset of $25.44. According to the applicant, the cost of the substitute graft procedures when performed with Architect® Px is $5,495.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $5,495 for Architect® Px exceeds the applicable APC amount for the service related to the category of devices of $1,411.21 by 389 percent ($5,495/$1,411.21 × 100 percent = 389 percent). Therefore, it appears that Architect® Px meets the first cost significance test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $5,495 for Architect® Px exceeds the device-related portion of the APC payment amount for the related service of $4.52 by 121,571 percent ($5,495/$4.52 × 100 percent = 121,571 percent). Therefore, we stated in the proposed rule that it appears that Architect® Px meets the second cost significance test.

Section 419.66(d)(3), the third cost significance test, requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $5,495 for Architect® Px and the portion of the APC payment amount for the device of

[3] Snyder, D.L. et al. Skin Substitutes for Treating Chronic Wounds. Technology Assessment Report. Project ID: HCPR0610. AHRQ. December 18, 2012.

[4] Alexander JH, Yeager DA, et al. Equine Pericardium as a Biological Covering for the Treatment of Diabetic Foot Wounds; a Prospective Study. J Am Podiatric Assoc., 2012 Sep–Oct.:102 (5): 352–358.

$4.52 exceeds 10 percent at 389 percent (($5,495 − $4.52)/$1,411.21) × 100 percent = 389 percent). Therefore, it appears that Architect® Px meets the third cost significance test. Based on the costs submitted by the applicant and the calculations noted earlier, we believe that Architect® Px meets the cost criterion at § 419.66(c)(3) for new device categories.

We invited public comments on whether Architect® Px meets the device pass-through payment criteria discussed in this section.

We did not receive any public comments relating to whether Architect® Px meets the device pass-through payment cost criterion. As stated earlier, we believe that Architect® Px meets the cost criterion at § 419.66(c)(3) for new device categories. However after consideration of the public comments we received, we are not approving device pass-through payment status for Architect® Px for CY 2018.

(2) Dermavest and Plurivest Human Placental Connective Tissue Matrix (HPCTM)

Aedicell, Inc. submitted an application for a new device category for transitional pass-through payment status for Dermavest and Plurivest human placental connective tissue matrix (HPCTM). Dermavest and Plurivest HPCTM use tissue sourced from the placental disk, amnion/chorion, and umbilical cord to replace or supplement damaged tissue. The applicant stated that Dermavest and Plurivest replace or supplement damaged or inadequate integumental tissue by providing a scaffold to entrap migrating cells for repopulation. The applicant stated that the products may be clinically indicated for the following conditions: Partial and full thickness wounds; pressure ulcers; venous ulcers; chronic vascular ulcers; diabetic ulcers; trauma wounds (abrasions, lacerations, second degree burns, and skin tears); drainage wounds; and surgical wounds (donor sites/grafts post mohs surgery, post laser surgery, and podiatric). Dermavest and Plurivest HPCTM are applied to the area of inadequate or damaged tissue, moistened if necessary and covered with a nonadherent secondary dressing. While the application does not distinguish between the Dermavest and Plurivest products, the AediCell Inc. Web site states that the two products differ by dosage. According to information on the Web site at *www.aedicell.com*, each product contains different tissue cell attachment proteins (CAP) and cytokine/growth factors (GF) profiles. There is a lower cytokine/GF concentration profile in Plurivest and a higher concentration of CAP and cytokine/GF in Dermavest.

With respect to the newness criterion at § 419.66(b)(1), the applicant indicated that the product conforms to the requirements for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) regulated solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271. For these products, FDA requires, among other things, that the manufacturer register and list its HCT/Ps with the Center for Biologics Evaluation and Research (CBER) within 5 days after beginning operations and update their registrations annually. AediCell, Inc. has an FDA field establishment identifier (FEI) under the HHS-FDA-Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) and submitted with its application the annual registration/listing for Dermavest and Plurivest dated November 9, 2015. The applicant noted that the initial registration for the manufacture of Dermavest was submitted to the CBER on October 28, 2013, and the registration of Plurivest was submitted the following year on November 14, 2014. The registration forms including these dates were not included in the application. Therefore, it is unclear if the newness criterion is met.

Comment: One commenter, the manufacturer, provided an FDA registration form for the product that indicated that there was change in information for the Dermavest product submitted on December 18, 2013. The manufacturer also submitted a document indicating that a registration form was submitted to FDA on October 20, 2014 to change the name of the product to Dermavest/Plurivest.

Response: Based on the information submitted by the manufacturer, we are unable to determine that Dermavest and Plurivest meet the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Dermavest and Plurivest are skin substitute products that are integral to the service provided, are used for one patient only, come in contact with human skin, and are applied in or on a wound or other skin lesion. The applicant also claimed Dermavest and Plurivest meet the device eligibility requirements of § 419.66(b)(4) because they are not instruments, apparatuses, implements, or items for which depreciation and financing expenses are recovered, and they are not supplies or materials furnished incident to a service.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through payment category that describes Dermavest and Plurivest HPCTM. The applicant proposed a category descriptor for Dermavest and Plurivest of ''Human placental connective tissue matrix (HPCTM), comprised of tissue sourced from the placental disk, amnion/chorion, and umbilical cord for the intention of replacing or supplementing damaged or inadequate integumental issue.'' We invited public comments on this issue.

Comment: One commenter, the manufacturer, supported CMS' statement that CMS had not identified an existing pass-through payment category that describes Dermavest and Plurivest HPTCM.

Response: At this time, we still have not identified an existing pass-through payment category that describes Dermavest and Plurivest HPCTM.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With respect to this criterion, the applicant provided several background studies showing general evidence that placental tissue, umbilical cord, and amnion membrane products are effective in the treatment of various wounds and ulcers. However, these studies were not specific to Dermavest and Plurivest HPCTM. The applicant submitted two poster presentations describing case studies that evaluated the wound healing time and wound characteristics of patients with diabetic and venous ulcers treated with Dermavest and Plurivest HPCTM. Both studies were described as case series and, as such, lacked blinding, randomization, and control groups. The first poster,[5] presented in 2015,

[5] Connell et al., Human placental connective tissue matrix in the treatment of chronic wounds: A prospective multi-center case series. 2015 at

described a prospective, multi-center case series with a small number of participants (n=15). The study evaluated wound healing time and wound characteristics of patients with various etiologies. The patients were treated with up to two 6 cm^2 pieces of Dermavest per application on wounds up to 44 cm^2. Results were presented for diabetic and venous ulcer cases and showed a week 4 percent area reduction (PAR) of 71 percent for diabetic ulcers and 50 percent for venous ulcers. Eighty percent of the diabetic ulcer cases and 50 percent of the venous ulcer cases had a week 4 PAR of greater than 40 percent.

The second poster,[6] presented in 2016, also described a case series that evaluated wound healing time and wound characteristics of patients with various etiologies (n=8). The poster stated that the patients were treated with pieces of HPCTM according to manufacturer guidelines on wounds ranging in size up to 3.8 cm^2. The methods presented in the poster do not specify whether the patients were treated with Dermavest or Plurivest, or both. The results presented in the poster compile Dermavest data from two case series presented at the Society for Advanced Wound Care (SAWC) annual meeting. It was unclear whether there was overlap between the patients used in the 2015 and 2016 case series included in the application. The compiled Dermavest data were compared to the 4-week PAR results for diabetic and venous ulcers from two other noncontemporaneous studies evaluating different skin replacement products. The results showed, at week 4, approximately 80 percent of the Dermavest-treated diabetic ulcer cases had a PAR of greater than 50 percent in comparison to approximately 60 percent of cases and approximately 30 percent of cases, respectively, in the comparison studies using other skin replacement products. The results also showed that, at week 4, approximately 60 percent of the Dermavest-treated venous ulcer cases had a PAR of greater than 40 percent in comparison to approximately 50 percent of cases and approximately 30 percent of cases in the comparison studies treated with other skin replacement products. There were multiple differences between the Dermavest studies included in the poster presentations and these two additional studies presented as comparators, including the number of patients included in the studies, the number of wounds treated, and the purpose of the study. Based on the results presented in the poster, the applicant concluded that HPCTM provides an effective alternative to other skin replacement products.

In the CY 2018 OPPS/ASC proposed rule, we stated that we were concerned that the research provided did not clinically demonstrate the active ingredients of the product(s) that might distinguish the product from others, the correct dosing of the product(s), the amount of durable wound closure with the product(s) compared to standard of care in studies with rigorous trial design/implementation, and the amount of durable wound closure with the product(s) compared to other products in studies with rigorous trial design/implementation. We stated in the proposed rule that, based on the evidence submitted with the application, we were not yet convinced that the Dermavest and Plurivest HPCTM provide a substantial clinical improvement over other treatments for wound care. We invited public comments on whether the Dermavest and Plurivest HPCTM meet this criterion.

Comment: One commenter, the manufacturer, provided information regarding the active ingredients and concentrations of active ingredients of the product as compared to other skin substitutes. The comment also included personal statements from physicians who used the product and attested to its clinical benefit over the current standard of care. The physicians' statements also noted that a randomized controlled trial that compares the product to the standard of care and to other advanced human tissue products, as well as registry studies, would be helpful in proving the substantial clinical improvement provided by Dermavest/Plurivest HPTCM. The manufacturer also stated that it was endeavoring to enter into a registry study and two randomized controlled trials using other high tiered skin substitutes as comparators.

Response: We appreciate the commenters' responses on the Dermavest and Plurivest HPCTM application. However, the commenters did not provide new empirical evidence that addressed our concerns that the studies included with the application were described as case series and, as such, lacked blinding, randomization, and control groups. At this time, we have not been able to determine that Dermavest and Plurivest HPCTM represents a substantial clinical improvement relative to existing therapies currently available for wound care.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that Dermavest and Plurivest HPCTM would be reported with CPT codes 15271, 15272, 15273, 15274, 15275, 15276, 15277, and 15278. CPT codes 15272, 15274, 15276, and 15278 are add-on codes assigned status indicator ''N'', which means payment is packaged under the OPPS. CPT codes 15271 and 15275 are assigned to APC 5054 (Level 4 Skin Procedures), and CPT codes 15273 and 15277 are assigned to APC 5055 (Level 5 Skin Procedures). To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5054 (Level 4 Skin Procedures), which had a CY 2016 payment rate of $1,411 and a device offset amount of $4.52 at the time the application was received. According to the applicant, the cost of a sheet of 2x3 cm Dermavest is $550, and the cost of a sheet of 2x3 cm Plurivest is $500.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $550 for Dermavest and Plurivest exceeds 39 percent of the applicable APC payment amount for the service related to the category of devices of $1,411 ($550/$1,411 × 100 = 39 percent). Therefore, we stated in the proposed rule that we believe Dermavest and Plurivest meet the first cost significance test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $550 for Dermavest and Plurivest exceeds the cost of the device-related portion of the APC payment amount for the related service of $4.52 by 12,168 percent

Society of Advanced Wound Healing (SAWC) Spring meeting.

[6] McGuire and Sebag, The use of a new placental acellular tissue product in the management of chronic wounds: A case series. 2016 at the Society of Advanced Wound Healing (SAWC) Spring meeting.

($550/$4.52) × 100 = 12,168 percent). Therefore, we stated in the proposed rule that we believe that Dermavest and Plurivest meet the second cost significance test.

The third cost significance test, at § 419.66(d)(3), requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $550 for Dermavest and Plurivest and the portion of the APC payment amount for the device of $4.52 exceeds the APC payment amount for the related service of $1,411 by 38.6 percent (($550 − $4.52)/$1,411 × 100 = 38.6 percent). Therefore, we stated in the proposed rule that we believe that Dermavest and Plurivest meet the third cost significance test.

We invited public comments on whether Dermavest and Plurivest meet the device pass-through payment cost criteria discussed in this section.

We did not receive any public comments on this issue. We continue to believe that Dermavest and Plurivest meet the device pass-through payment cost criteria.

After consideration of the public comments we received, we are not approving device pass-through payment status for the Dermavest and Plurivest HPCTM for CY 2018.

(3) FlōGraft®/Flōgraft Neogenesis®

Applied Biologics, LLC submitted an application for a new device category for transitional pass-through payment status for FlōGraft®/Flōgraft Neogenesis®. FlōGraft®/Flōgraft Neogenesis® is an injectable, human placental amniotic fluid. It is an allograft derived from human birth tissue recovered from a live, healthy C-section birth. The allograft is used to augment tissue to bone and tissue to tissue repairs. The allograft is implanted at the surgical site at the end of the procedure using a needle and syringe under direct visualization. The applicant claimed that the product helps drive healing towards native tissue regeneration and away from scar formation. FlōGraft® has a standardized potency of 2 million cells. FlōGraft Neogenesis® has a standardized potency of 1.5 million cells. The applicant indicated that the product may be used with several surgical procedures, including joint replacement procedures, traumatic bone and soft tissue injury, meniscal repairs, meniscal transplantation, articular cartilage restoration, foot and ankle repairs, and chronic wounds.

With respect to the newness criterion at § 419.66(b)(1), the applicant indicated that FlōGraft® and Flōgraft Neogenesis® conform to the requirements for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) regulated solely under section 361 of the PHS Act and 21 CFR part 1271. For these products, FDA requires, among other things, that the manufacturer register and list their HCT/Ps with the Center for Biologics Evaluation and Research (CBER) within 5 days after beginning operations and update their registrations annually. Applied Biologics, LLC has two FDA field establishment identifiers (FEI) under the HHS-FDA-Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Both registration forms list the product as ''FlōGraft®''. The applicant submitted an initial registration/listing for one FEI dated June 8, 2015, as well as an annual registration/listing for a different FEI dated December 1, 2014. The first date of U.S. sale for FlōGraft® was May 23, 2013. It is not clear when the initial CBER filing occurred for the FlōGraft® product. Therefore, it is unclear if the newness criterion for the FlōGraft® product is met.

Comment: One commenter, the manufacturer, supplied information indicating that the initial registration forms for FlōGraft® and FlōGraft Neogenesis® were submitted on February 24, 2015 and were validated by FDA on June 8, 2015.

Response: Based on the information submitted by the manufacturer, we believe that the product meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, FlōGraft® and Flōgraft Neogenesis® are integral to the service provided, are used for one patient only, come in contact with human skin, and are applied in or on a wound or other skin lesion. The applicant also claimed FlōGraft® and Flōgraft Neogenesis meet the device eligibility requirements of § 419.66(b)(4) because they are not instruments, apparatuses, implements, or items for which depreciation and financing expenses are recovered, and they are not supplies or materials furnished incident to a service.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through payment device category that describes FlōGraft®/Flōgraft Neogenesis®. The application suggested a payment device category for FlōGraft®/Flōgraft Neogenesis® with a category descriptor of ''Injectable Amniotic Fluid Allograft''. We invited public comments on this issue.

We did not receive any public comments on this issue, and at this time, we have not identified an existing pass-through category that describes FlōGraft®/Flōgraft Neogenesis®.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With respect to the substantial clinical improvement criterion, the applicant submitted several peer-reviewed publications that provided general evidence that amniotic fluid and amniotic membrane-based products significantly reduce recovery time. However, these studies did not include the use of the FlōGraft®/Flōgraft Neogenesis® product. The applicant did list several studies in the application that involved the use of the FlōGraft®/Flōgraft Neogenesis® product. Of these studies, five unpublished studies were available for review. The five studies submitted with the application were described as case studies, case series, or retrospective cohort studies. The studies lacked random allocation, blinding, and a comparison group. The first study [7] described a retrospective cohort study of 30 patients. The studies showed that 93 percent of the patients (n=14) who received a FlōGraft® injection, coupled with conservative, nonsurgical treatment plan to treat their Morton's Nerve entrapment condition, had their issue resolved compared to 20 percent of patients (n=3) who did not receive FlōGraft® injection, coupled with conservative, nonsurgical treatment plan to treat their Morton's Nerve entrapment condition. A greater percentage of patients who did not receive a FlōGraft® injection with their conservative treatment required surgery (80 percent versus 7 percent). Patients who required surgery had a 95-percent

[7] Bregman, Peter. (2014). Addressing Morton's Nerve Entrapment Surgically and Non-surgically with FloGraft.

success rate when surgery was coupled with a FlōGraft® injection.

The next study [8] was a retrospective analysis that involved 27 patients who were treated for stalled wounds. The patients had a broad spectrum of etiologies. Over a 12-month period, the applicant indicated that 96 percent of wounds that had stalled demonstrated rapid acceleration towards closure within a 21-day period when treated with FlōGraft®. The article recommended a randomized controlled trial (RCT) to confirm the results. The applicant also submitted two case studies,[9] [10] each involving one patient, which described the use of FlōGraft® to treat distal fibula fracture and tarsal tunnel compression neuropathy. Lastly, the application included a study [11] which presented the results from a case study of one patient as well as a retrospective cohort of 34 patients who received a Broström-Evans procedure with the FlōGraft® product. In general, the studies submitted lacked a clear description of the outcome variable and study population, and did not include statistical analysis.

Based on the evidence submitted, we stated in the proposed rule that we believe there is insufficient data to determine whether FlōGraft®/Flōgraft Neogenesis® offers a substantial clinical improvement over other treatments for wound care. We invited public comments on whether the FlōGraft®/Flōgraft Neogenesis® meets the substantial clinical improvement criterion.

Comment: Several commenters described the clinical benefits that they have observed using the FlōGraft® product in the treatment of wounds, bone, and soft tissue repairs. Other commenters described their current, ongoing studies involving the impact of FlōGraft® on rotator cuff healing after repair. One study described a randomized single blind study (n=20). One commenter was enthusiastic about the potential impact the product could have on improving healing for patients with rotator cuff injuries, while another commenter presented a more neutral position and stated that he could not confirm that the use of the product would impact the healing, but hoped that the study would guide the use of the product in the future. Other commenters submitted case studies of wound care patients treated with FlōGraft®. One commenter submitted several studies related to amniotic fluid and amniotic membrane-based products; however, none of these studies were specific to the FlōGraft® product.

Response: We appreciate the commenters' responses on the FlōGraft®/Flōgraft Neogenesis® product. However, the commenters did not provide new empirical evidence that addressed our concerns regarding the evidence of substantial clinical improvement that was submitted with the application. These concerns included the lack of a clear description of the outcome variable and study population and the lack of statistical analysis. The comments also did not address our concerns that the studies submitted with the application were case studies, case series, or retrospective cohort studies that lacked random allocation, blinding, and a comparison group. The commenters also discussed studies that did not include the use of FlōGraft®/Flōgraft Neogenesis® and studies that were still in progress. At this time, we have not been able to determine that FlōGraft®/Flōgraft Neogenesis® represents a substantial clinical improvement relative to existing therapies currently available for wound care.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated several CPT codes would be used to report FlōGraft®/Flōgraft Neogenesis®, including CPT codes 29826, 29827, 29828, 23473, 23420, 23412, 27605, 27650, 29891, 29888, 29889, 28008, 22551, 22856, 27179, 29861, and 29862. To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. These CPT codes are assigned to APCs 5121 through 5125 (Level 1 through Level 5 Musculoskeletal Procedures). For our calculations, we used APC 5121 (Level 1 Musculoskeletal Procedures), which had a CY 2016 payment rate of $1,455 and a device offset of $15.86 at the time the application was received. According to the applicant, the FlōGraft®/Flōgraft Neogenesis® product is available in a variety of vial sizes, the largest size being 18 cc with a cost of $19,925.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. We used the highest priced product for this determination. The estimated average reasonable cost of $19,925 for FlōGraft®/Flōgraft Neogenesis® exceeds the applicable APC payment amount for the service related to the category of devices of $1,455 by 1,369 percent ($19,925/$1,455 × 100 = 1,369 percent). Therefore, we stated in the proposed rule that we believe FlōGraft®/Flōgraft Neogenesis® meets the first cost significance test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The average reasonable cost of $19,925 for FlōGraft®/Flōgraft Neogenesis® exceeds the device-related portion of the APC payment amount of $15,86 by 125,360 percent ($19,925/$15.86) × 100 = 125,630 percent). Therefore, in the proposed rule, we stated that we believe that FlōGraft®/Flōgraft Neogenesis® meets the second cost significance test.

The third cost significance test, at § 419.66(d)(3), requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the average reasonable cost of $19,925 for FlōGraft®/Flōgraft Neogenesis® and the portion of the APC payment amount for the device of $15.86 exceeds the APC payment amount for the related service of $1,455 by 1,368 percent (($19,925 − $15.86)/$1,455 × 100 = 1,368 percent). Therefore, in the proposed rule, we stated that we believe FlōGraft®/Flōgraft Neogenesis® meets the third cost significance test.

We invited public comments on whether FlōGraft®/Flōgraft Neogenesis® meets the device pass-through payment cost criteria discussed in this section.

We did not receive any public comments on this issue. We continue to believe that FlōGraft®/Flōgraft Neogenesis® meets the device pass-through payment cost criteria.

[8] Gottleib, et al. FloGraft Rapidly Moves Stalled Wounds Into the Proliferative Phase.

[9] Jacoby, Richard. Case Study 221: Non-surgical Resolution of Distal Fibula Fracture with Flograft Implant; 82 YO Male.

[10] Jacoby, Richard. Tarsal Tunnel Compression Neuropathy Case Study Using Flograft.

[11] Maling, Scott. A Case Series: A retrospective analysis of 34 patients receiving modified Bronstom-Evans procedure with Flograft reduce time to full mobility by 52%.

After consideration of the public comments we received, we are not approving device pass-through payment status for the FlōGraft®/Flōgraft Neogenesis® product for CY 2018.

(4) Kerecis™ Omega3 Wound (Skin Substitute)

Kerecis, LLC submitted an application for a new device category for transitional pass-through payment status for Kerecis™ Omega3 Wound. Kerecis™ Omega3 Wound is made from acellular fish skin from wild Atlantic cod (Gadus morhua) caught in the North Atlantic Ocean that is used to regenerate damaged human tissue in chronic wounds. The applicant claimed that there is no disease transmission risk and noted that the fish skin is not required to undergo the viral inactivation process that the FDA dictates for tissues from farm animals. The applicant noted that the Omega3 fatty acids offer multiple health benefits, including anti-inflammation. Kerecis™ Omega3 Wound is supplied as a sterile, single-use sheet in peel-open pouches. Kerecis™ Omega3 Wound does not elicit an immune response because the major antigenic components present within cell membranes are removed in a gentle manner during processing. Unlike mammalian and human sourced products, the fish skin possesses extremely low risk of disease transmission and offers no known cultural or religious constraints for usage. The fish skin product is both halal and kosher compatible and avoids potential conflicts with Sikhism and Hinduism (Vaishnavism).

With respect to the newness criterion at § 419.66(b)(1), the applicant received FDA clearance for Kerecis™ Omega3 Wound through the premarket notification section 510(k) process on October 23, 2013 and its June 1, 2016 application was within 3 years of FDA clearance.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Kerecis™ Omega3 Wound is a skin substitute product that is integral to the service provided, is used for one patient only, comes in contact with human skin, and is surgically inserted into the patient. The applicant also claimed Kerecis™ Omega3 Wound meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through payment category that describes Kerecis™ Omega3 Wound. The applicant proposed a pass-through payment device category for Kerecis™ Omega3 Wound with category descriptor of ''Piscine skin substitute.'' We invited public comments on this issue.

We did not receive any public comments on this issue. As we stated earlier, we have not identified an existing pass-through category that describes Kerecis™ Omega3 Wound. Therefore, for the reasons discussed earlier, we believe Kerecis™ Omega3 Wound meets the eligibility criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With regard to the substantial clinical improvement criterion, the applicant stated that individuals who would normally refuse to use skin substitute products from animal sources, including pigs, cows, horses, and sheep, would use Kerecis™ Omega3 Wound because it is a fish-based skin substitute. The applicant also asserted that Kerecis™ Omega3 Wound provides several beneficial outcomes, including faster resolution of the disease process compared to similar products, decreased antibiotic use, decreased pain, and reduced amounts of device-related complications.

The applicant cited three studies in support of the application. The first study [12] was a parallel-group, double-blinded, randomized controlled trial undertaken to determine if healing time of whole thickness biopsy wounds treated with Kerecis™ Omega3 Wound is noninferior to that of wounds treated with porcine SIS ECM (Oasis). The study was an intention-to-treat study. Participants had two 4-mm full thickness punch wounds made on the proximal anterolateral aspect of their nondominant arm. The study population was comprised of volunteers aged between 18 and 67 years with most volunteers between the ages of 18 and 30. There were 80 volunteers who received Kerecis™ Omega3 Wound and 82 volunteers who received porcine SIS ECM (Oasis).

The results showed that, at 21 days, 58 (72.5 percent) of the fish skin ADM group were healed, compared with 46 (56 percent) of the porcine SIS ECM group. At 25 days, 62 (77.5 percent) of the fish skin ADM and 53 (65 percent) of the porcine SIS ECM group had healed. At the completion of the trial (28 days), 76 of the 80 wounds treated with fish skin ADM (95 percent) and 79 of the 82 wounds treated with porcine SIS ECM (96.3 percent) were healed. The odds ratio of a fish skin ADM-treated wound being healed as compared with that treated with porcine SIS ECM at any given time point was estimated to be 4.75. The difference between the treatments was statistically significant (P = 0.041). The immunological part of the study was designed to detect autoimmune reactions in those individuals treated with Kerecis™ Omega3 Wound. There was no evidence of antibodies forming in the presence of Kerecis™ Omega3 Wound.

There were issues with this study that may limit its usefulness to determine substantial clinical improvement including the use of nonpatient volunteers; studying the healing of biopsy sites rather than actual wounds requiring treatment; and the use of a 1-month endpoint of care instead of a longer period, such as a 6-month endpoint of care.

The second study [13] was a case series study of 18 patients to assess the percentage of wound closure area from baseline after 5 weekly fish-skin graft applications with at least one ''hard-to-heal'' criterion. Patients underwent application of the fish skin for 5 sequential weeks, followed by 3 weeks of standard care. Wound area, skin assessments, and pain were analyzed weekly.

The study results showed a 40-percent decrease in wound surface area (P <0.05) and a 48-percent decrease in wound depth was seen with 5 weekly applications of the fish-skin graft and secondary dressing (P <0.05). Complete closure was seen in 3 of 18 patients by

[12] Tumi Baldursson, T, MD, Ph.D. et al. Healing Rate and Autoimmune Safety of Full-Thickness Wounds Treated With Fish Skin Acellular Dermal Matrix Versus Porcine Small-Intestine Submucosa: A Noninferiority Study; The International Journal of Lower Extremity Wounds 2015, Vol. 14(1) 37–43.

[13] Yang, CK et al. A Prospective, Postmarket, Compassionate Clinical Evaluation of a Novel Acellular Fish-skin Graft Which Contains Omega-3 Fatty Acids for the Closure of Hard-to-heal Lower Extremity Chronic Ulcers. Wounds 2016;28(4): 112–118.

the end of the study phase. This study did not use a comparator group to measure whether there is substantial clinical improvement with Kerecis™ Omega3 Wound compared to other skin substitute products.

The third study [14] was a case series study of five patients with diabetes mellitus and complicated wounds in the lower limbs with exposed bone segments. The five patients had a total of seven wounds. Initial debridement occurred in the operating room, followed by application of wound matrix and covered with silicone mesh. All seven wounds healed and the patients did not have to have planned amputations on the limbs with the wounds. The mean duration of treatment to achieve full closure of the wound was 25 ± 10 weeks and ranged from 13 to 41 weeks. This study did not have a comparator group to determine if there was substantial clinical improvement with Kerecis™ Omega3 Wound compared to other skin substitute products.

There are no clinical data provided by the applicant to suggest that Kerecis™ Omega3 Wound provides a substantial clinical improvement over other similar skin substitute products. We invited public comments on whether Kerecis™ Omega3 Wound meets the substantial clinical improvement criterion.

Comment: One commenter, the manufacturer, stated that Kerecis™ Omega3 Wound significantly improves acute wound healing, nearly eliminates risk from side effects and adverse events, and provides a skin substitute option for beneficiaries who have allergic reactions or personal objections to mammalian or human sourced skin substitutes. The commenter referred to a study, believed to be the first study reviewed in the proposed rule,[15] and stated that it was the largest study performed in skin substitute research and that the study showed substantial clinical improvement from Kerecis™ Omega3 Wound. The commenter believed it had submitted more comparative data than skin substitute products that had previously received pass-through payment approval.

Lastly, the commenter believed that a skin substitute product that eliminates religious objections to its use, because Kerecis™ Omega3 Wound is fish sourced and not a mammalian or human sourced skin substitute, provides a significant benefit to beneficiaries with those objections, as they now have access to skin substitute products when previously skin substitute products may not be available to them.

Response: The commenter did not provide information to demonstrate that Kerecis™ Omega3 Wound represents a substantial clinical improvement relative to other wound care products currently available on the market. The commenter did not provide additional studies to support its claims of improvement with acute wound healing and low risk of side effects and adverse events. The commenter also did not address the concerns of the first study reviewed for this criterion, including the use of nonpatient volunteers; studying the healing of biopsy sites rather than actual wounds requiring treatment; and the use of an unrealistic 1-month endpoint of care instead of a 6-month endpoint of care. Instead, the manufacturer simply stated the study ''epitomizes'' substantial clinical improvement.

The commenter stated that other skin substitute products that had presented less evidence of substantial clinical improvement had previously been approved for pass-through payment status. However, we believe that the commenter may have been referring to skin substitutes approved for transitional pass-through payments before these products were subject to the transitional pass-through payment approval for medical devices. Since CY 2015, skin substitutes have been evaluated using the medical device pass-through payment process (79 FR 66885 through 66888), which includes the criterion for substantial clinical improvement. Applicants must demonstrate that the device under consideration for pass-through status will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. The commenter did not provided additional information showing substantial clinical improvement.

Finally, the commenter stated that Kerecis™ Omega3 Wound should meet the substantial clinical improvement criterion because it provides a skin substitute option for beneficiaries with allergies or personal objections to mammalian or human sourced products. However, the commenter did not provide any studies nor cite any data to show that this population would receive a substantial clinical improvement through the use of Kerecis™ Omega3 Wound, as compared to the wound care treatments available to this group of beneficiaries. Therefore, we determine that Kerecis™ Omega3 Wound does not meet the criterion for substantial clinical improvement.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. With respect to the cost criterion, the applicant stated that Kerecis™ Omega3 Wound would be reported with CPT codes 15271 through 15278, which cover the application of skin substitute grafts to different areas of the body for high-cost skin substitutes. To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. CPT codes 15271 through 15278 are assigned to either APC 5054 (Level 4 Skin Procedures), with a CY 2016 payment rate of $1,411.21 and a device offset amount of $4.52, or APC 5055 (Level 5 Skin Procedures), with a CY 2016 payment rate of $2,137.49 and a device offset amount of $25.44. According to the applicant, the cost of substitute graft procedures when performed with Kerecis™ Omega3 Wound is $2,030.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $2,030 for Kerecis™ Omega3 Wound exceeds the applicable APC payment amount for the service related to the category of devices of $1,411.21 by 144 percent ($2,030/$1,411.21 × 100 percent = 144 percent). Therefore, we stated in the proposed rule that it appears that Kerecis™ Omega3 Wound meets the first cost significance test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The average reasonable cost of $2,030 for Kerecis™

[14] Trinh, TT, et al. Marine Omega3 wound matrix for: the treatment of complicated wounds; Phlebologie 2016; 45: 93–98.

[15] Tumi Baldursson, T, MD, Ph.D. et al. Healing Rate and Autoimmune Safety of Full-Thickness Wounds Treated With Fish Skin Acellular Dermal Matrix Versus Porcine Small-Intestine Submucosa: A Noninferiority Study; The International Journal of Lower Extremity Wounds 2015, Vol. 14(1) 37–43.

Omega3 Wound exceeds the device-related portion of the APC payment amount of $4.52 by 44,911 percent ($2,030/$4.52 × 100 percent = 44,911 percent). Therefore, it appears that Kerecis™ Omega3 Wound meets the second cost significance test.

The third cost significance test, at § 419.66(d)(3), requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the average reasonable cost of $2,030 for Kerecis™ Omega3 Wound and the portion of the APC payment amount for the device of $4.52 exceeds the APC payment amount for the related service of $1,411 by 144 percent (($2,030 − $4.52)/$1,411.21) × 100 percent = 144 percent). Therefore, we stated in the proposed rule that it appears that Kerecis™ Omega3 Wound meets the third cost significance test. Based on the costs submitted by the applicant and the calculations noted earlier, it appears that Kerecis™ Omega3 Wound meets the cost criterion.

We invited public comments on whether Kerecis™ Omega3 Wound meets the device pass-through payment criteria discussed in this section.

We did not receive any public comments for this section. We confirm that Kerecis™ Omega3 Wound meets the cost criteria for new device categories.

After consideration of the public comments we received, we are not approving device pass-through payment status for Kerecis™ Omega3 Wound for CY 2018.

(5) X–WRAP®

Applied Biologics, LLC submitted an application for a new device category for transitional pass-through payment status for X–WRAP®. X–WRAP® is a chorion-free, amnion membrane allograft that can be used as a biological wrap or patch at any surgical site. It is used as a treatment for surgical or traumatic injury to bone or soft tissue. It is used to minimize adhesions, reduce inflammation, and promote soft tissue healing. The X–WRAP® is made from the intermediate amniotic epithelial layer of the placenta, recovered from a Cesarean delivery of pre-screened donors. It is available in a variety of sizes and is used as a biologic augmentation to a variety of orthopedic repairs.

With respect to the newness criterion at § 419.66(b)(1), the applicant indicated that X–WRAP® conforms to the requirements for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) regulated solely under section 361 of the PHS Act and 21 CFR part 1271. For these products, FDA requires, among other things, that the manufacturers register and list their HCT/Ps with the Center for Biologics Evaluation and Research (CBER) within 5 days after beginning operations and update their registrations annually. Applied Biologics, LLC has a FDA field establishment identifier (FEI) under the HHS-FDA-Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). The applicant submitted an annual registration/listing dated December 30, 2015. It is not clear when the initial CBER filing occurred for the X–WRAP® product, and therefore, it is unclear if the newness criterion for X–WRAP® is met.

Comment: One commenter, the manufacturer, supplied information indicating that the initial registration form for X–WRAP® was submitted on February 24, 2015 and validated by FDA on June 8, 2015.

Response: Based on the information submitted by the manufacturer, we believe that the product meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, X–WRAP® is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. The applicant also claimed X–WRAP® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through payment device category that describes X–WRAP®. The applicant proposed a pass-through device category for X–WRAP® with a category descriptor of ''Amniotic Membrane Soft Tissue Allografts''. We invited public comments on this issue.

We did not receive any public comments on this issue, and at this time, we have not identified an existing pass-through category that describes X–WRAP®.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With regard to the substantial clinical improvement criterion, the applicant submitted a list of studies in the application that showed general effectiveness of amniotic fluid and amniotic membrane-based products. However, these studies were not specific to the X–WRAP® product. The applicant also submitted one study [16] that was a retrospective review with prospective follow-up of patients (n=8) with recurrent surgical primary cubital tunnel syndrome (CuTS) who had undergone at least two previous ulnar nerve surgeries before having an ulnar neurolysis with X–WRAP® dry amniotic membrane barrier. The results showed that the participants experienced significant improvement in VAS pain scores, QuickDASH outcome scores, and grip strength in comparison to these scores prior to the surgery. Mean VAS improved by 3.5, from 7.3 to 3.8 (P <.0001). Mean QuickDASH improved by 30, from 80 to 50 (P <.0001). Grip strength improved by 25 pounds on average (P <.0001), a mean improvement of 38 percent relative to the contralateral side compared with preoperative measurements. Also, none of the patients reported progression or worsening of their symptoms compared with preoperatively. The applicant's conclusions from the article were that using the X–WRAP® amniotic membrane with revision neurolysis was a safe and effective treatment for primary cubital syndrome. The study lacked a comparison arm and did not include group assignment or blinding of patients.

Based on the evidence submitted, we believe there are insufficient data to determine whether X–WRAP® offers a substantial clinical improvement over other treatments for wound care. We invited public comments on whether the X–WRAP® meets the substantial clinical improvement criterion.

Comment: Commenters described the clinical benefits that they have observed using the X–WRAP® product in the treatment of wounds, bone, and soft

[16] Gaspar, M.P., et al. (2016). Recurrent cubital tunnel syndrome treated with revision neurolysis and amniotic membrane nerve wrapping. Journal of Shoulder and Elbow surgery, 25, 2057–2065.

tissue repairs. One commenter submitted several studies related to amniotic fluid and amniotic membrane-based products; however, none of these studies were specific to the X–WRAP® product.

Response: We appreciate the commenters' responses on the X–WRAP® product. However, the commenters did not provide new empirical evidence that addressed our concerns regarding the evidence of substantial clinical improvement that was submitted with the application, specifically that this evidence was limited to one retrospective study that lacked a comparison arm and did not include group assignment or blinding of patients. At this time, we have not been able to determine that X–WRAP® represents a substantial clinical improvement relative to existing therapies currently available for wound care.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that several CPT codes would be used to report X–WRAP®, including: CPT codes 29826, 29827, 29828, 23473, 23420, 23412, 27605, 27650, 29891, 29888, 29889, 28008, 22551, 22856, 27179, 29861, 29862, 15271, 15272, 15273, and 15277. To meet the cost criterion for device pass-through payment, a device must pass all three tests for cost threshold for at least one APC. These CPT codes are assigned to APCs 5121 through 5125 (Level 1 through Level 5 Musculoskeletal Procedures) and APCs 5054 and 5055 (Level 4 and Level 5 Skin Procedures). For our calculations, we used APC 5121 (Level 1 Musculoskeletal Procedures), which had a CY 2016 payment rate of $1,455 and a device offset amount of $15.86 at the time the application was received. According to the applicant, the X–WRAP® product is available in several sizes, the largest being 4x8 cm with a cost of $5,280.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $5,280 for X–WRAP® exceeds the applicable APC payment amount for the service related to the category of devices of $1,455 by 363 percent ($5,280/$1,455 × 100 = 363 percent). Therefore, we stated in the proposed rule that it appears that X–WRAP® meets the first cost significance test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device related portion of the APC found on the offset list). The average reasonable cost of $5,280 for X–WRAP® exceeds the device-related portion of the APC payment amount of $15.86 by 33,291 percent ($5,280/$15.86) × 100 = 33,291 percent). Therefore, we stated in the proposed rule that it appears that X–WRAP® meets the second cost significance test.

The third cost significance test, at § 419.66(d)(3), requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the average reasonable cost of $5,280 for X–WRAP® and the portion of the APC payment amount for the device of $15.86 exceeds the APC payment amount for the related service of $1,455 by 361 percent (($5280 − $15.86)/$1455 × 100 = 361 percent). Therefore, we stated in the proposed rule that it appears that X–WRAP® meets the third cost significance test.

We invited public comments on whether X–WRAP® meets the device pass-through payment cost criteria discussed in this section.

We did not receive any public comments on this issue. We continue to believe that X–WRAP® meets the device pass-through payment cost criteria.

After consideration of the public comments we received, we are not approving device pass-through payment status for the X–WRAP® product for CY 2018.

B. Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive APCs were defined as those APCs with a device offset greater than 40 percent (79 FR 66795). In assigning device-intensive status to an APC, the device costs of all of the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilize devices, and the device costs for the associated HCPCS codes exceed the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs and is discussed in detail in section IV.B.4. of this final rule with comment period. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422). For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

2. HCPCS Code-Level Device-Intensive Determination

As stated above, prior to CY 2017, the device-intensive methodology assigned device-intensive status to all procedures requiring the implantation of a device, which were assigned to an APC with a device offset greater than 40 percent. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that given APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status to all procedures that require the implantation of a device and have an individual HCPCS code-level device offset of greater than 40 percent, regardless of the APC assignment. Under this policy, all procedures with significant device costs (defined as a device offset of more than 40 percent) are assigned device-intensive status, regardless of their APC placement. Also, we believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that such a methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status to procedures without a significant device

cost but which are granted such status because of APC assignment.

Under our CY 2017 finalized policy, procedures that have an individual HCPCS code-level device offset of greater than 40 percent are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and device credits. Therefore, all procedures requiring the implantation of a medical device and that have an individual HCPCS code-level device offset of greater than 40 percent are subject to the device edit and no cost/full credit and partial credit device policies, discussed in sections IV.B.3. and IV.B.4. of this final rule with comment period, respectively.

In addition, for new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation of a medical device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent is not calculated from claims data; instead, it is applied as a default until claims data are available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant medical devices is to ensure ASC access for new procedures until claims data become available. However, in certain rare instances, for example, in the case of a very expensive implantable device, we may temporarily assign a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation of a medical device, device-intensive status will be applied to the code if the HCPCS code-level device offset is greater than 40 percent, according to our finalized policy of determining device-intensive status by calculating the HCPCS code-level device offset.

The full listing of proposed CY 2018 device-intensive procedures was included in Addendum P to the proposed rule (which is available via the Internet on the CMS Web site). The full listing of the final CY 2018 device-intensive procedures is included in Addendum P to this final rule with comment period.

In response to comments received in the CY 2017 OPPS/ASC final rule with comment period, we specified that additional information for our consideration of an offset percentage higher than the default of 41 percent for new HCPCS codes describing procedures requiring the implantation (or in some cases the insertion) of a medical device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically at *outpatientpps@cms.hhs.gov.* Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

We did not propose any changes to this policy for CY 2018.

Comment: Several commenters suggested that CMS use alternate device offset percentage thresholds for assigning device-intensive status. One of those commenters suggested that the device-intensive designation be given for any specified procedure with a HCPCS code level device offset percentage of greater than 30 percent. Another commenter suggested that CMS apply the device-intensive designation to any procedure for which the individual HCPCS code level device offset is greater than 40 percent of the procedure's unadjusted ASC payment rate. In addition, one commenter requested that CMS provide clarification on the criteria for device-intensive procedures, specifically with respect to temporarily inserted devices.

Response: We thank the commenters for their suggestions. However, we continue to believe that our current methodology to assign device-intensive status to all procedures that require the implantation of a device and have an individual HCPCS code-level device offset of greater than 40 percent is appropriate. With respect to the request for clarification about the criteria for device-intensive procedures pertaining to temporarily inserted devices, we would like to clarify that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria: (1) All procedures must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and (3) the device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

Comment: One commenter supported the proposed designation of CPT code 28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint) as a device-intensive procedure. A few commenters requested that the following HCPCS codes be assigned device-intensive status: HCPCS codes 55874 (placeholder code 55X87) (Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed); 0275T (Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (e.g., fluoroscopic, ct), single or multiple levels, unilateral or bilateral; lumbar); and 28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method).

Response: We thank the commenter for its support for our proposed designation of CPT code 28740. With respect to the commenters' request that we assign the device-intensive designation to HCPCS codes 55874, 0275T, and 28297, we note that the device offset percentage for all three of these procedures (as identified by the above mentioned HCPCS codes or predecessor codes) is not above the 40 percent threshold, and therefore, these procedures are not eligible to be assigned device-intensive status.

Comment: Several commenters suggested that CMS develop a mechanism that prevents significant payment reductions for device-intensive procedures due to wage index adjustments.

Response: In response to the commenters' suggestion that CMS develop a mechanism that prevents significant payment reductions for device-intensive procedures due to wage index adjustments, we note that we did not include such a proposal in the CY 2018 proposed rule. However, we will take this comment into consideration for future rulemaking.

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we

finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined (individual HCPCS code-level device offset greater than 40 percent) device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure.

We did not propose any changes to this policy for CY 2018.

Comment: One commenter requested that CMS restore the device-to-procedure and procedure-to-device edits. Another commenter requested that CMS adopt an additional policy for device-intensive procedures that have a device offset percentage above 75 percent, that would implement device-to-procedure and procedure-to-device edits for all such procedures (having a device offset percentage above 75 percent) and would only utilize claims that passed those edits for establishing the geometric mean cost and the HCPCS-level device offset for those procedures. Also, as part of this commenter's suggested new policy, the commenter requested that CMS only allow clinically similar, device-intensive procedures with a device offset above 75 percent to be grouped into an APC together and that all other procedures be excluded (both nondevice-intensive procedures and device-intensive procedures that have a device offset percentage below 75 percent).

Response: As we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66794), we continue to believe that the elimination of device-to-procedure edits and procedure-to-device edits is appropriate due to the experience hospitals now have in coding and reporting these claims fully. More specifically, for the more costly devices, we believe the C–APCs will reliably reflect the cost of the device if charges for the device are included anywhere on the claim. We remind commenters that, under our current policy, hospitals are still expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. We also remind commenters that, as with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place. In addition, we remind commenters that, under our current policy, the APC assignment of a device-intensive procedure has no bearing on the procedure's device-intensive designation. With respect to the commenter's request for an additional policy specifically for device-intensive procedures that have a device offset percentage above 75 percent, for the reasons stated above in this comment response, we do not believe that such a policy is needed.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim. For CY 2015, we continued our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three

criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized our policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In addition, for CY 2017 and subsequent years, we finalized our policy to use the following three criteria for determining the procedures to which our final policy applies: (1) All procedures must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and (3) the procedure must be device intensive; that is, the device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We did not propose any changes to this policy for CY 2018 and did not receive any public comments on this policy.

5. Payment Policy for Low-Volume Device-Intensive Procedures

For CY 2016, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act and used the median cost (instead of the geometric mean cost per our standard methodology) to calculate the payment rate for the implantable miniature telescope procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which is the only code assigned to APC 5494 (Level 4 Intraocular Procedures) (80 FR 70388). We note that, as stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45656), we proposed to reassign the procedure described by CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) for CY 2017, but it would be the only procedure code assigned to APC 5495. The payment rates for a procedure described by CPT code 0308T (including the predecessor HCPCS code C9732) were $15,551 in CY 2014, $23,084 in CY 2015, and $17,551 in CY 2016. The procedure described by CPT code 0308T is a high-cost device-intensive surgical procedure that has a very low volume of claims (in part because most of the procedures described by CPT code 0308T are performed in ASCs), and we believe that the median cost is a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for this procedure because the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. We stated that, in future rulemaking, we would consider proposing a general policy for the payment rate calculation for very low-volume device-intensive APCs (80 FR 70389).

For CY 2017, we proposed and finalized a payment policy for low-volume device-intensive procedures that is similar to the policy applied to the procedure described by CPT code 0308T in CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79660 through 79661), we established our current policy that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost, for the reasons described above for the policy applied to the procedure described by CPT code 0308T in CY 2016. The CY 2017 final rule geometric mean cost for the procedure described by CPT code 0308T (based on 19 claims containing the device HCPCS C-code in accordance with the device-intensive edit policy) was approximately $21,302, and the median cost was approximately $19,521. The final CY 2017 payment rate (calculated using the median cost) is approximately $18,984.

For CY 2018, in the CY 2018 OPPS/ASC proposed rule (82 FR 33620), we proposed to continue with our current policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC based on calculations using the median cost instead of the geometric mean cost. For CY 2018, this policy would continue to apply only to a procedure described by CPT code 0308T in APC 5495 because this APC is the only clinical APC containing a device-intensive procedure with fewer than 100 total claims in the APC. As we have stated before (81 FR 79660), we believe that this approach will help to mitigate significant year-to-year payment rate fluctuations while preserving accurate claims data-based payment rates for low-volume device-intensive procedures. The CY 2018 proposed rule median cost for the procedure described by CPT code 0308T was approximately $17,643.75. The proposed CY 2018 payment rate (calculated using the median cost and the claims that reported the device consistent with our device edit policy for device intensive procedures) was approximately $16,963.69.

Comment: Some commenters supported CMS' proposal to base payment on the median cost instead of the geometric mean cost for any device-intensive procedure that is assigned to an APC with fewer than 100 total claims. Other commenters requested that CMS limit the impact of geometric mean cost reductions on payment rates for low-volume procedures by a certain percentage to ensure payment stability for low-volume procedures.

Response: We thank commenters for their support. With respect to the commenters' request to limit the impact of the geometric mean cost reductions on payment rates for low volume procedures by a certain percentage, we disagree with commenters that such a percentage-based limitation is necessary. We continue to believe our current policy—establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC based on calculations using the median cost instead of the geometric mean cost—will help to mitigate significant year-to-year payment rate fluctuations while preserving accurate claims data-based payment rates for low-volume device-intensive procedures.

After consideration of the public comments we received, we are finalizing our proposal, without modification, that the payment rate for

any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost. The CY 2018 final rule median cost for the procedure described by CPT code 0308T is $17,550.18. The final CY 2018 payment rate (calculated using updated median cost and the claims that reported the device consistent with our device edit policy for device-intensive procedures) is $17,560.07.

V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout this final rule with comment period, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. A ''biological'' as used in this final rule with comment period includes (but is not necessarily limited to) a ''biological product'' or a ''biologic'' as defined in the Public Health Service Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. CY 2018 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site).

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this final rule with comment period, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

The pass-through application and review process for drugs and biologicals is described on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.*

2. 3-Year Transitional Pass-Through Payment Period for All Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for newly approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a product's pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through drugs and biologicals newly approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs and biologicals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a prospective basis, for the maximum pass-through payment period for each pass-through drug without exceeding the statutory limit of 3 years.

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2017

In the CY 2018 OPPS/ASC proposed rule (82 FR 33621), we proposed that the pass-through payment status of 19 drugs and biologicals would expire on December 31, 2017, as listed in Table 21 of the proposed rule (82 FR 33622). All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2017. These drugs and biologicals were approved for pass-through payment status on or before January 1, 2016. In accordance with the policy finalized last year and described above, pass-through payment status for drugs and biologicals newly approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as

supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is $120 for CY 2018), as discussed further in section V.B.2. of this final rule with comment period. In the CY 2018 OPPS/ASC proposed rule (82 FR 33622), we proposed that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we proposed to provide separate payment at the applicable relative ASP-based payment amount (which was proposed at ASP+6 percent for CY 2018, and is finalized at ASP+6 percent for CY 2018, as discussed further in section V.B.3. of this final rule with comment period).

Comment: Several commenters responded to the proposed expiration of pass-through status for HCPCS code A9586 (Florbetapir f18) on December 31, 2017. (We note that the brand name for the radiopharmaceutical described by HCPCS code A9586 is Amyvid®. Amyvid is a FDA-approved radioactive diagnostic agent for Positron Emission Tomography (PET) imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease and other causes of cognitive decline. Amyvid was approved for drug pass-through payment status effective January 1, 2015.)

One commenter, the manufacturer of Amyvid, urged CMS to extend pass-through payment status for another year on the basis that CMS could not have paid a legitimately billed claim for Amyvid in CY 2015, given the manufacturer's assertion regarding CED trial sites' dates of approval and start dates for patient enrollment. In addition, while the commenter acknowledged that the period of drug and biological pass-through payment status starts on the first date on which payment is made for the drug or biological as an outpatient hospital service (42 CFR 419.64(c)(2)), the commenter believed that an erroneous payment by Medicare should not have triggered the start of pass-through payment for Amyvid in 2015. In addition, the commenter asserted that expiration of pass-through payment status for Amyvid prior to completion of the CED trial will adversely affect the trial results. The commenter requested that, if CMS finalized expiration of pass-through payment status as proposed, CMS create a new APC for PET procedures with Amyvid to avoid violating the 2 times rule—which provides that items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group. The commenter stated that the median cost of Amyvid is approximately $2,756, over two times the median cost of the PET scan procedure.

One commenter, a manufacturer of another radiopharmaceutical, recommended that CMS allow for those products whose pass-through payment status will expire after a period of at least 2 years and no more than 3 years to expire as proposed, as a matter of applying policy consistently.

Several commenters recommended that CMS allow products covered by Medicare in the context of coverage with evidence development (CED) clinical trial to retain their pass-through status for the duration of the CED trial.

Response: CMS issued a Medicare National Coverage Determination (NCD) on September 27, 2013, which allows conditional coverage of amyloid PET under CED. Currently, there are three Medicare-approved amyloid PET CED trials. The first CED trial was approved on April 2, 2014. The second CED trial was approved on March 3, 2015. The third CED trial was approved January 5, 2016. Information on these clinical trials is available on the CMS amyloid PET Web page available via the Internet at: *https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Amyloid-PET.html.* The effective date of Medicare billing for CED trial sites is the CMS approval date. CMS has provided billing instructions for providers and practitioner that specify proper coding for clinical trial claims. For example, providers and practitioner must report certain diagnosis codes, procedure codes, modifiers, and a national clinical trial number. Therefore, providers enrolled in one of these trials could have begun appropriate billing Medicare for the amyloid PET procedures and associated Amyloid PET tracers beginning April 2, 2014.

Based on our claims analysis, we found that HCPCS code A9586 was billed by hospital providers 14 times in CY 2015, with 1 claim being paid. Based on our review of provider enrollment in the CED trials, it appears that this paid Medicare claim from CY 2015 was submitted from a CED clinical trial participant and not paid in error as the commenter suggests. According to section 1833(t)(6)(C)(i)(II) of the Act and the regulations at 42 CFR 419.66(g), the pass-through payment eligibility period begins on the first date on which pass-through payment is made. Because there is a paid claim from CY 2015, the pass-through payment period for HCPCS code A9586 began in CY 2015. Therefore, based on the CY 2015 paid claim for HCPCS code A9586 as a hospital outpatient service, which triggered the start of the pass-through payment period, we are expiring pass-through payment status on December 31, 2017. From the start of the pass-through payment period through December 31, 2017, Medicare will have provided an OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2017. Extending pass-through payment status into CY 2018 would cause pass-through payments for HCPCS code A9586 to extend into a fourth year, thereby exceeding the pass-through payment period authorized by section 1833(t)(6)(C)(i)(II) of the Act.

In addition, regarding the commenters' concern that expiration of pass-through payment status for Amyvid, and subsequent packaging of it as a ''policy-packaged'' drug, will skew trial results (presumably because providers will not receive an ASP-based payment), we disagree, given that analysis of CY 2016 claims data across different sites of care shows that the vast majority of billings for HCPCS code A9586 is concentrated in the physician office and the independent diagnostic testing facility (IDTF) setting. Further, we note that hospitals are not precluded from billing for HCPCS code A9586 in the context of a CED trial once its pass-through payment status expires. We also note that the payment for HCPCS A9586 would be reflected in the payment rate for the associated procedure.

With respect to the request that we create a new APC for PET procedures with Amyvid, we do not believe it is appropriate, prudent, or practicable to create unique APCs for specific drugs or biologicals or other individual items

that are furnished with a particular procedure or procedures. We disagree with the commenter's assertion that packaging of Amyvid with the associated PET procedure described by CPT code 78814 (Pet image w/ct lmtd) creates a 2 times rule violation in APC 5594 (Level 4 Nuclear Medicine) (we refer readers to section III.B. of this final rule with comment period for discussion of 2 times rule) and believe that the commenter may have misunderstood the application of the 2 times rule. Specifically, we note that, in determining the APCs with a 2 times rule violation, we do not consider the cost of an individual packaged item that may be furnished with a procedure or service, but rather the geometric mean cost of the service (which includes aggregate cost of packaged items that may be furnished with a procedure). Moreover, we disagree with the commenter's statement that the median cost of Amyvid is approximately $2,756. While it is correct that the CY 2017 pass-through payment for Amyvid is $2,756, the pass-through payment rate of ASP+6 percent is not indicative of the cost incurred by hospitals to acquire, store, handle, and dispense Amyvid. Our analysis of the updated CY 2016 claims data used for CY 2018 ratesetting for this CY 2018 OPPS/ASC final rule with comment period shows that the median cost of Amyvid is $1,275.75, which when combined with the aggregate cost of packaged items that may be furnished with CPT code 78814, would not create a 2 times rule violation.

With respect to the commenters' request that we allow drug or biological pass-through payment status for products covered by CED for the duration of the CED trial, we reiterate that the statute limits the period of pass-through payment eligibility to at least 2 years, but no more than 3 years, after the product's first payment as a hospital outpatient service under Medicare Part B. As such, we are unable to extend pass-through payment status beyond 3 years.

Finally, with respect to the commenter's support of our proposal to finalize the expiration of pass-through payment status as proposed for consistent policy application, we agree with the commenter.

In summary, we are finalizing our proposal to expire pass-through payment status for HCPCS code A9586 on December 31, 2017. Because pass-through payment was effective in CY 2015, HCPCS code A9586 will have had pass-through payment status for at least 2 years but no more than 3 years in accordance with section 1833(t)(6) of the Act.

Comment: Several commenters requested that CMS not package payment for Omidria® (described by HCPCS code C9447) upon expiration of pass-through payment status on December 31, 2017, and continue to pay separately for the drug at ASP+6 percent. One commenter, the manufacturer of Omidria, reiterated many previous arguments (81 FR 79667) for why CMS should dispense with classifying Omidria as drug that functions as a surgical supply when used in a surgical procedure. Specially, the commenter made the following arguments:

- The language used to construct the ''packaging as a surgical supply'' policy is overly broad and not consistent with Congressional intent that requires clinically comparable APC groups. CMS has not defined surgery or provided a rationale for applying different packaging policies to surgery than would be applied to other drugs with therapeutic indications;
- Mischaracterization of drugs used in surgery as ''supplies'', given regulatory requirements that apply to drugs. The FDA-approved label indicates its specific use in intraocular procedures;
- Packaging Omidria and other drugs as surgical supplies creates barriers to access, especially in ASC settings, low-volume HOPDs, and hospitals with low percentage of insured patients (presumably because providers may choose lower cost alternatives because separate payment would no longer be made);
- Packaging Omidria and other drugs as surgical supplies may affect quality of care improvements and patient outcomes; and
- Packaging drugs as ''surgical supplies'' interferes with physician discretion and is inconsistent with the principles that guide packaging under the OPPS.

A few commenters requested that CMS consider a narrow exception to the ''drug as a supply'' packaging policy to enable separate payment for Omidria.

Response: We have addressed many of these comments in prior rulemaking. We refer readers to the CY 2017 OPPS/ASC final rule with comment period for a detailed discussion on why we believe Omidria is a drug that functions as a surgical supply (81 FR 79668). We did not propose any policy changes to the criteria applied to a drug that functions as a surgical supply when used in a surgical procedure in the CY 2018 OPPS/ASC proposed rule, nor do we believe the commenters provided any new information that would cause us to change our position that Omidria is a drug that functions as a surgical supply. Therefore, we are not addressing these comments in this final rule with comment period. However, in the proposed rule, we did solicit comments on packaging policies generally, including drugs that function as a surgical supply, and will take responses to the comment solicitation, along with these commenters' recommendations and suggestions, into consideration in future rulemaking.

Comment: Commenters urged CMS to apply quarterly expiration of drug pass-through payment to drugs and biologicals first added to the pass-through payment list in CYs 2015 and 2016 that would otherwise transition off pass-through payment in less than 3 years. Commenters suggested CMS could apply the quarterly expiration of pass-through payment policy to devices approved for pass-through payment status in CY 2015 or 2016 because it would not cause harm to providers or beneficiaries. As stated earlier in this section, one commenter suggested that CMS allow for those products whose pass-through payment status will expire after a period of at least 2 years and no more than 3 years to expire as proposed, as a matter of applying policy consistently.

Response: As finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), the quarterly expiration of pass-through payment policy applies to drugs and biologicals newly approved for pass-through payment in CY 2017. We note that, even prior to the policy change adopted in CY 2017 rulemaking, the Agency's prior policy practice of making drug pass-through payments for a minimum of 2 years, but not more than 3 years, was consistent with statutory authority. Further, once a drug's pass-through payment status period expires, its costs are packaged into the associated procedure(s) with which it is billed, and accordingly, reversing past expirations of pass-through payment would potentially cause payment rates established for a prior year for certain services to be incorrect.

We agree with the commenter who stated that we should expire the drug-pass-through payment status for drugs and biologicals as proposed, to allow for consistent application of our policy.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to expire the pass-through payment status of the 19 drugs and biologicals listed in Table 69 below on December 31, 2017.

TABLE 69—DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2017

CY 2018 HCPCS code	CY 2018 long descriptor	Final CY 2018 status indicator	Final CY 2018 APC	Pass-through payment effective date
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	N	N/A	01/01/2015
C9447	Injection, phenylephrine and ketorolac, 4 ml vial	N	N/A	01/01/2015
J0596	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	K	9445	04/01/2015
J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	K	9452	04/01/2015
J0875	Injection, dalbavancin, 5 mg	K	1823	01/01/2015
J1833	Injection, isavuconazonium sulfate, 1 mg	K	9456	10/01/2015
J2407	Injection, oritavancin, 10 mg	K	1660	01/01/2015
J2502	Injection, pasireotide long acting, 1 mg	K	9454	07/01/2015
J2547	Injection, peramivir, 1 mg	K	9451	04/01/2015
J2860	Injection, siltuximab, 10 mg	K	9455	07/01/2015
J3090	Injection, tedizolid phosphate, 1 mg	K	1662	01/01/2015
J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	K	9450	04/01/2015
J8655	Netupitant (300 mg) and palonosetron (0.5 mg)	K	9448	04/01/2015
J9032	Injection, belinostat, 10 mg	K	1658	01/01/2015
J9039	Injection, blinatumomab, 1 mcg	K	9449	04/01/2015
J9271	Injection, pembrolizumab, 1 mg	K	1490	01/01/2015
J9299	Injection, nivolumab, 1 mg	K	9453	07/01/2015
Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter	N	N/A	01/01/2015
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	N	N/A	10/01/2015

The final packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

4. Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Payment Status in CY 2018

In the CY 2018 OPPS/ASC proposed rule (82 FR 33622), we proposed to continue pass-through payment status in CY 2018 for 38 drugs and biologicals. None of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2017. These drugs and biologicals, which were approved for pass-through payment status between January 1, 2016, and July 1, 2017, were listed in Table 22 of the proposed rule (82 FR 33623). The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status through July 1, 2017 were assigned status indicator ''G'' in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2018, we proposed to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2018. We proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2018 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which was proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which was proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2018 because, if not for their pass-through payment status, payment for these products would be packaged into the associated procedure.

In addition, we proposed to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2018 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2018, consistent with our CY 2017 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2018, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which was proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through payment drugs and biologicals without ASP information. If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

Comment: Commenters supported CMS' proposal to provide payment at ASP+6 percent for drugs, biologicals, contrast agents, and radiopharmaceuticals that are granted pass-through payment status.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to provide

payment for drugs, biologicals, diagnostic and therapeutic radiopharmaceuticals, and contrast agents that are granted pass-through payment status based on the ASP methodology. If a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2018, we will follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we will provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through payment drugs and biologicals without ASP information. If WAC information also is not available, we will provide payment for the pass-through payment radiopharmaceutical at 95 percent of its most recent AWP.

The 50 drugs and biologicals that continue to have pass-through payment status for CY 2018 or have been granted pass-through payment status as of January 2018 are shown in Table 70 below.

TABLE 70—DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2018

CY 2017 HCPCS code	CY 2018 HCPCS code	CY 2018 long descriptor	CY 2018 status indicator	CY 2018 APC	Pass-through payment effective date
A9515	A9515	Choline C 11, diagnostic, per study dose	G	9461	04/01/2016
A9587	A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie	G	9056	01/01/2017
A9588	A9588	Fluciclovine f-18, diagnostic, 1 millicurie	G	9052	01/01/2017
C9140	J7210	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 I.U.	G	9043	01/01/2017
C9460	C9460	Injection, cangrelor, 1 mg	G	9460	01/01/2016
C9482	C9482	Injection, sotalol hydrochloride, 1 mg	G	9482	10/01/2016
C9483	J9022	Injection, atezolizumab, 10 mg	G	9483	10/01/2016
C9484	J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017
C9485	J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017
C9486	J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017
C9488	C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017
C9489	J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017
C9490	J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017
C9491	J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017
C9492	C9492	Injection, durvalumab, 10 mg	G	9492	10/01/2017
C9493	C9493	Injection, edaravone, 1 mg	G	9493	10/01/2017
C9494	J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017
J0570	J0570	Buprenorphine implant, 74.2 mg	G	9058	01/01/2017
J1942	J1942	Injection, aripiprazole lauroxil, 1 mg	G	9470	04/01/2016
J2182	J2182	Injection, mepolizumab, 1 mg	G	9473	04/01/2016
J2786	J2786	Injection, reslizumab, 1 mg	G	9481	10/01/2016
J2840	J2840	Injection, sebelipase alfa, 1 mg	G	9478	07/01/2016
J7179	J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco.	G	9059	01/01/2017
J7202	J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.	G	9171	10/01/2016
J7207	J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	G	1844	04/01/2016
J7209	J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u.	G	1846	04/01/2016
J7322	J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg.	G	9471	04/01/2016
J7328	J7328	Hyaluronan or derivative, Gelsyn-3, for intra-articular injection, 0.1 mg.	G	1862	04/01/2017
J7342	J7342	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479	07/01/2016
J7503	J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg.	G	1845	04/01/2016
J9034	J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017
J9145	J9145	Injection, daratumumab, 10 mg	G	9476	07/01/2016
J9176	J9176	Injection, elotuzumab, 1 mg	G	9477	07/01/2016
J9205	J9205	Injection, irinotecan liposome, 1 mg	G	9474	04/01/2016
J9295	J9295	Injection, necitumumab, 1 mg	G	9475	04/01/2016
J9325	J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU).	G	9472	04/01/2016
J9352	J9352	Injection, trabectedin, 0.1 mg	G	9480	07/01/2016
N/A	J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018
Q5101	Q5101	Injection, Filgrastim (G–CSF), Biosimilar, 1 microgram	G	1822	01/01/2016
Q5102	Q5102	Injection, Infliximab, Biosimilar, 10 mg	G	1847	04/01/2017
Q9982	Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries.	G	9459	01/01/2016
Q9983	Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries.	G	9458	01/01/2016
Q9989	J3358	Ustekinumab, for Intravenous Injection, 1 mg	G	9487	04/01/2017
N/A	C9014	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018
N/A	C9015	Injection, c-1 esterase inhibitor (human), Haegarda, 10 units.	G	9015	01/01/2018

TABLE 70—DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2018—Continued

CY 2017 HCPCS code	CY 2018 HCPCS code	CY 2018 long descriptor	CY 2018 status indicator	CY 2018 APC	Pass-through payment effective date
N/A	C9016	Injection, triptorelin extended release, 3.75 mg	G	9016	01/01/2018
N/A	C9024	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine.	G	9302	01/01/2018
N/A	C9028	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018
N/A	C9029	Injection, guselkumab, 1 mg	G	9029	01/01/2018
N/A	J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg.	G	9301	01/01/2018

5. Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals To Offset Costs Packaged Into APC Groups

Under the regulations at 42 CFR 419.2(b), nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged in the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Also under 42 CFR 419.2(b), nonpass-through drugs and biologicals that function as supplies in a surgical procedure are packaged in the OPPS. This category includes skin substitutes and other surgical-supply drugs and biologicals. As described earlier, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for policy packaged drugs, biologicals, and radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. This amount reflecting the portion of the APC payment associated with predecessor products is called the payment offset.

The payment offset policy applies to all policy packaged drugs, biologicals, and radiopharmaceuticals. For a full description of the payment offset policy as applied to diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes, we refer readers to the discussion in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70430 through 70432). In the CY 2018 OPPS/ASC proposed rule (82 FR 33624), for CY 2018, as we did in CY 2017, we proposed to continue to apply the same policy packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. The proposed APCs to which a payment offset may be applicable for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes were identified in Table 23 of the proposed rule.

Comment: A few commenters requested that CMS separate the costs of diagnostic radiopharmaceuticals and stress agents from the ''packaged drug cost'' in the APC offset file published with the yearly proposed and final rules.

Response: We thank the commenter for this recommendation. However, we do not believe that the suggested change is necessary at this time. The offset amount is the portion of each APC payment rate that could reasonably be attributed to the cost of a predecessor contrast agent, diagnostic radiopharmaceutical, or stress agent when considering a new contrast agent, diagnostic radiopharmaceutical, or stress agent for pass-through payment and has no bearing on APC assignment. The exact data used to calculate all of the proposed and final payment rates, including the associated offset amounts, for this CY 2018 OPPS final rule with comment are available for purchase under a CMS data use agreement through the CMS Web site available via the Internet at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/IdentifiableDataFiles/index.html*.

After consideration of the public comments we received, we are finalizing our proposal, without modification, for CY 2018, to continue to apply the same policy-packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes as we did in CY 2017.

TABLE 71—APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET ARE APPLICABLE IN CY 2018

CY 2018 APC	CY 2018 APC title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services.
5592	Level 2 Nuclear Medicine and Related Services.
5593	Level 3 Nuclear Medicine and Related Services.
5594	Level 4 Nuclear Medicine and Related Services.
Contrast Agent	
5571	Level 1 Imaging with Contrast.
5572	Level 2 Imaging with Contrast.
5573	Level 3 Imaging with Contrast.
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services.
5593	Level 3 Nuclear Medicine and Related Services.
Skin Substitute	
5054	Level 4 Skin Procedures.
5055	Level 5 Skin Procedures.

We also are finalizing our proposal to continue to post annually on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through payment device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold

packaged drugs and biologicals for every OPPS clinical APC.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $110 for CY 2017 (81 FR 79665).

Following the CY 2007 methodology, for this CY 2018 OPPS/ASC final rule with comment period, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2018 and rounded the resulting dollar amount ($118.52) to the nearest $5 increment, which yielded a figure of $120. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from CMS' Office of the Actuary.

Therefore, for this CY 2018 OPPS/ASC final rule with comment period, using the CY 2007 OPPS methodology, we are finalizing a packaging threshold for CY 2018 of $120.

b. Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals Under the Cost Threshold (''Threshold-Packaged Drugs'')

In the CY 2018 OPPS/ASC proposed rule (82 FR 33625), to determine the proposed CY 2018 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2016 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2016 claims processed before January 1, 2017 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of the proposed rule, or for the following policy-packaged items that we proposed to continue to package in CY 2018: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2018, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we proposed for separately payable drugs and biologicals for CY 2018, as discussed in more detail in section V.B.2.b. of the proposed rule) to calculate the CY 2018 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2016 (data that were used for payment purposes in the physician's office setting, effective April 1, 2017) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2018, we proposed to use payment rates based on the ASP data from the first quarter of CY 2017 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site) because these were the most recent data available for use at the time of development of the proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2017. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2016 hospital claims data to determine their per day cost.

We proposed to package items with a per day cost less than or equal to $120, and identify items with a per day cost greater than $120 as separately payable. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2016 HCPCS codes that were reported to the CY 2017 HCPCS codes that we displayed in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) for proposed payment in CY 2018.

Comment: Many commenters requested that CMS eliminate the threshold packaging policy and pay separately for all drugs and biologicals described by a unique HCPCS code. Several commenters expressed concern with the annual increases in the drug packaging threshold, citing that yearly increases have outpaced conversion factor updates and place a financial burden on hospitals. A few commenters recommended that CMS delay the proposed increase in the packaging threshold for drugs or freeze the packaging threshold at the current level ($110).

Response: We have received and addressed similar comments in prior rules and most recently in CY 2017 OPPS/ASC final rule with comment (81 FR 79666). As we stated in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68086), we believe that packaging certain items is a fundamental component of a prospective payment system, that updating the packaging threshold of $50 for the CY 2005 OPPS is consistent with industry and government practices, and that the PPI for Prescription Drugs is an appropriate mechanism to gauge Part B drug inflation. Therefore, because packaging is a fundamental component of a prospective payment system that continues to provide important flexibility and efficiency in the delivery of high quality hospital outpatient services, we are not adopting the commenters' recommendations to pay separately for all drugs, biologicals, and radiopharmaceuticals for CY 2018, eliminate the packaging threshold, and delay updating the packaging threshold or freeze the packaging threshold at $110.

After consideration of the public comments we received, and consistent with our methodology for establishing the packaging threshold using the most recent PPI forecast data, we are adopting a CY 2018 packaging threshold of $120.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final

determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in this CY 2018 OPPS/ASC final rule with comment period, we used ASP data from the first quarter of CY 2017, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective July 1, 2017, along with updated hospital claims data from CY 2016. We note that we also used these data for budget neutrality estimates and impact analyses for this CY 2018 OPPS/ASC final rule with comment period.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for this final rule with comment period are based on ASP data from the third quarter of CY 2017. These data are the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2017. These payment rates will be updated in the January 2018 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2018. For items that do not currently have an ASP-based payment rate, we proposed to recalculate their mean unit cost from all of the CY 2016 claims data and updated cost report information available for this CY 2018 final rule with comment period to determine their final per day cost.

Consequently, as stated in the CY 2018 OPPS/ASC proposed rule (82 FR 33625), the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for this final rule with comment period. Under such circumstances, in the CY 2018 OPPS/ASC proposed rule, we proposed to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the proposed CY 2018 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2017. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2018, consistent with our historical practice, we proposed to apply the following policies to these HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2017 and that were proposed for separate payment in CY 2018, and that then have per day costs equal to or less than the CY 2018 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for this CY 2018 final rule, would continue to receive separate payment in CY 2018.
- HCPCS codes for drugs and biologicals that were packaged in CY 2017 and that were proposed for separate payment in CY 2018, and that then have per day costs equal to or less than the CY 2018 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for this CY 2018 final rule, would remain packaged in CY 2018.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2018 but then have per day costs greater than the CY 2018 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for this CY 2018 final rule, would receive separate payment in CY 2018.

We did not receive any public comments on our proposal to recalculate the mean unit cost for items that do not currently have an ASP-based payment rate from all of the CY 2016 claims data and updated cost report information available for this CY 2018 final rule with comment period to determine their final per day cost. We also did not receive any public comments on our proposal to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780), when the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the final rule with comment period. Therefore, for CY 2018, we are finalizing these two CY 2018 proposals without modification.

c. Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned briefly earlier, in the OPPS, we package several categories of drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than that at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: ''We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy'' (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

We did not make any proposals to revise our policy-packaged drug policy. We solicited public comment on the general OPPS packaging policies as discussed in section II.A.3.d. of this final rule with comment period.

Comment: Several commenters requested that CMS revise its packaging

policies to allow for separate payment for Cysview® (hexaminolevulinate HCl), which is described by HCPCS code C9275, according to the ASP methodology. The commenters also provided recommendations in response to the general comment solicitation on packaging under the OPPS.

Response: We appreciate the comments in response to the packaging solicitation, including feedback on the ''packaging as a supply'' policy and will consider these recommendations in future rulemaking. However, because we did not propose to modify our policy-packaged drug policy for drugs that function as a supply when used in a diagnostic test or procedure, or receive information from commenters that caused us to believe that Cysview® is not a drug that functions as a supply when used in a diagnostic test or procedure and, accordingly, should be paid separately, payment for HCPCS code C9275 will continue to be packaged with the primary procedure in CY 2018.

Comment: Numerous commenters requested that CMS pay separately for Exparel®, an FDA approved post-surgical analgesia drug. Several commenters, including many commenters who received care from the same provider, shared their experience with receiving Exparel® after their knee replacement surgery and urged CMS to pay hospitals and/or physicians for the use of Exparel®.

Response: We refer readers to the CY 2015 OPPS/ASC final rule with comment (79 FR 66874 and 66875) for a detailed discussion on our decision to package Exparel® (bupivacaine liposome injectable suspension) described by HCPCS code C9290 (Injection, bupivicaine liposome, 1 mg) as a drug that functions as a supply in a surgical procedure. Because we did not propose to modify our packaged drug policy for drugs that function as a surgical supply when used in a surgical procedure, and believe payment for HCPCS code C9290 is appropriately packaged with the primary surgical procedure, payment for HCPCS code C9290 will remain packaged in CY 2018.

Comment: A few commenters recommended that CMS continue to apply the nuclear medicine procedure to radiolabeled product edits to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future.

Response: We do not agree with commenters that we should reinstate the nuclear medicine procedure to radiolabeled product edits, which required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure for payment under the OPPS to be made. The edits were in place between CY 2008 and CY 2014 (78 FR 75033). We believe the period of time in which the edits were in place was sufficient for hospitals to gain experience reporting procedures involving radiolabeled products and to grow accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those radiolabeled products. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

Comment: One commenter recommended that CMS use ASP information, when voluntarily reported by the manufacturer, as a better price input to account for the packaged costs of the diagnostic radiopharmaceuticals and more appropriately reflect hospitals' actual acquisition costs. This commenter also requested that CMS provide an additional payment for radiopharmaceuticals that are granted pass-through payment status.

Response: We disagree with commenter's recommendation that we use voluntarily-reported ASP information for nonpass-through payment for radiopharmaceuticals as an approximation of their acquisition cost. Packaging hospital costs based on hospital claims data is how all the costs of all packaged items are factored into payment rates for associated procedures under the OPPS, and we do not believe it is appropriate to depart from that policy for radiopharmaceuticals.

Radiopharmaceuticals for which we have not established a separate APC will receive packaged payment under the OPPS. We provide payment for diagnostic radiopharmaceuticals based on a proxy for average acquisition cost. We continue to believe that the line-item estimated cost for a diagnostic radiopharmaceutical in our claims data is a reasonable approximation of average acquisition and preparation and handling costs for diagnostic radiopharmaceuticals.

In addition, we note that not all manufacturers would be able to submit ASP data through the established ASP reporting methodology. Therefore, if we were to use ASP data to package the costs of some diagnostic radiopharmaceuticals, but use hospital claims data for others, our methodologies for packaging the costs of diagnostic radiopharmaceuticals into their associated nuclear medicine procedures would be inconsistent among nuclear medicine procedures. The foundation of a system of relative weights is the relativity of the costs of all services to one another, as derived from a standardized system that uses standardized inputs and a consistent methodology. Adoption of a ratesetting methodology for certain APCs containing nuclear medicine procedures that is different from the standard APC ratesetting methodology would undermine this relativity. For this reason, we do not believe it would be appropriate to use external pricing information in place of the costs derived from the claims and Medicare cost report data because to do so would distort the relativity that is fundamental to the integrity of the OPPS.

With respect to the request to provide an additional payment for radiopharmaceuticals that are granted pass-through payment status, the commenter did not provide information on what expenses or costs incurred by providers would be covered by an additional payment. We continue to believe that a single payment is appropriate for radiopharmaceuticals with pass-through payment status in CY 2018 and that the payment rate of ASP+6 percent is appropriate to provide payment for both the radiopharmaceutical's acquisition cost and any associated nuclear medicine handling and compounding costs.

d. High Cost/Low Cost Threshold for Packaged Skin Substitutes

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to finalize the packaging of skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933).

Skin substitutes assigned to the high cost group are described by HCPCS codes 15271 through 15278. Skin substitutes assigned to the low cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin substitutes that are assigned to each group. Specifically, claims billed with HCPCS code 15271, 15273, 15275, or 15277 are used to calculate the

geometric mean costs for procedures assigned to the high cost group, and claims billed with HCPCS code C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low cost group (78 FR 74935).

Each of the HCPCS codes described above are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures) (HCPCS codes C5271, C5275, and C5277); APC 5054 (Level 4 Skin Procedures) (HCPCS codes C5273, 15271, 15275, and 15277); or APC 5055 (Level 5 Skin Procedures) (HCPCS code 15273). In CY 2017, the payment rate for APC 5053 (Level 3 Skin Procedures) was $466, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,468, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $2,575. This information also is available in Addenda A and B of the CY 2017 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site).

We have continued the high cost/low cost categories policy since CY 2014, and in the CY 2018 OPPS/ASC proposed rule (82 FR 33626 through 33627), we proposed to continue it for CY 2018 with the modification discussed below. Under this current policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high cost group or the low cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high cost/low cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435). For CY 2018, as in CY 2016 and CY 2017, we proposed to continue to determine the high/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. For CY 2018, as for CY 2017, we proposed to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, as described in more detail later in this section, for CY 2018, as for CY 2017, we proposed to assign any skin substitute with an MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group. For CY 2018, we proposed that any skin substitute product that was assigned to the high cost group in CY 2017 would be assigned to the high cost group for CY 2018, regardless of whether it exceeds or falls below the CY 2018 MUC or PDC threshold.

For this CY 2018 OPPS/ASC final rule with comment period, consistent with the methodology as established in the CY 2014 through CY 2017 final rules with comment period, we analyzed updated CY 2016 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The final CY 2018 MUC threshold is $46 per cm^2 (rounded to the nearest $1) (proposed at $47 per cm^2) and the final CY 2018 PDC threshold is $861 (rounded to the nearest $1) (proposed at $755).

For CY 2018, we proposed to continue to assign skin substitutes with pass-through payment status to the high cost category. However, there are no skin substitutes that are proposed to have pass-through payment status for CY 2018. We proposed to assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we stated in the proposed rule that we would use WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. We also stated in the proposed rule that new skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2018 MUC threshold. For a discussion of our existing policy under which we assign skin substitutes without pricing information to the low cost category until pricing information is available, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70436).

Some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high cost group to the low cost group which, under current payment rates, can be a difference of approximately $1,000 in the payment amount for the same procedure. In addition, these stakeholders were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute stakeholders requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and also requested that CMS consider whether it might be appropriate to establish a new cost group in between the low cost group and the high cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year to year shifts for skin substitute products between the high cost and low cost groups through multiple initiatives implemented since CY 2014, including: establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP+6 percent as the primary methodology to assign products to the high cost or low cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high cost group (80 FR 70434 through 70435).

In order to allow additional time to evaluate concerns and suggestions from stakeholders about the volatility of the MUC and PDC thresholds, for CY 2018, we proposed that a skin substitute that was assigned to the high cost group for CY 2017 would be assigned to the high cost group for CY 2018, even if it does not exceed the CY 2018 MUC or PDC thresholds. Our analysis has found that seven skin substitute products that would have otherwise been assigned to the low cost group for CY 2018 would instead be assigned to the high cost group under this proposed policy. The skin substitute products affected by this proposed policy were identified with an ''*'' in Table 24 of the proposed rule (82 FR 33627 through 33628). For CY 2019 and subsequent years, we requested public comments on how we should calculate data for products in determining the MUC and PDC

thresholds that are included in the high cost group solely based on assignment to the high cost group in CY 2017.

We stated in the proposed rule that the goal of our proposal to retain the same skin substitute cost group assignments in CY 2018 as in CY 2017 is to maintain similar levels of payment for skin substitute products for CY 2018 while we study our current skin substitute payment methodology to determine whether refinement to the existing policies is consistent with our policy goal of providing payment stability for skin substitutes. We requested public comments on the methodologies that are used to calculate pricing thresholds as well as the payment groupings that recognize a low cost group and a high cost group. We stated that we are especially interested in suggestions that are based on analysis of Medicare claims data from hospital outpatient departments that might better promote improved payment stability for skin substitute products under the OPPS. This proposal was intended to apply for CY 2018 to allow time for the public to submit other ideas that could be evaluated for the CY 2019 rulemaking.

In summary, we proposed to assign skin substitutes with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group, unless the product was assigned to the high cost group in CY 2017, in which case we proposed to assign the product to the high cost group for CY 2018, regardless of whether it exceeds the CY 2018 MUC or PDC threshold. We also proposed to assign to the high cost group skin substitute products that exceed the CY 2018 MUC or PDC threshold and assign to the low cost group skin substitute products that did not exceed either the CY 2017 or CY 2018 MUC or PDC thresholds and were not assigned to the high cost group in CY 2017. We proposed to continue to use payment methodologies including ASP+6 percent, WAC+6 percent, or 95 percent of AWP for skin substitute products that have pricing information but do not have claims data to determine if their costs exceed the CY 2018 MUC threshold. Finally, we proposed to continue to assign new skin substitute products without pricing information to the low cost group.

Comment: Several commenters responded to CMS' request for public comments on the methodologies that are used to calculate pricing thresholds as well as the payment groupings that recognize a low cost group and a high cost group with the goal of improving payment stability for skin substitute products in the OPPS. The commenters covered such issues as: Improving the quality of claims data CMS uses to determine the MUC and PDC thresholds; using ASP pricing data for the skin substitutes either in addition to or in place of claims data to determine the MUC and PDC thresholds; limiting annual changes to the MUC and PDC thresholds to the change in the consumer price index; adding more cost groups where skin substitutes may be assigned; ending the packaging of skin substitute products in general and ending packaging costs for add-on codes into the primary service codes for skin substitute procedures; establishing device offsets when the cost of a skin substitute used in a procedure is more than 40 percent of total cost of the procedure; and reducing incentives that favor the use of more expensive skin substitutes or products that require an excessive number of applications.

Response: We appreciate the feedback we received from the commenters. We will continue to study issues related to the payment of skin substitutes and take these comments into consideration for future rulemaking.

Comment: One commenter requested that PuraPly and PuraPly antimic reported with HCPCS code Q4172 retain its pass-through status in CY 2018. The commenter believed that giving PuraPly and PuraPly antimic an additional year of pass-through payment status would be consistent with CMS' policy proposal to assign all skin substitute products that were in the high cost skin substitute group in CY 2017 to the high cost skin substitute group in CY 2018. The commenter believed that, consistent with the spirit of this proposal, PuraPly and PuraPly antimic should receive the same payment treatment in CY 2017 as it did in CY 2018; that is, continued pass-through payment status.

Response: PuraPly and PuraPly antimic (HCPCS code Q4172) became eligible for drug and biological pass-through payments effective January 1, 2015. Therefore, 2017 is the third year of pass-through payment status for these skin substitutes. Section 1833(t)(6)(B)(iii) provides for temporary pass-through payments for devices for a period of at least 2 years but not more than 3 years. Extending PuraPly and PuraPly antimic for a fourth year of pass-through payment status would be contrary to the statute. Therefore, PuraPly and PuraPly antimic will be assigned to the high-cost skin substitute group for CY 2018 and the product will receive payment in the same manner as other skin substitute products assigned to the high cost group.

Comment: One commenter opposed CMS' proposal to assign all skin substitutes that qualified for the high cost group in CY 2017 to the high cost group in CY 2018, including those skin substitutes that would have not met either the MUC or PDC threshold in CY 2018 and would have instead been assigned to the low-cost group. The commenter stated that the products included in the high cost group that otherwise would have been assigned to the low cost group have generated enough payment data for CMS to estimate their costs. The commenter believed the proposal would encourage excessive use of the skin substitute products that should have been assigned to the low cost group.

Response: We appreciate the concerns of the commenter. However, as we stated in the proposed rule, we aim to encourage the goal of payment stability for all skin substitute products to help hospitals anticipate future costs related to skin substitute procedures. The MUC has nearly doubled since CY 2016, with an increase from $25 per cm^2 to the proposed CY 2018 threshold of $47 per cm^2. Likewise, the PDC has fluctuated over $300, between $715 and $1,050, since it was established in CY 2016. We requested suggestions from the public to help address these stability issues in future rulemaking. We believe allowing all skin substitute products assigned to the high cost group in CY 2017 to remain in the high cost group for CY 2018 gives us time to consider revisions to the payment of skin substitute procedures and products while avoiding substantial payment reductions to hospitals during our review period.

Comment: Several commenters supported the proposal to assign all skin substitutes that qualified for the high cost group in CY 2017 to the high cost group in CY 2018, including those skin substitutes that would have not met either the MUC or PDC threshold in CY 2018 and would have instead been assigned to the low cost group.

Response: We appreciate the commenters' support.

Comment: One commenter supported the proposed assignment of HCPCS code Q4150 (Allowrap DS or Dry 1 sq cm) to the high cost group.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposals without modification for CY 2018. Table 72 below displays the CY 2018 cost category assignment for each skin substitute product.

For this final rule with comment period, we have identified 10 skin

substitute products that would otherwise have been assigned to the low cost group for CY 2018, but will instead be assigned to the high cost group under our policy to include in the high cost group for CY 2018 any skin substitute that was in the high cost group for CY 2017. The skin substitute products affected by this policy are identified with an asterisk ''*'' in Table 72 below.

TABLE 72—SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2018

CY 2018 HCPCS code	CY 2018 short descriptor	CY 2017 high/low assignment	CY 2018 high/low assignment
C9363	Integra Meshed Bil Wound Mat	High	High.
Q4100	Skin Substitute, NOS	Low	Low.
Q4101	Apligraf	High	High.
Q4102	Oasis Wound Matrix	Low	Low.
Q4103	Oasis Burn Matrix	High	High.*
Q4104	Integra BMWD	High	High.
Q4105	Integra DRT	High	High.*
Q4106	Dermagraft	High	High.
Q4107	GraftJacket	High	High.
Q4108	Integra Matrix	High	High.*
Q4110	Primatrix	High	High.*
Q4111	Gammagraft	Low	Low.
Q4115	Alloskin	Low	Low.
Q4116	Alloderm	High	High.
Q4117	Hyalomatrix	Low	Low.
Q4121	Theraskin	High	High.
Q4122	Dermacell	High	High.
Q4123	Alloskin	High	High.*
Q4124	Oasis Tri-layer Wound Matrix	Low	Low.
Q4126	Memoderm/derma/tranz/integup	High	High.
Q4127	Talymed	High	High.*
Q4128	Flexhd/Allopatchhd/Matrixhd	High	High.
Q4131	Epifix	High.	High
Q4132	Grafix core and grafixpl core, per square centimeter	High	High.
Q4133	Grafix prime and grafixpl prime, per square centimeter	High	High.
Q4134	hMatrix	Low	Low.
Q4135	Mediskin	Low	Low.
Q4136	Ezderm	Low	Low.
Q4137	Amnioexcel or Biodexcel, 1cm	High	High.
Q4138	Biodfence DryFlex, 1cm	High	High.
Q4140	Biodfence 1cm	High	High.
Q4141	Alloskin ac, 1cm	High	High.*
Q4143	Repriza, 1cm	High	High.
Q4146	Tensix, 1CM	High	High.
Q4147	Architect ecm, 1cm	High	High.*
Q4148	Neox cord 1k, neox cord rt, or clarix cord 1k, per square centimeter	High	High.
Q4150	Allowrap DS or Dry 1 sq cm	High	High.
Q4151	AmnioBand, Guardian 1 sq cm	High	High.
Q4152	Dermapure 1 square cm	High	High.
Q4153	Dermavest 1 square cm	High	High.
Q4154	Biovance 1 square cm	High	High.
Q4156	Neox 100 or clarix 100, per square centimeter	High	High.
Q4157	Revitalon 1 square cm	High	High.
Q4158	Kerecis omega3, per square centimeter	High	High.*
Q4159	Affinity 1 square cm	High	High.
Q4160	NuShield 1 square cm	High	High.
Q4161	Bio-Connekt per square cm	High	High.*
Q4163	Woundex, bioskin, per square centimeter	High	High.
Q4164	Helicoll, per square cm	High	High.
Q4165	Keramatrix, per square cm	Low	Low.
Q4166	Cytal, per square cm	Low	Low.
Q4167	Truskin, per square cm	Low	Low.
Q4169	Artacent wound, per square cm	High	High.
Q4170	Cygnus, per square cm	Low	Low.
Q4172	PuraPly, PuraPly antimic	High	High.
Q4173	Palingen or palingen xplus, per sq cm	High	High.
Q4175	Miroderm, per square cm	High	High.
Q4176	Neopatch, per square centimeter	Low	Low.
Q4178	Floweramniopatch, per square centimeter	Low	Low.
Q4179	Flowerderm, per square centimeter	Low	Low.
Q4180	Revita, per square centimeter	Low	Low.
Q4181	Amnio wound, per square centimeter	Low	Low.
Q4182	Transcyte, per square centimeter	Low	Low.

*These products do not exceed either the MUC or PDC threshold for CY 2018, but are assigned to the high cost group because they were assigned to the high cost group in CY 2017.

e. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believed that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33628), we proposed to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2018.

For CY 2018, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2016 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for the CY 2018 OPPS/ASC proposed rule, and as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2016 claims data to make the proposed packaging determinations for these drugs: HCPCS code J7100 (infusion, dextran 40,500 ml) and HCPCS code J7110 (infusion, dextran 75,500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to the proposed CY 2018 drug packaging threshold of $120 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2018 drug packaging threshold of $120 (so that all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2018 was displayed in Table 25 of the CY 2018 OPPS/ASC proposed rule (82 FR 33629).

We did not receive any public comments on this proposal. Therefore, for CY 2018, we are finalizing our CY 2018 proposal, without modification, to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages. Table 73 below displays the final packaging status of each drug and biological HCPCS code to which the finalized methodology applies for CY 2018.

TABLE 73—HCPCS CODES TO WHICH THE CY 2018 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2018 HCPCS code	CY 2018 long descriptor	CY 2018 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml = 1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

2. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. We refer to this alternative methodology as the ''statutory default.'' Most physician Part B drugs are paid at ASP+6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.[17]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In the CY 2018 OPPS/ASC proposed rule (82 FR 33630), we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We continued this policy of paying for separately payable drugs and biologicals at the statutory default for CY 2014, CY 2015, CY 2016, and CY 2017 (81 FR 79673).

b. CY 2018 Payment Policy

In the CY 2018 OPPS/ASC proposed rule (82 FR 33630), for CY 2018, we proposed to continue our payment policy that has been in effect from CY 2013 to present and pay for separately payable drugs and biologicals at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We proposed that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. We also proposed that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scalar is not applied in determining payments for these separately paid drugs and biologicals.

We note that we proposed, as specified below, to pay for separately payable, nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent. We refer readers to the full discussion of this proposal in section V.B.7. of the proposed rule and this final rule with comment period.

Comment: Numerous commenters supported CMS' proposal to continue to pay for separately payable drugs and biologicals based on the statutory default rate of ASP+6 percent.

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). The ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals for CY 2018. In addition, we are finalizing our proposal that payment for separately payable drugs and biologicals be included in the budget neutrality adjustments, under the requirements of section 1833(t)(9)(B) of the Act, and that the budget neutral weight scalar is not applied in determining payment of these separately paid drugs and biologicals. We refer readers to section V.B.7. of the final rule with comment period for the final payment policy for drugs acquired with a 340B discount.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this final rule with comment period (available via the Internet on the CMS Web site), which illustrate the final CY 2018 payment of

[17] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: *http://www.medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.*

ASP+6 percent for separately payable nonpass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective October 1, 2017, or WAC, AWP, or mean unit cost from CY 2016 claims data and updated cost report information available for this final rule with comment period. In general, these published payment rates are not the same as the actual January 2018 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2018 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of 2017 (July 1, 2017 through September 30, 2017) will be used to set the payment rates that are released for the quarter beginning in January 2018 near the end of December 2017. In addition, payment rates for drugs and biologicals in Addenda A and B to this final rule with comment period for which there was no ASP information available for October 2017 are based on mean unit cost in the available CY 2016 claims data. If ASP information becomes available for payment for the quarter beginning in January 2018, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for this final rule with comment period (reflecting October 2017 ASP data) that do not have ASP information available for the quarter beginning in January 2018. As stated in the CY 2018 OPPS/ASC proposed rule (82 FR 33630), these drugs and biologicals will then be paid based on mean unit cost data derived from CY 2016 hospital claims. Therefore, the payment rates listed in Addenda A and B to this final rule with comment period are not for January 2018 payment purposes and are only illustrative of the CY 2018 OPPS payment methodology using the most recently available information at the time of issuance of this final rule with comment period.

c. Biosimilar Biological Products

For CY 2016 and CY 2017, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPS/ASC proposed rule (82 FR 33630), for CY 2018, we proposed to continue this same payment policy for biosimilar biological products.

We noted in the proposed rule that public comments on the Medicare Part B biosimilar biological product payment policy should be submitted in response to the biosimilar biological product payment policy comment solicitation in the CY 2018 MPFS proposed rule.

Comment: Several comments urged CMS to assign separate HCPCS codes for each biosimilar biological product rather than combining biosimilar biological products of the same reference product into one HCPCS code. Some commenters who addressed the biosimilar payment policy as it relates to the 340B proposal stated that current policy (adopted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70445)) for pass-through payment for biosimilar biological products is restricted to the first biosimilar biological product of a reference product. The commenters believed that, if the 340B proposal is finalized as proposed, the preclusion on pass-through payment eligibility for second and subsequent biosimilar biological products of the same reference product would be significantly disadvantaged by the reduced payment if purchased with a 340B discount. These commenters urged CMS to reevaluate pass-through payment eligibility for biosimilar biological products and their payment under the 340B payment proposal in the proposed rule.

Response: Comments related to policy for coding for biosimilar biological products are outside of the scope of the CY 2018 OPPS/ASC proposed rule. As we indicated in the CY 2018 OPPS/ASC proposed rule, commenters should refer to the CY 2018 MPFS final rule for discussion of the biosimilar biological product coding policy. With respect to comments regarding OPPS payment for biosimilar biological products, in the CY 2018 MPFS final rule, CMS finalized a policy to implement separate HCPCS codes for biosimilar biological products. Therefore, consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, HCPCS coding for biosimilar biological products will be based on policy established under the CY 2018 MPFS rule.

Comments related to 340B and biosimilar biological products are discussed in section V.B.7. of this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposed payment policy for biosimilar biological products, with the following technical correction: All biosimilar biological products will be eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

3. Payment Policy for Therapeutic Radiopharmaceuticals

In the CY 2018 OPPS/ASC proposed rule (82 FR 33630), for CY 2018, we proposed to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2018. Therefore, we proposed for CY 2018 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also proposed to rely on CY 2016 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is unavailable. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524). The proposed CY 2018 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals were in Addenda A and B to the proposed rule (which are

available via the Internet on the CMS Web site).

Comment: Commenters supported continuation of the policy to pay ASP+6 percent for therapeutic radiopharmaceuticals, if available, and to base payment on the mean unit cost derived from hospital claims data when not available. Commenters also requested that CMS examine ways to compensate hospitals for their documented higher overhead and handling costs associated with radiopharmaceuticals.

Response: We appreciate the commenters' support. However, as we stated earlier in section V.B.1.c. of this final rule with comment period in response to a similar request for additional radiopharmaceutical payment, we continue to believe that a single payment is appropriate for radiopharmaceuticals with pass-through payment status in CY 2018 and that the payment rate of ASP+6 percent is appropriate to provide payment for both the radiopharmaceutical's acquisition cost and any associated nuclear medicine handling and compounding costs incurred by the hospital pharmacy. Payment for the radiopharmaceutical and radiopharmaceutical processing services is made through the single ASP-based payment. We refer readers to the CMS guidance document available via the Internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Archives.html* for details on submission of ASP data for therapeutic radiopharmaceuticals.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent. We also are finalizing our proposal to continue to rely on CY 2016 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The CY 2018 final rule payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site).

4. Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States would like to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, and conversion to such production has begun. We expect that this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68321).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation is that this additional payment will be needed for the duration of the industry's conversion to alternative methods to producing Tc-99m without HEU. We also stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68316). We have reassessed this payment for CY 2018 and did not identify any new information that would cause us to modify payment. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33631), for CY 2018, we proposed to continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources.

Comment: Commenters supported CMS' proposal to provide an additional $10 payment for the marginal cost of radioisotopes produced by non-HEU sources and supported continuation of the policy. However, the commenters requested that CMS update the payment amount using the hospital market basket update or hospital cost data. The commenters also requested that CMS assess whether the collection of a beneficiary copayment could discourage hospital adoption.

Response: We appreciate the commenters' support. As discussed in the CY 2013 OPPS/ASC final rule with comment period, we did not finalize a policy to use the usual OPPS methodologies to update the non-HEU add-on payment (77 FR 68317). The purpose for the additional payment is limited to mitigating any adverse impact of transitioning to non-HEU sources and is based on the authority set forth at section 1833(t)(2)(E) of the Act. Accordingly, because we do not have authority to waive beneficiary copayment for this incentive payment, we believe it is unnecessary to assess whether a beneficiary copayment liability would deter a hospital from reporting HCPCS code Q9969. Furthermore, reporting of HCPCS code Q9969 is optional. Hospitals that are not experiencing high volumes of significantly increased costs are not obligated to request this additional payment (77 FR 68323).

Comment: One commenter requested that CMS publish HCPCS code volume and cost data in the proposed and final rule ''Drug Blood Brachy Cost Statistics'' files yearly.

Response: We appreciate the request and will consider revising the content of the ''Drug Blood Brachy Cost statistics'' file to include data on HCPCS code Q9969 for future rulemaking. In the interim, claims data on HCPCS code Q9969 are available for purchase in the claims data sets released with publication of this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue the policy of providing an additional $10 payment for radioisotopes produced by non-HEU sources for CY 2018, which will be the sixth year in which this policy is in effect in the OPPS. We will continue to reassess this policy annually, consistent with the original policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68319).

5. Payment for Blood Clotting Factors

For CY 2017, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (81 FR 79676). That is, for CY 2017, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in

physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2017 updated furnishing fee was $0.209 per unit.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33631), for CY 2018, we proposed to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update was based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we were not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

Comment: Commenters' supported CMS' proposal to continue to pay for a blood clotting factor furnishing fee in the hospital outpatient department.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS Web site.

6. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes but Without OPPS Hospital Claims Data

In the CY 2018 OPPS/ASC proposed rule (82 FR 33631), for CY 2018, we proposed to continue to use the same payment policy as in CY 2017 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data, which describes how we determine the payment rate for drugs, biologicals, or radiopharmaceuticals without an ASP. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2018 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data was listed in Addendum B to the proposed rule, which is available via the Internet on the CMS Web site.

Comment: One commenter, the manufacturer of Mylotarg®, requested that CMS change the dose descriptor for HCPCS code J9300 from ''Injection, gemtuzumab ozogamicin, 5 mg'' to ''Injection, gemtuzumab ozogamicin, 0.1 mg,'' to accommodate the new 4.5 mg vial size for Mylotarg®. The commenter noted that HCPCS code J9300 was inactive for a period of time because the prior version of gemtuzumab ozogamicin was removed from the market. As such, HCPCS code J9300 is assigned status indicator ''E2 (items and services for which pricing information and claims data are not available).'' The commenter also requested that CMS change the status indicator from ''E2'' to a payable status indicator.

Response: This comment is outside of the scope of the proposed rule. Requests for changes to Level II Alphanumeric HCPCS codes should be submitted to the CMS HCPCS Workgroup using CMS' standard procedures. Information on the Level II HCPCS code process is available via the Internet on the CMS Web site, which is publicly available at: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSCODINGPROCESS.html.*

After consideration of the public comments we received, we are finalizing our CY 2018 proposal without modification, including our proposal to assign drug or biological products status indicator ''K'' and pay for them separately for the remainder of CY 2018 if pricing information becomes available. The CY 2018 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

7. Alternative Payment Methodology for Drugs Purchased Under the 340B Program

a. Background

The 340B Program, which was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992, is administered by the Health Resources and Services Administration (HRSA) within HHS. The 340B Program allows participating hospitals and other health care providers to purchase certain ''covered outpatient drugs'' (as defined under section 1927(k) of the Act and interpreted by HRSA through various guidance documents) at discounted prices from drug manufacturers. The statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients, and providing care that is more comprehensive.[18]

The 340B statute defines which health care providers are eligible to participate in the program (''covered entities''). In addition to Federal health care grant recipients, covered entities include hospitals with a Medicare disproportionate share hospital (DSH) percentage above 11.75 percent. However, under Public Law 111–148, section 7101 expanded eligibility to critical access hospitals (CAHs), children's hospitals with a DSH adjustment greater than 11.75 percent, sole community hospitals (SCHs) with a DSH adjustment percentage of 8.0 percent or higher, rural referral centers (RRCs) with a DSH adjustment percentage of 8.0 percent or higher, and freestanding cancer hospitals with a DSH adjustment percentage above 11.75 percent. In accordance with section 340B(a)(4)(L)(i) of the Public Health Service Act, all participating hospital types must also meet other criteria.

HRSA calculates the ceiling price for each covered outpatient drug. The ceiling price is the drug's average manufacturer price (AMP) minus the unit rebate amount (URA), which is a

[18] The House report that accompanied the authorizing legislation for the 340B Program stated: ''In giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'' (H.R. Rept. No. 102–384(II), at 12 (1992)).

statutory formula that varies depending on whether the drug is an innovator single source drug (no generic available), an innovator multiple source drug (a brand drug with available generic(s)), or a non-innovator multiple source (generic) drug.[19] The ceiling price represents the maximum price a participating drug manufacturer can charge a covered entity for the drug. However, covered entities also have the option to participate in HRSA's Prime Vendor Program (PVP), under which the prime vendor can negotiate even deeper discounts (known as ''subceiling prices'') on some covered outpatient drugs. By the end of FY 2015, the PVP had nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the 340B ceiling price.[20]

As we discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33632 and 33633), several recent studies and reports on Medicare Part B payments for 340B purchased drugs highlight a difference in Medicare Part B drug spending between 340B hospitals and non-340B hospitals as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost.[21] [22] [23] Links to the full reports referenced in this section can be found in the cited footnotes.

In its May 2015 Report to Congress, MedPAC analyzed Medicare hospital outpatient claims (excluding CAHs) along with information from HRSA on which hospitals participate in the 340B Program. MedPAC included data on all separately payable drugs under the OPPS except for vaccines and orphan drugs provided by freestanding cancer hospitals, RRCs, and SCHs. To estimate costs that 340B hospitals incur to acquire drugs covered under the OPPS, MedPAC generally used the formula for calculating the 340B ceiling price: (AMP)—unit rebate amount (URA) × drug package size. The URA is determined by law and depends upon whether a drug is classified as single source, innovator multiple source, non-innovator multiple source, a clotting factor drug, or an exclusively pediatric drug. CMS provides this URA information to States as a courtesy. However, drug manufacturers remain responsible for correctly calculating the URA for their covered outpatient drugs. More information on the URA calculation and the Medicaid Drug Rebate Program may be found on the Web site at: *https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html.*

Because MedPAC did not have access to AMP data, it used each drug's ASP as a proxy for AMP. MedPAC noted that ASP is typically slightly lower than AMP. The AMP is defined under section 1927(k)(1) of the Act as the average price paid to the manufacturer by wholesalers in the United States for drugs distributed to the retail pharmacy class of trade, minus customary prompt pay discounts. Manufacturers participating in Medicaid are required to report AMP data quarterly to the Secretary, and these prices are confidential. As described under section 1847A of the Act, the ASP is a manufacturer's unit sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume, prompt pay, and cash discounts. Certain sales are exempt from the calculation of ASP, including sales at a nominal charge and 340B discounts.

In addition, MedPAC noted that, due to data limitations, its estimates of ceiling prices are conservative and likely higher (possibly much higher) than actual ceiling prices. Further details on the methodology used to calculate the average minimum discount for separately payable drugs can be found in Appendix A of MedPAC's May 2015 Report to Congress. In this report, MedPAC estimated that, on average, hospitals in the 340B Program ''receive a minimum discount of 22.5 percent of the [ASP] for drugs paid under the [OPPS].''

In its March 2016 Report to Congress (page 79), MedPAC noted that another report, which MedPAC attributed to the Office of the Inspector General (OIG), recently estimated that discounts across all 340B providers (hospitals and certain clinics) average 33.6 percent of ASP, allowing these providers to generate significant profits when they administer Part B drugs. According to the U.S. Government Accountability Office (GAO) report, the amount of the 340B discount ranges from an estimated 20 to 50 percent discount, compared to what the entity would have otherwise paid to purchase the drug. In addition, participation in the PVP often results in a covered entity paying a subceiling price on some covered outpatient drugs (estimated to be approximately 10 percent below the ceiling price) (U.S. Department of Health and Human Services, HRSA FY 2018 Budget Justification). Participation in the PVP is voluntary and free.

As noted in the CY 2018 OPPS/ASC proposed rule, with respect to chemotherapy drugs and drug administration services, MedPAC examined Medicare Part B spending for 340B and non-340B hospitals for a 5-year period from 2008 to 2012 and found that ''Medicare spending grew faster among hospitals that participated in the 340B Program for all five years than among hospitals that did not participate in the 340B Program at any time during [the study] period'' (MedPAC May 2015 Report to Congress, page 14). This is just one example of drug spending increases that are correlated with participation in the 340B Program and calls into question whether Medicare's current policy to pay for separately payable drugs at ASP+6 percent is appropriate in light of the discounted rates at which 340B hospitals acquire such drugs.

Further, GAO found that ''in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals.'' According to the GAO report, this indicates that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis. For example, in 2012, average per beneficiary spending at 340B DSH hospitals was $144, compared to approximately $60 at non-340B hospitals. The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status (GAO Report 15–442, page 20).

Under the OPPS, all hospitals (other than CAHs, which are paid based on 101 percent of reasonable costs as required by section 1834(g) of the Act) are currently paid the same rate for separately payable drugs (ASP+6

[19] 42 U.S.C. 256b(a)(1–2). Occasionally, a drug's URA is equal to its AMP, resulting in a 340B ceiling price of $0. In these instances, HRSA has advised manufacturers to charge covered entities $0.01 per unit.

[20] Department of Health and Human Services. 2017. Fiscal Year 2018 Health Resources and Services Administration justification of estimates for appropriations committees. Washington, DC: HHS. Available at: *https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf.*

[21] Office of Inspector General. ''Part B Payment for 340B Purchased Drugs. OEI–12–14–00030''. November 2015. Available at: *https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf.*

[22] Medicare Payment Advisory Commission. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015. Available at: *http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0.*

[23] Government Accountability Office. ''Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals GAO–15–442''. June 2015. Available at: *https://www.gao.gov/assets/680/670676.pdf.*

percent), regardless of whether the hospital purchased the drug at a discount through the 340B Program. Medicare beneficiaries are liable for a copayment that is equal to 20 percent of the OPPS payment rate, which is currently ASP+6 percent (regardless of the 340B purchase price for the drug). Based on an analysis of almost 500 drugs billed in the hospital outpatient setting in 2013, the OIG found that, for 35 drugs, the ''difference between the Part B [payment] amount and the 340B ceiling price was so large that, in at least one quarter of 2013, the beneficiary's coinsurance alone . . . was greater than the amount a covered entity spent to acquire the drug'' (OIG November 2015, Report OEI–12–14–00030, page 9).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68655), we requested comments regarding the drug costs of hospitals that participate in the 340B Program and whether we should consider an alternative drug payment methodology for participating 340B hospitals. As noted above, in the time since that comment solicitation, access to the 340B Program was expanded under section 7101 of Public Law 111–148, which amended section 340B(a)(4) of the Public Health Service Act to expand the types of covered entities eligible to participate in the 340B Program. It is estimated that covered entities saved $3.8 billion on outpatient drugs purchased through the 340B Program in 2013.[24] In addition, the number of hospitals participating in the program has grown from 583 in 2005 to 1,365 in 2010 and 2,140 in 2014 (MedPAC May 2015 Report to Congress). In its November 2015 report entitled ''Part B Payments for 340B-Purchased Drugs,'' the OIG found that Part B payments were 58 percent more than 340B ceiling prices, which allowed covered entities to retain approximately $1.3 billion in 2013 (OEI–12–14–00030, page 8). Given the growth in the number of providers participating in the 340B Program and recent trends in high and growing prices of several separately payable drugs administered under Medicare Part B to hospital outpatients, we stated in the CY 2018 OPPS/ASC proposed rule that we believe it is timely to reexamine the appropriateness of continuing to apply the current OPPS methodology of ASP+6 percent to hospitals that have acquired those drugs under the 340B Program at significantly discounted rates.

MedPAC and OIG have recommended alternative drug payment methodologies for hospitals that participate in the 340B Program. In its March 2016 Report to Congress, MedPAC recommended a legislative proposal related to payment for Part B drugs furnished by 340B hospitals under which Medicare would reduce payment rates for 340B hospitals' separately payable 340B drugs by 10 percent of the ASP and direct the program savings from reducing Part B drug payment rates to the Medicare funded uncompensated care pool.[25] In its November 2015 report, the OIG described three options under which both the Medicare program and Medicare beneficiaries would be able to share in the program savings realized by hospitals and other covered entities that participate in the 340B Program (OEI–12–14–00030, pages 11–12). These options included: (1) Paying ASP with no additional add-on percentage; (2) paying ASP minus 14.4 percent; and (3) making payment based on the 340B ceiling price plus 6 percent of ASP for each 340B purchased drug (OEI–12–14–00030, page 11). Analysis in several of these reports notes limitations in estimating 340B-purchased drugs' acquisition costs; the inability to identify which drugs were purchased through the 340B Program within Medicare claims data was one of those limitations.

b. OPPS Payment Rate for 340B Purchased Drugs

In the CY 2018 OPPS/ASC proposed rule (82 FR 33633 through 33634), we proposed changes to our current Medicare Part B drug payment methodology for 340B hospitals that we believe would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. Such changes would allow the Medicare program and Medicare beneficiaries to pay less for drugs when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program.

Our goal is to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs while recognizing the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Medicare expenditures on Part B drugs have been rising and are projected to continue to rise faster than overall health spending, thereby increasing this sector's share of health care spending due to a number of underlying factors such as new higher price drugs and price increases for existing drugs.[26] [27] While we recognize the intent of the 340B Program, we believe it is inappropriate for Medicare to subsidize other activities through Medicare payments for separately payable drugs. We believe that any payment changes we adopt should be limited to separately payable drugs under the OPPS, with some additional exclusions. As a point of further clarity, CAHs are not included in this 340B policy change because they are paid under section 1834(g) of the Act. As stated in the CY 2018 OPPS/ASC proposed rule, these exclusions are for: (1) Drugs on pass-through payment status, which are required to be paid based on the ASP methodology, and (2) vaccines, which are excluded from the 340B Program. In addition, we solicited public comments on whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment.

Data limitations inhibit our ability to identify which drugs were acquired under the 340B Program in the Medicare OPPS claims data. This lack of information within the claims data has limited researchers' and our ability to precisely analyze differences in acquisition cost of 340B and non-340B acquired drugs with Medicare claims data. Accordingly, in the CY 2018 OPPS/ASC proposed rule (82 FR 33633), we stated our intent to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B Program. Because a significant portion of hospitals paid under the OPPS participate in the 340B Program, we stated our belief that it is appropriate to presume that a separately payable drug reported on an OPPS claim was purchased under the 340B Program, unless the hospital identifies that the drug was not purchased under the 340B Program. We stated in the proposed rule that we intended to provide further details about this modifier in this CY

[24] U.S. Department of Health and Human Services, HRSA FY 2015 Budget Justification, p. 342.

[25] Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at: *http://www.medpac.gov/docs/default-source/reports/chapter-3-hospital-inpatient-and-outpatient-services-march-2016-report-.pdf?sfvrsn=0.*

[26] Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. Issue Brief: Medicare Part B Drugs: Pricing and Incentives. 2016. Available at: *https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf.*

[27] Department of Health and Human Services: Office of the Assistant Secretary for Planning and Evaluation. Issue Brief: Observations on Trends in Prescription Drug Spending. March 8, 2016. Available at: *https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf.*

2018 OPPS/ASC final rule with comment period and/or through subregulatory guidance, including guidance related to billing for dually eligible beneficiaries (that is, beneficiaries covered under Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B Program.

A summary of public comments received and our responses pertaining to the modifier are included later in this section. As described in detail later in this section, we are implementing the modifier such that it is required for drugs that were acquired under the 340B Program instead of requiring its use on drugs that were *not* acquired under the 340B Program. In addition, we are establishing an informational modifier for use by certain providers who will be excepted from the 340B payment reduction.

Further, we note that the confidentiality of ceiling and subceiling prices limits our ability to precisely calculate the price paid by 340B hospitals for a particular covered outpatient drug. We recognize that each separately payable OPPS drug will have a different ceiling price (or subceiling price when applicable). Accordingly, we stated in the proposed rule that we believe using an average discounted price was appropriate for our proposal. Therefore, for CY 2018, we proposed to apply an average discounted price of 22.5 percent of the ASP for nonpass-through separately payable drugs purchased under the 340B Program, as estimated by MedPAC (MedPAC's May 2015 Report to Congress, page 7).

In the near-term, we believe that the estimated average minimum discount MedPAC calculated—22.5 percent of the ASP—adequately represents the average minimum discount that a 340B participating hospital receives for separately payable drugs under the OPPS. Given the limitations in calculating a precise discount for each OPPS separately payable drug, we did not attempt to do so for the proposed rule. Instead, we stated that we believed that using the analysis from the MedPAC report is appropriate and noted that the analysis is spelled out in detail and can be replicated by interested parties. As MedPAC noted, its estimate was conservative and the actual average discount experienced by 340B hospitals is likely much higher than 22.5 percent of the ASP. As GAO mentioned, discounts under the 340B Program range from 20 to 50 percent of the ASP (GAO–11–836, page 2). We believe that such reduced payment would meet the requirements under section 1833(t)(14)(A)(iii)(II) of the Act, which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary. We do not have hospital acquisition cost data for 340B drugs and, therefore, proposed to continue to pay for these drugs under our authority at section 1833(t)(14)(A)(iii)(II) of the Act at ASP, and then to adjust that amount by applying a reduction of 22.5 percent, which, as explained throughout this section, is the adjustment we believe is necessary for drugs acquired under the 340B Program.

Specifically, in the CY 2018 OPPS/ASC proposed rule, we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. However, we proposed to exercise the Secretary's authority to adjust the applicable payment rate as necessary and, for separately payable drugs and biologicals (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program, we proposed to adjust the rate to ASP minus 22.5 percent, which we believe better represents the average acquisition cost for these drugs and biologicals.

As indicated earlier, because ceiling prices are confidential, we are unable to publicly disclose those prices or set payment rates in a way that would allow the public to determine the ceiling price for a particular drug. We believe that the MedPAC analysis that found the average minimum discount of 22.5 percent of ASP adequately reflects the average minimum discount that 340B hospitals paid under the OPPS receive. In addition, we believe that using an average discount to set payment rates for OPPS separately payable drugs would achieve the dual goals of (1) adjusting payments to better reflect resources expended to acquire such drugs, and (2) protecting the confidential nature of discounts applied to a specific drug. Moreover, we do not believe that Medicare beneficiaries should be liable for a copayment rate that is tied to the current methodology of ASP+6 percent when the actual cost to the hospital to purchase the drug under the 340B Program is much lower than the ASP for the drug.

We note that MedPAC excluded vaccines from its analysis because vaccines are not covered under the 340B Program, but it did not exclude drugs with pass-through payment status. Further, because data used to calculate ceiling prices are not publicly available, MedPAC instead estimated ''the lower bound of the average discount received by 340B hospitals for drugs paid under the [OPPS]'' (MedPAC May 2015 Report to Congress, page 6). Accordingly, it is likely that the average discount is higher, potentially significantly higher, than the average minimum of 22.5 percent that MedPAC found through its analysis. In the proposed rule, we encouraged the public to analyze the analysis presented in Appendix A of MedPAC's May 2015 Report to Congress.

As noted earlier, we believe that the discount amount of 22.5 percent below the ASP reflects the average minimum discount that 340B participating hospitals receive for drugs acquired under the 340B Program, and in many cases, the average discount may be higher for some covered outpatient drugs due to hospital participation in the PVP, substitution of ASP (which includes additional rebates) for AMP, and that drugs with pass-through payment status were included rather than excluded from the MedPAC analysis. We believe that a payment rate of ASP+6 percent does not sufficiently recognize the significantly lower acquisition costs of such drugs incurred by a 340B-participating hospital. Accordingly, as noted earlier, we proposed to reduce payment for separately payable drugs, excluding drugs on pass-through payment status and vaccines, that were acquired under the 340B Program by 22.5 percent of ASP for all drugs for which a hospital does not append on the claim the modifier mentioned in the proposed rule and discussed further in this final rule with comment period. (As detailed later in this section, we are instead requiring hospitals to append the applicable modifier on the claim line with any drugs that were acquired under the 340B Program.)

Finally, as detailed in the impact analysis section (section XIX.A.5.a.2) of the proposed rule, we also proposed that the reduced payments for separately payable drugs and biologicals purchased under the 340B Program are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scalar is not applied in determining payments for these separately paid drugs and biologicals purchased under the 340B Program. In that section, we also solicited public comments on whether we should apply all or part of the savings generated by this payment reduction to increase payments for specific services paid under the OPPS, or under Part B generally, in CY 2018,

rather than simply increasing the conversion factor. In particular, we requested public comments on whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured. In addition, we requested public comments on whether savings associated with this proposal would result in unnecessary increases in the volume of covered services paid under the OPPS that should be adjusted in accordance with section 1833(t)(2)(F) of the Act. More information on the impact estimate associated with this proposal was included in section XIX.A.5.a.2. of the proposed rule. A summary of the public comments received on the impact estimate, along with our responses to those comments and our estimate of this provision for this final rule with comment period, are included in section XVIII.A.5. of this final rule with comment period.

c. Summaries of Public Comments Received and Our Responses

(1) Overall Comments

Comment: Several commenters, including organizations representing physician oncology practices, pharmaceutical research and manufacturing companies, a large network of community-based oncology practices, and several individual Medicare beneficiaries, supported the proposal. Some of these commenters commended CMS for its proposal, which they believed would help address the growth of the 340B Program, stem physician practice consolidation with hospitals, and preserve patient access to community-based care.

One of these commenters stated that the proposals would reduce drug costs for seniors by an estimated $180 million a year; help to stop hospital ''abuses'' of the 340B program; and help reverse the ''perverse incentives'' that have driven the closure and consolidation of the nation's community cancer care system.

Another commenter, representing a large network of community-based oncology practices, noted that since 2008, 609 community cancer practices have been acquired or become affiliated with hospitals, with 75 percent of those community cancer practices acquired by 340B-participating hospitals. The commenter stated that the consolidation in oncology care has resulted in a 30 percent shift in the site of service for chemotherapy administration from the physician office setting to the more costly hospital outpatient setting.

One commenter, an organization representing community oncology practices, cited several issues that the proposal would help address, including that only a small minority of 340B participating hospitals are using the program to benefit patients in need; cancer patients in need are being denied care at 340B participating hospitals or placed on wait lists; and hospitals are making extreme profits on expensive cancer drugs and are consolidating the nation's cancer care system, reducing patient choice and access and shifting care away from the private, physician-owned community oncology clinics into the more expensive 340B hospital setting, which is increasing costs for Medicare and its beneficiaries. In addition, this commenter stated that the increasing scope and magnitude of required 340B discounts are increasing drug prices to record-breaking levels as manufacturers factor these discounts into pricing decisions. The commenter also cited a report that it recently released that suggests, and provides anecdotal evidence supporting, that some 340B hospitals offered little charity care and turned away some patients in need because those patients were uninsured.[28]

With respect to the magnitude of the proposed payment reduction of ASP minus 22.5 percent, one commenter noted that although the proposed decrease in payment may seem ''severe,'' ASP minus 22.5 percent is the minimum discount that hospitals in the 340B Program receive. The commenter further noted that, with 340B discounts on brand drugs approaching, and even exceeding, 50 percent, there is still substantial savings—on the order of 50 percent drug margins—for hospitals to use to provide direct and indirect patient benefits. The commenter also noted that this proposal would result in cost-sharing savings to Medicare beneficiaries, for whom drug cost is an important component of overall outpatient cancer care costs.

Some commenters urged HHS, specifically CMS and HRSA, to work with Congress to reform the 340B Program. One commenter requested greater transparency and accountability on how 340B savings are being used, as well as a specific definition of the ''340B patient,'' which the commenter noted would require a legislative change.

Response: We thank the commenters for their support. As mentioned in the proposed rule, we share the commenters' concern that current Medicare payments for drugs acquired under the 340B Program are well in excess of the overhead and acquisition costs for drugs purchased under the 340B Program. We continue to believe that our proposal would better align Medicare payment for separately payable drugs acquired under the 340B Program with the actual resources expended to acquire such drugs. Importantly, we continue to believe that Medicare beneficiaries should be able to share in the savings on drugs acquired through the 340B Program at a significant discount. We also appreciate the comments supporting the proposed payment amount for drugs acquired under the 340B Program of ASP minus 22.5 percent, which we believe, like several commenters, is an amount that allows hospitals to retain a profit on these drugs for use in the care of low-income and uninsured patients. As detailed later in this section, we are finalizing our proposal, with modifications, in response to public comments.

As previously stated, CMS does not administer the 340B Program. Accordingly, feedback related to eligibility for the 340B Program as well as 340B Program policies are outside the scope of the proposed rule and are not addressed in this final rule with comment period.

Comment: Several commenters expressed concern with the rising cost of drugs and the impact on beneficiaries and taxpayers. These commenters offered varied opinions on whether the proposal would achieve CMS' goal of lowering drug prices and reducing beneficiary out-of-pocket costs. Some commenters stated that the proposal has the potential to alleviate the financial burden that high-cost drugs place on patients. Other commenters stated that, because the proposal does not address the issue of expansion of 340B entities, the volume of 340B discounted drugs, and the affordability of drugs, especially oncology drugs, CMS should not finalize the proposal.

One commenter, an individual who supported the proposal, stated that although the majority of patients with Medicare Part B coverage have supplemental coverage to pay their coinsurance, significant numbers do not have this additional protection. The commenter noted that, for a drug that is paid at $10,000 per month, the price reduction would save a beneficiary approximately $500 a month, which may be the difference between getting treatment and foregoing treatment due to financial reasons.

Another commenter, a large organization with many members who

[28] Community Oncology Alliance. Report: ''How Abuse of the 340B Program is Hurting Patients'' September 2017. Available at: *https://www.communityoncology.org/wp-content/uploads/2017/09/COA_340B-PatientStories_FINAL.pdf.*

are Medicare beneficiaries, stated that the proposal would provide a measure of price relief to the 16 percent of Medicare beneficiaries without supplemental coverage. The commenter also expressed concern that the proposal would have serious health implications for beneficiaries in safety-net hospitals. The commenter urged HHS to develop proposals that will lower underlying drug prices, but did not provide any specific examples of such proposals. Another commenter stated that the cost of drugs is becoming unsustainable and applying the proposed policy is a decent ''baby step'' in controlling a situation that is ''grossly'' unfair to American taxpayers, especially when the development of new drugs is frequently funded to a large extent by taxpayers through Federal grants.

In addition, one commenter, a large organization representing its physician and medical student members, commented that it shares the Administration's interest in addressing the rising costs of drugs and biologicals. The commenter appreciated that the proposal would address a longstanding concern: That the current payment policy for Part B drugs creates strong incentives to move Medicare beneficiary care from lower cost sites of care (such as physician offices) to higher cost sites of care (such as hospital outpatient departments). The commenter noted that many smaller physician practices have had to refer cancer and other patients who need chemotherapy and other expensive drugs to the hospital outpatient setting because the ASP+6 percent payment does not always cover a physician's acquisition cost, thereby undermining continuity of care and creating burdens for frail and medically compromised patients.

This commenter also stated that, given the 340B Program's focus on low-income patients, it is imperative to ensure that an across-the-board reduction actually reflects the size of the 340B discount to avoid creating barriers to access, should both physician practices and the hospital outpatient departments be unable to cover actual acquisition costs. Further, the commenter noted that it is essential that ''a bright line policy does not inadvertently deleteriously impact patient access in all sites of care.'' Finally, the commenter stated that, while the proposed policy alters the relative disparity between payments for some hospital outpatient departments and physician practices, it still does not address the persistent challenges physician practices face in obtaining payment that covers acquisition costs.

Response: We thank the commenters' for their feedback and share their concern about the high cost of drugs and their effect on Medicare beneficiaries. As discussed in detail later in this section, we are finalizing a change to the payment rate for certain Medicare Part B drugs purchased by hospitals through the 340B Program in order to lower the cost of drugs for seniors and ensure that they benefit from the discounts provided through the program. We look forward to working with Congress to provide HHS additional 340B programmatic flexibility, which could include tools to provide additional considerations for safety net hospitals, which play a critical role in serving our most vulnerable populations.

As a general matter, we note that, even though many beneficiaries have supplemental coverage, beneficiaries often pay a premium for such supplemental coverage and those plans make coinsurance payments for the beneficiary. Thus, to the extent Medicare would be lessening the coinsurance amount such supplemental plans would have to make, we would expect the price of such plans to decrease or otherwise reflect these lower costs in the future, thereby lowering the amount that beneficiaries pay for supplemental plan coverage. Further, for those Medicare beneficiaries who do not have supplemental coverage at all or who have a supplemental plan that does not cover all of a beneficiary's cost-sharing obligation, the proposed policy would directly lower out-of-pocket spending for 340B-acquired drugs for those beneficiaries.

In addition, we note that in the hospital setting, not only are beneficiaries liable for cost-sharing for drugs they receive, but they also incur a ''facility fee'' solely because the drug was furnished in the hospital setting. As described in section II.A.3.b. of this final rule with comment period, for CY 2018, we are adopting a policy to conditionally package Level 1 and Level 2 Drug Administration services and believe that these steps, taken together, may help encourage site-neutral care in that beneficiaries may receive the same drugs and drug administration services at the physician office setting without a significant difference in their financial liability between settings.

As previously stated, we believe that ASP minus 22.5 percent is a lower bound estimate of the average discount given to hospitals participating in the 340B Program. Accordingly, we disagree that this proposal represents a ''bright-line'' policy that would hinder safety-net hospitals' ability to treat patients.

While the commenter's request that HHS develop proposals to lower underlying drug prices is outside the scope of the proposals made in the proposed rule, we note that lowering the price of pharmaceuticals is a top priority, and we are committed to finding ways for Medicare payment policy not to incentivize use of overpriced drugs. With respect to Medicare Part B drug payment under the OPPS, we believe that reducing payments on 340B purchased drugs to better align with hospital acquisition costs directly lowers drug costs for those beneficiaries who receive a covered outpatient drug from a 340B participating hospital by reducing their copayments. Further, to the extent that studies have found that 340B participating hospitals tend to use more high cost drugs, we believe that this proposal helps address the incentive for hospitals to utilize these drugs in this manner solely for financial reasons.

The expansion of 340B entities, the volume of 340B discounted drugs, and the affordability of drugs are outside the authority conferred by section 1833(t) of the Act (and, thus, are outside the scope of the proposed rule), and we see no reason to withdraw the proposal solely on account of these issues not being addressed by the proposal. Likewise, we note that the public comments on Medicare Part B drug payment in the physician office setting are also outside the scope of the proposed rule, and, therefore, are not addressed in this final rule with comment period.

Comment: Several commenters, including organizations representing 340B-eligible safety-net hospitals in urban and rural areas and teaching hospitals, were generally opposed to the proposed changes and urged CMS to withdraw the proposal from consideration. As detailed further below, these commenters believed that the Secretary lacks statutory authority to impose such a large reduction in the payment rate for 340B drugs, and contended that such change would effectively eviscerate the 340B Program. The commenters further noted that Medicare payment cuts of this magnitude would greatly ''undermine 340B hospitals' ability to continue programs designed to improve access to services—the very goal of the 340B Program.''

These commenters urged that, rather than ''punitively targeting'' 340B safety-net hospitals serving vulnerable patients, including those in rural areas, CMS instead redirect its efforts to halt the ''unchecked, unsustainable increases'' in the price of drugs.

Response: We do not believe that our proposed policy ''punitively'' targets safety-net hospitals. The current OPPS payment rate of ASP+6 percent significantly exceeds the discounts received for covered outpatient drugs by hospitals enrolled in the 340B Program, which can be as much as 50 percent below ASP (or higher through the PVP). As stated throughout this section, ASP minus 22.5 percent represents the average minimum discount that 340B enrolled hospitals paid under the OPPS receive. We also have noted that 340B participation does not appear to be well-aligned with the provision of uncompensated care, as some commenters suggested. As stated earlier in this section, while the commenter's request that HHS develop proposals to lower underlying drug prices is outside the scope of the proposals made in the proposed rule, we note that lowering the price of pharmaceuticals is a top priority.

(2) Comments on the Statutory Authority for the 340B Payment Proposal

Many commenters challenged the statutory authority of various aspects of the proposal. These comments are summarized into the broad categories below. For the reasons stated below, we disagree with these comments and believe that our proposal is within our statutory authority to promulgate.

• *Secretary's Authority To Calculate and Adjust 340B-Acquired Drug Payment Rates*

Comment: Commenters asserted that section 1833(t)(14)(A)(iii)(II) of the Act does not authorize CMS to ''calculate and adjust'' the payment rate in a manner that would ''eviscerate'' the 340B Program as it applies to 340B hospitals. Some commenters asserted that the plain and ordinary meaning of the terms ''calculate'' and ''adjust'' express a limited and circumscribed authority to set the payment rate. The commenters noted that the Oxford Dictionaries define ''calculate'' as ''determine (the amount or number of something) mathematically;'' likewise, to ''adjust'' is to ''alter or move (something) slightly in order to achieve the desired fit, appearance, or result.'' Consequently, the commenters asserted that section 1833(t)(14)(A)(iii)(II) of the Act restricts the agency to mathematically determining ''an appropriate, slight alteration.'' Further, they posited that the law does not convey the power to adopt what they referred to as a novel, sweeping change to the payment rate that is a significant numerical departure from the previous rate and that would result in a reduction in payment to 340B hospitals of at least $900 million, according to the agency's own estimates, or $1.65 billion, according to the commenter's estimates.

Another commenter stated that the Secretary's limited adjustment authority under section 1833(t)(14)(A)(iii)(II) of the Act does not ''extend so far as to gut'' what it referred to as an ''explicit statutory directive''. For example, the commenter referred the agency to *Pettibone Corp.* v. *United States,* 34 F.3d 536, 541 (7th Cir. 1994) (an agency's authority to interpret a statute ''must not be confused with a power to rewrite'').

Some commenters, including an organization representing over 1,300 providers enrolled in the 340B Program, argued that the proposal would take away almost the entire 340B discount for many 340B drugs, especially brand name drugs (which they asserted were many of the drugs affected by the proposal). These commenters asserted that the Secretary does not have the authority to calculate and adjust 340B-acquired drug rates in this manner and noted that the standard 340B ceiling price for a brand name drug is AMP minus 23.1 percent, although the price can be lower if the drug's best price is lower or if the manufacturer increases the price of the drug more quickly than the rate of inflation. In addition, the commenters asserted that if a brand name drug's 340B ceiling price was based on the standard formula, the proposal would strip the hospital of nearly all its 340B savings because ''AMP has been found to be close to ASP.'' Thus, the commenters asserted, the proposed payment rate of ASP minus 22.5 percent is nearly identical to AMP minus 23.1 percent, leaving the hospital with ''virtually no 340B savings.''

Some commenters stated that the proposal mistakenly assumes that 340B hospitals purchase most 340B drugs at subceiling prices negotiated by the PVP. These commenters noted that some hospitals estimate that less than 10 percent of the drugs affected by the proposal are available at a subceiling price.

In addition, some commenters contended that subclause (I) of section 1833(t)(14)((A)(iii) establishes that the payment rate for subsequent years be set to the average acquisition cost of the drug taking into account hospital acquisition costs survey data collected through surveys meeting precise statutory requirements, and that such subclause does not provide adjustment authority for the agency. They stated that subclause (II) of section 1833(t)(14)((A)(iii) of the Act directs CMS, where acquisition cost data are not available, to set payment rates by reference to ASP provisions. Considered in context, the commenters stated that the statute reflects Congress's intent to limit CMS' authority to set payment rates and, consequently, is consistent with adjustment authority under subclause (II)—to convey only limited authority for any agency to adjust the payment rate. The commenters referred to *Roberts* v. *Sea-Land Servs., Inc.,* 566 U.S. 93, 101 (2012) (Statutory provisions ''. . . cannot be construed in a vacuum. It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme'') to support their conclusions, although the commenters did not elaborate on the particular relevance of this case.

Finally, some commenters raised concern over the Secretary's use of the May 2015 MedPAC estimate as support for the 340B payment proposal. These commenters stated that the Secretary did not conduct his own independent analysis to support the payment proposal nor did he provide justification for use of MedPAC's analysis. One commenter stated that the Secretary cannot implement a payment cut of the magnitude proposed without providing a sufficient and replicable methodology that supports the proposal and that relying on a MedPAC analysis does not suffice for this ''important fiduciary, and legal, requirement.''

Response: We believe our authority under section 1833(t)(14)(A)(iii)(II) of the Act to ''calculate and adjust'' drug payments ''as necessary for purposes of this paragraph'' gives the Secretary broad discretion to adjust payments for drugs, which we believe includes an ability to adjust Medicare payment rates according to whether or not certain drugs are acquired at a significant discount. We disagree that this Medicare payment policy would effectively eviscerate the 340B Program and note that this proposal solely applies to applicable drug payments under the Medicare program; it does not change a hospital's eligibility for the 340B program. Further, under our proposal, we anticipate that the Medicare payment rate would continue to exceed the discounted 340B price the hospital received under the 340B program.

As previously stated, MedPAC's estimate of ASP minus 22.5 percent represents a lower bound estimate of the average minimum discount and the actual discount is likely much higher—up to 50 percent higher, according to some estimates, for certain drugs. In

some cases, beneficiary coinsurance alone exceeds the amount the hospital paid to acquire the drug under the 340B Program (OIG November 2015, Report OEI–12–14–00030, page 9). We did not receive public comments suggesting an alternative minimum discount off the ASP that would better reflect the hospital acquisition costs for 340B-acquired drugs. We believe this is notable because hospitals have their own data regarding their own acquisition costs, as well as data regarding OPPS payment rates for drugs. The fact that hospitals did not submit comments suggesting an alternative minimum discount that would be a better, more accurate reflection of the discount at issue is instructive for two reasons. One, it gives us confidence that our suggested payment of ASP minus 22.5 percent is, in fact, the low bound of the estimate and keeps Medicare payment within the range where hospitals will not be underpaid for their acquisition costs of such drugs. Two, it gives us confidence that the affected hospital community does not believe there is some other number, such as ASP minus 24 percent or ASP minus 17 percent, that would be a better, more accurate measure of what Medicare Part B should pay for drugs acquired at a discount through the 340B Program. Given the limitations in calculating a precise discount for each OPPS separately payable drug, we did not attempt to do so for the proposed rule. Instead, we stated that we believed that using the analysis from the MedPAC report is appropriate because MedPAC's estimate is based on all drugs separately paid under the OPPS except for vaccines, which are not eligible for 340B prices. Furthermore, the analysis is publicly available and can be replicated by interested parties.

With respect to the comments about the PVP, as previously stated, by the end of FY 2015, the PVP had nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the 340B ceiling price. Participation in the PVP is voluntary and free, and we are aware of no reason that an eligible entity would not participate.

Furthermore, we disagree that the Secretary's authority under section 1834(t)(14)(A)(iii)(II) of the Act to calculate and adjust drugs rates as necessary is limited to what some might consider minor changes and find no evidence in the statute to support that position. As previously stated, we believe that ASP minus 22.5 percent represents the average minimum discount that hospitals paid under the OPPS received for drugs acquired under the 340B Program and reiterate that, in many instances, the discount is much higher. Thus, we are using this authority to apply a downward adjustment that is necessary to better reflect acquisition costs of those drugs.

• *Authority To Vary Payment by Hospital Group*

Comment: Some commenters asserted that only subparagraph (I), and not subparagraph (II), of section 1833(t)(14)(A)(iii) of the Act permits CMS to vary payment ''by hospital group.'' These commenters suggested that, by including ''by hospital group'' in subparagraph (I) and omitting it in subparagraph (II), Congress expressed its intent that CMS may not vary prices by hospital group under subparagraph (II). They further commented that the subparagraph (II) methodology must apply to ''the drug,'' and CMS may not vary payment for the same drug based upon the type of hospital.

Response: We disagree with the commenters who argue that the proposed policy would exceed the Secretary's authority under the statute by inappropriately varying payments for drugs by ''hospital group'' because we rely on section 1833(t)(14)(A)(iii)(II) of the Act, even though the explicit authority to vary payment rates by hospital group is in subclause (I) of section 1833(t)(14)(A)(iii) of the Act, not subclause (II). As noted above, we believe our authority under section 1833(t)(14)(A)(iii)(II) of the Act to ''calculate and adjust'' drug payments ''as necessary for purposes of this paragraph'' gives the Secretary broad discretion to adjust payments for drugs, which we believe includes an ability to adjust payment rates according to whether or not certain drugs are acquired at a significant discount for Medicare beneficiaries. Although we acknowledge that hospitals are eligible to receive drugs at discounted rates under the 340B Program if they qualify as a ''covered entity'' for purposes of the 340B Program, not all drugs for which a covered entity submits a claim for payment under the OPPS are necessarily acquired under the 340B Program. The OPPS payment for those drugs not acquired under the 340B Program would continue to be paid at ASP+6 percent.

We also note generally that the OPPS statute authorized the Secretary to establish appropriate Medicare OPPS payment rates for covered outpatient drugs. After specifically setting forth the payment methodology for 2004 and 2005, Congress provided that the Secretary could set OPPS drug prices in one of two ways: Using the average acquisition cost for the drug for that year, or using the average price for that drug in the year. However, in either case, prices set using either benchmark may be adjusted by the Secretary. Such adjustments may occur under section 1833(t)(14)(A)(iii)(II) of the Act if the Secretary determines they are ''necessary for purposes of'' section 1833(t)(14) of the Act, and this paragraph of the Medicare OPPS statute repeatedly discusses terms like ''hospital acquisition cost'' and ''variation in hospital acquisition costs'', and specifically notes in one section that it is within the Secretary's authority to determine that the payment rate for one drug ''may vary by hospital group.'' It would be odd for Congress to have a significant delegation of authority to the Secretary, use these specific terms and considerations throughout section 1833(t)(14) of the Act, and then assume the Secretary is foreclosed from taking into account those considerations in adjusting ASP ''as necessary for purposes'' of section 1833(t)(14) of the Act. The Secretary is generally empowered to adjust drug prices ''as necessary'' for the overall purposes of section 1833(t)(14) of the Act, and there is nothing in section 1833(t)(14) of the Act to indicate the Secretary is foreclosed from varying Medicare OPPS payment for a drug, depending on whether a 340B hospital acquired that drug at such a substantially lower acquisition cost.

• *Authority To Establish Payment Rates in the Absence of Acquisition Cost Survey Data and Authority To Base Payment on an Average Discount*

Comment: Some commenters, including a commenter representing teaching hospitals, stated that the Secretary ignored the statutory directive in section 1833(t)(14) of the Act to set payment rates at the average acquisition cost for specific drugs and not to use averages for all drugs. In addition, the commenters stated that section 1833(t)(14) of the Act requires the Secretary to rely on an average of acquisition cost data and sales prices for a given drug, not an average discount that is applied to all drugs acquired under the 340B Program.

One commenter stated that the Secretary impermissibly conflates the two alternative methods for setting payment rates, ''essentially discarding Congress' requirement that any survey data used in setting payment rates must be derived from statistically rigorous surveys.'' This commenter asserted that the Secretary is using MedPAC's estimate of average discounts as a proxy

or replacement for the surveys required under subsection (iii)(I).

Response: We disagree that section 1833(t)(14)(A)(iii)(II) of the Act requires use of survey data and note that, unlike subclause (I) of this section, subclause (II) does not require taking survey data into account for determining average price for the drug in the year. We continue to believe that section 1833(t)(14)(A)(iii)(II) of the Act grants the Secretary the authority to calculate and adjust rates as necessary in the absence of acquisition cost. Moreover, under section 1833(t)(14)(A) of the Act, there still will be one starting, baseline price for an applicable drug, that is, the rate that applies under 1842(o), 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary. For drugs not acquired under the 340B Program, we will continue to utilize that price (ASP+6 percent), which as we have explained ''requires no further adjustment'' because it ''represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.'' However, for drugs acquired through the 340B Program, we are adjusting that price downward (ASP minus 22.5 percent) to more closely align with the hospital acquisition cost for a drug when purchased at a discounted price under the 340B Program. In the absence of acquisition costs from hospitals that purchase drugs through the 340B Program, we believe it is appropriate to exercise our authority to adjust the average price for 340B-acquired drugs, which are estimated to be acquired at an average minimum discount of ASP minus 22.5 percent. Importantly, because we are not using authority under section 1833(t)(14)(A)(iii)(I) of the Act (as the commenter suggested), we disagree with the commenter's suggestion that the Secretary is using the MedPAC analysis to stand in the place of the survey requirement under subclause (I).

• *Current Agency View Contrasts With Longstanding Practice*

Comment: Some commenters contended that the proposal contrasts sharply with the agency's previous view and longstanding practice of applying the statutory scheme of section 1833(t)(14) of the Act. These commenters noted that since CMS began relying on subclause (II) in 2012 to set the payment rate, the agency has never invoked the discretionary authority. The commenters stated that, instead, CMS stated that the statutory default of ASP+6 percent ''requires no further adjustment'' because it ''represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.'' Moreover, the commenters added, CMS has applied the statutory default rate without further adjustment in each subsequent year. They asserted that the CY 2018 proposal, in contrast, departs dramatically from longstanding prior practice and adopts a substantially reduced payment rate of ASP minus 22.5 percent for drugs acquired under a 340B Program.

Response: As discussed in the earlier background section, section 1833(t)(14)(A)(iii)(II) of the Act grants the Secretary authority to adjust, as necessary for purposes of paragraph (14) of section 1833(t) of the Act, the applicable payment rate for separately payable covered outpatient drugs under the OPPS. Specifically, we believe that the proposed reduced payment for 340B-acquired drugs would meet the requirements under section 1833(t)(14)(A)(iii)(II) of the Act, which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, *as calculated and adjusted by the Secretary as necessary for purposes of this paragraph* (paragraph (14) of section 1833(t) of the Act) (emphasis added). We do not have hospital acquisition cost data for 340B drugs and, therefore, we proposed to continue to pay for these drugs under the methodology in our authority at section 1833(t)(14)(A)(iii)(II) of the Act which we determined to be ASP, and then to adjust that amount by applying a reduction of 22.5 percent to that payment methodology, which, as explained throughout this section, is the adjustment we believe is necessary to more closely align with the acquisition costs for drugs acquired under the 340B Program.

As previously stated, we believe that using an average discount to set payment rates for separately payable 340B-acquired drugs will achieve the dual goals of (1) adjusting payments to better reflect resources expended to acquire such drugs and (2) protecting the confidential nature of discounts applied to a specific drug. Furthermore, our proposed and finalized policy will lower OPPS payment rates for Medicare beneficiaries who receive drugs at hospitals subject to the 340B payment reduction.

In addition, we do not believe that the fact that we have not historically utilized our adjustment authority under section 1833(t)(14)(A)(iii)(II) of the Act to adjust payment amounts for separately payable 340B-acquired drugs means we are permanently barred from adjusting these payments where, as here, we have provided a reasoned explanation for doing so. We continue to believe, as the commenter noted, that ASP+6 percent requires no further adjustment for drugs that are not acquired under the 340B Program because, at this time, we have not found similar evidence of the difference between the statutory benchmark (ASP+6 percent) and average hospital acquisition costs for such drugs. However, that is not the case for 340B-acquired drugs. As explained in detail throughout this section, we believe that a payment amount of ASP minus 22.5 percent for drugs acquired under the 340B Program is better aligned to hospitals' acquisition costs and thus this adjustment, for drugs acquired under the 340B Program, is necessary for Medicare OPPS payment policy.

• *Violation of Section 340B of the Public Health Service Act*

Comment: Some commenters stated that the proposed payment reduction would violate the 340B statute, which expressly defines the types of hospitals that may receive the benefits of 340B discounts. One commenter asserted that the payment proposal would ''hijack Congress' carefully crafted statutory scheme by seizing 340B discounts from hospitals and transferring the funds to providers that Congress excluded from the 340B Program,'' thereby violating section 340B of the Public Health Service Act. The commenter further noted that discounts under the 340B Program are only available to ''covered entities'' that are defined by law and that Congress thus intended the benefits of the program to accrue to these providers only. The commenter contended that Congress' reference to Medicare definitions when describing covered entities demonstrates that it considered the Medicare program when it adopted the 340B Program and decided not to grant discounts to all Medicare hospitals. Rather, the commenter believed that Congress made a deliberate decision to limit the benefits of the 340B Program only to Medicare hospitals that serve large numbers of low-income or other underprivileged patients. In addition, the commenter stated that when Congress has intended Federal health care programs to intrude upon the 340B Program, it has been crystal clear.

In contrast, commenters asserted that Congress has been wholly silent on the relationship between 340B and Medicare Part B, which indicates Congress's intent that Medicare should not ''encroach'' upon the 340B Program

by ''redistributing [340B] discounts to non-340B providers.'' The commenters noted that the 340B statute and Medicare have coexisted for several years and that Congress has had ample opportunity to amend the Medicare statute governing Part B payments and/or the 340B statute to expressly permit CMS to reduce Medicare payments to 340B hospitals, but has not done so. As an example, the commenters cited legislation enacted in 2010, in which Congress amended both the 340B and the Medicare statutes, but did not authorize CMS to redistribute 340B savings to non-340B hospitals or to Part B generally.

Commenters further asserted that the proposed cut to 340B hospitals is also contrary to Congress's intent for the 340B Program to enable safety-net providers to reach more patients and furnish more comprehensive services and would undermine this purpose by preventing the operation of the 340B statute. These commenters suggested that, although manufacturers would still have to give 340B discounts, 340B participating hospitals would receive no benefit from those discounts; thus, the statutory purpose of 340B would be fatally undermined.

Response: We do not believe that this proposal under section 1833(t) of the Act is in conflict with section 340B of the Public Health Service Act. Section 1833(t) of the Act governs Medicare payment policies for covered hospital outpatient department services paid under the OPPS, while section 340B of the Public Health Service Act governs eligibility and program rules for participation in the 340B Program. There are no references in either section of law to each other. In fact, the failure of either statute to reference the other proves the opposite—that each statute stands on its own and neither is hindered or rendered null and void by the other. There is no requirement in the Public Health Service Act that the 340B Program ''guarantee'' or provide a certain profit from the Medicare program. Likewise, there is no requirement in section 1833(t) of the Act to pay a particular rate for a hospital enrolled in the 340B Program. We agree with the commenters that Congress was aware of both the 340B Program and the OPPS and of the programs' relationships to one another. However, we believe that the silence of each statute with respect to the other should not be viewed as a constraint on the broad authority conferred to the Secretary under section 1833(t) of the Act to establish payment rates under the OPPS.

Furthermore, we are unaware of legislative history or other evidence to corroborate the commenters' belief that Congress' silence on the relationship between 340B and Medicare Part B OPPS payments should be viewed as constraining the Secretary's ability under section 1833(t)(14) of the Act as to how to calculate payment rates for drugs acquired under the 340B Program under the OPPS. While legislative silence can be difficult to interpret, we note that Congress' silence regarding the 340B Program in enacting Medicare OPPS payment for certain drugs would create the opposite inference. The 340B Program existed well before Congress enacted the Medicare OPPS and payment for certain drugs. If Congress wanted to exempt 340B drugs or entities with a 340B agreement from Medicare OPPS payment for drugs generally, it easily could have done so. Instead, Congress provided for Medicare OPPS drug payments ''as calculated and adjusted by the Secretary as necessary,'' without any mention of, or restriction regarding, the already existent 340B Program.

We also disagree with commenters who believe that implementing the OPPS payment methodology for 340B-acquired drugs as proposed will ''eviscerate'' or ''gut'' the 340B Program. As discussed earlier in the background section, the findings from several 340B studies conducted by the GAO, OIG, and MedPAC show a wide range of discounts that are afforded to 340B hospitals, with some reports finding discounts of up to 50 percent. As stated in the proposed rule, we believe ASP minus 22.5 percent is a conservative estimate of the discount for 340B-acquired drugs and that even with the reduced payment, hospitals will continue to receive savings that can be directed at programs and services to carry out the intent of the 340B Program.

With respect to the comment that the proposal would frustrate the intent of the 340B Program and redirect Medicare payments to other hospitals that do not participate in the 340B Program, we reiterate that we proposed to redistribute the savings in an equal and offsetting manner to all hospitals paid under the OPPS, including those in the 340B Program, in accordance with the budget neutrality requirements under section 1833(t)(9)(B) of the Act. However, we remain interested in exploring ways to better target the offsetting amount to those hospitals that serve low-income and uninsured patients, as measured by uncompensated care. Details on the redistribution of funds are included in section XVIII. of this final rule with comment period.

• Proposal Is Procedurally Defective and Inconsistent With Advisory Panel Recommendations

Comment: Some commenters contended that the proposal is procedurally defective under the OPPS statute. The commenters asserted that the Secretary's justification for the proposed reduced rate rests, in part, on intertwined issues related to clinical use and hospital cost of drugs. The commenters objected to CMS' reference to studies suggesting that 340B hospitals may be unnecessarily prescribing more drugs and/or more expensive drugs relative to non-340B hospitals as support for proposing a payment rate that eliminates the differential between acquisition cost and Medicare payment. These commenters cited other studies in an effort to refute the evidence presented in the proposed rule.[29] [30] The commenters believed that CMS should have asked the HOP Panel to consider the intertwined issues of drug cost and clinical use prior to making a proposal to reduce payment for 340B-acquired drugs, and the Secretary should have consulted with the HOP Panel in accordance with section 1833(t)(9)(A) of the Act, as part of the process of review and revision of the payment groups for covered outpatient department services and the relative payment weights for the groups. The commenters argued that, because the Secretary did not consult with the HOP Panel before publishing its 340B payment proposal, the Secretary acted contrary to the statute. The commenters noted that at the August 21, 2017 meeting of the HOP Panel that occurred after publication of the proposed rule, the Panel urged that CMS not finalize the proposed payment reduction.

At the August 21, 2017 meeting of the HOP Panel, the Panel made the following recommendations with respect to the proposed policy for OPPS payment for drugs acquired under the 340B Program:

The Panel recommended that CMS:

• Not finalize its proposal to revise the payment rate for drugs purchased under the 340B Program;

• Collect data from public comments and other sources, such as State

[29] Dobson Davanzo & Associates, Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals (Nov. 15, 2016). Available at: *http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf.*

[30] Dobson DaVanzo, Analysis of the Proportion of 340B DSH Hospital Services Delivered to Low-Income Oncology Drug Recipients Compared to Non-340B Provider (2017). Available at: *http://www.340bhealth.org/files/LowIncomeOncology.pdf*;

Medicaid programs in Texas and New York, on the potential impact of revising the payment rate, implementing a modifier code, and the effects of possible mechanisms for redistributing the savings that result from changing the payment rate; and

• Assess the regulatory burden of changing the payment rate and the potential impact on 340B hospitals of redistributing dollars saved.

In addition, one commenter suggested that the proposal was ''procedurally defective'' because the proposal was solely articulated through preamble and did not propose to amend the Code of Federal Regulations (CFR). The commenter asserted that the proposal cannot be implemented without a change to the Medicare regulations and stated that the Medicare statute requires CMS to issue regulations when altering the substantive standards for payment.[31] The commenter stated that the proposal falls squarely within this requirement because it would change the substantive legal standard governing payments to 340B hospitals for separately payable drugs.

Another commenter stated that CMS' proposal also violates section 1833(t)(2)(E) of the Act because the agency is not authorized and did not offer a reasoned basis for applying savings achieved as a result of its proposal to reduce significantly payments to 340B hospitals to Part B services generally. Likewise, a few commenters stated that the Administrative Procedure Act (APA) requires the Secretary to offer a ''reasoned basis'' for proposing to take an unprecedented action. The commenters suggested that, as a matter of longstanding policy and practice, the Secretary has never applied such a sweeping change to drug rates nor has it ever applied savings from OPPS outside of the OPPS.

Response: We remind the commenters that our proposal was based on findings that ASP minus 22.5 percent reflects the minimum average discount that hospitals in the 340B Program receive. We are familiar with the reports the commenters referenced in their comments. However, we continue to believe, based on numerous studies and reports, that 340B participation is not well correlated to the provision of uncompensated care and is associated with differences in prescribing patterns and drug costs. For example, as noted earlier in this section, GAO found that ''in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals,'' thus indicating that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis.

With respect to the HOP Panel, we believe that this comment reflects a misunderstanding of the Panel's role in advising the Secretary. Section 1833(t)(9)(A) of the Act provides that the Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

The provisions described under section 1833(t)(9)(A) of the Act do not impose an obligation on the Secretary to consult with the HOP Panel *prior* to issuing a notice of proposed rulemaking nor do they require the Secretary to adopt the Panel's recommendation(s). Rather, the statute provides that the Secretary shall consult with the Panel on policies affecting the clinical integrity of the ambulatory payment classifications and their associated weights under the OPPS. The Secretary met the requirement of section 1833(t)(9)(A) of the Act at the HOP Panel August 21, 2017 meeting in which the Panel made recommendations on this very proposed policy. The HOP Panel's recommendations, along with public comments to the proposed rule, have all been taken into consideration in the development of this final rule with comment period.

While we are not accepting the HOP Panel's recommendation not to finalize the payment reduction for drugs purchased under the 340B Program, as discussed later in this section, we are modifying our position on the modifier in an effort to ease administrative burden on providers, taking into account the way in which the modifier is used in several State Medicaid programs, as the Panel recommended. In addition, we have collected data from public comments on the potential impact of revising the payment rate, implementing a modifier, and the effects of possible mechanisms for redistributing the ''savings'' (or the dollars that result) from changing the payment rate and have assessed the regulatory burden of changing the payment rate and the potential impact on 340B hospitals of redistributing dollars saved, all of which were steps the HOP Panel recommended we take.

Regarding the comments asserting that the Secretary is out of compliance with procedures used to promulgate regulations as described under section 1871 of the Act (42 U.S.C. 1395hh), we note that we have received public comments on our interpretation of the Medicare statute, and we respond to those comments above. We further note that we did not establish in the Code of Federal Regulations the rates for separately payable, nonpass-through drugs and biologicals in past rulemakings. Because we have not adopted regulation text that prescribes the specific payment amounts for separately payable, nonpass-through drugs and biologicals, there was no regulation text to amend to include our proposed payment methodology for drugs acquired under the 340B Program. However, this does not mean that payment rates for separately payable drugs were not available to the public. That information is available in Addendum B to this final rule with comment period, which lists the national payment rates for services paid under the OPPS, including the payment rates for separately payable drugs and biologicals based on ASP+6 percent. We note that we have not provided the reduced payment rates for separately payable drugs and biologicals acquired under the 340B Program in Addendum B, but hospitals can arrive at those rates using the ASP+6 percent rate that is included in Addendum B. Finally, with respect to comments on redistribution of the dollars that result from the 340B payment policy, we are finalizing our proposal to achieve budget neutrality for the payment reduction for 340B-acquired drugs through an increase in the conversion factor. We disagree that our proposal to apply budget neutrality in accordance with section 1833(t)(9)(B) of the Act violates the APA or statutory authority. Further, we note that if we decide to take a different approach with respect to the redistribution of funds for budget neutrality in the future, we will consider such approach in future rulemaking.

• Impact on Medicare Beneficiary Cost-Sharing

Comment: Some commenters noted that Medicare beneficiaries, including dual-eligible Medicare beneficiaries,

[31] ''No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation. . . .'' Section 1871 of the Social Security Act (42 U.S.C. 1395hh).

would not directly benefit from a lowered drug copayment amount. The commenters noted that many beneficiaries have supplemental insurance that covers their out-of-pocket drug costs, in whole or in part. These commenters asserted that the proposal would actually increase their out-of-pocket costs for other Part B benefits.

Response: The cost-sharing obligation for Medicare beneficiaries is generally 20 percent of the Medicare payment rate. While many Medicare beneficiaries may have supplemental coverage that covers some or all of their out-of-pocket expenses, not all beneficiaries have such coverage. This policy will lower both the amount that a beneficiary is responsible to pay as well as the amount that any supplemental insurance, including the Medicaid program, will pay on behalf of the beneficiary. While we are implementing this policy in a budget neutral manner equally across the OPPS for CY 2018 for non-drug items and services, we may revisit how any savings from the lowered drug payment rate for 340B drugs may be allocated in the future and continue to be interested in ways to better target the savings to hospitals that serve the uninsured and low-income populations or that provide a disproportionate share of uncompensated care.

In addition, as noted earlier in this section, in the hospital setting, not only are beneficiaries liable for cost-sharing for drugs they receive, but they also incur a ''facility fee'' solely because the drug was furnished in the hospital setting. As described in section II.A.3.b. of this final rule with comment period, for CY 2018, we are adopting a policy to conditionally package Level 1 and Level 2 drug administration services and believe that these steps taken together may help encourage site-neutral care in that beneficiaries may receive the same drugs and drug administration services at the physician office setting without a significant difference in their financial liability between settings.

• *Calculation of Savings*

Comment: Commenters disagreed with CMS' impact estimate and a few commenters provided their own analysis of the 340B drug payment proposal. One commenter believed that even if CMS implements the policy as proposed, in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor, payments for non-drug APCs would increase across hospitals by approximately 3.7 percent (in contrast to CMS' estimate of 1.4 percent). According to the commenter, this redistribution would result in a net decrease in payments to 340B hospitals of approximately 2.6 percent, or approximately $800 million. The commenter asserted that CMS' proposal would remove $800 million intended to support what it referred to as the congressionally mandated mission of 340B hospitals from these already vulnerable facilities and redistribute these dollars to other hospitals that do not participate in the 340B Program. Likewise, the commenter challenged CMS' suggested alternative approaches to achieving budget neutrality, such as applying offsetting savings to specific services within the OPPS or outside of the OPPS to Part B generally (such as to physician services under the Medicare Physician Fee Schedule), which the commenter believed would similarly penalize these most vulnerable hospitals and inhibit their efforts to carry out the purpose of the 340B Program. Finally, other commenters noted that implementing the proposed policy in a non-budget neutral manner would effectively ''gut'' the 340B Program.

Response: With respect to comments on the proposed distribution of savings, we refer readers to section XVIII. of this 2018 OPPS/ASC final rule with comment for discussion on the redistribution of savings that result from the estimated impact of the 340B policy as well as calculation of budget neutrality. Briefly, for CY 2018, we are implementing the alternative payment methodology for drugs purchased under the 340B Program in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor for nondrug services. Therefore, the resulting savings from the 340B payment policy will be redistributed pro rata through an increase in rates for non-drug items and services under the OPPS. We have already addressed comments relating to the assertion that our proposal would ''gut'' or ''eviscerate'' the 340B Program. Likewise, we have addressed the interaction between our authority under section 1833(t)(14)(A) of the Act relative to section 340B of the Public Health Service Act in our responses above.

(3) Other Areas

Comment: MedPAC commented reiterating its recommendations to Congress in its March 2016 Report to the Congress. Specifically, MedPAC commented that it recommended that payment rates for all separately payable drugs provided in a 340B hospital should be reduced to 10 percent of the ASP rate (resulting in ASP minus 5.3 percent after taking application of the sequester into account). MedPAC noted that its March 2016 report also included a recommendation to the Congress that savings from the reduced payment rates be directed to the Medicare-funded uncompensated care pool, which would target hospitals providing the most care to the uninsured, and in that way benefit indigent patients, and that payments be distributed in proportion to the amount of uncompensated care that hospitals provide. MedPAC believed that legislation would be needed to direct drug payment savings to the uncompensated care pool and noted that current law requires the savings to be retained with the OPPS to make the payment system budget neutral. MedPAC encouraged the Secretary to work with Congress to enact legislation necessary to allow MedPAC's recommendation to be implemented, if such recommendation could not be implemented administratively. MedPAC further noted that legislation would also allow Medicare to apply the policy to all OPPS separately payable drugs, including those on pass-through payment status.

Response: We thank MedPAC for its comments and for its clarification that its recommendation that ''[t]he Congress should direct the Secretary of the Department of Health and Human Services to reduce Medicare payment rates for 340B hospitals' separately payable 340B drugs by 10 percent of the average sales price (ASP)'' was intended to be 10 percent lower than the current Medicare rate of ASP+6 percent and would result in a final OPPS payment of ASP minus 5.3 percent when taking the sequester into account. However, we do not believe that reducing the Medicare payment rate by only 10 percentage points below the current payment rate of ASP+6 percent (that is, ASP minus 4 percent) would better reflect the acquisition costs incurred by 340B participating hospitals. In its May 2015 Report to the Congress, MedPAC estimated that the average minimum discount for a 340B hospital paid under the OPPS was ASP minus 22.5 percent, which it noted was a conservative, ''lower bound'' estimate. Further, in its March 2016 Report to the Congress, MedPAC stated that, ''[i]n aggregate, the Office of Inspector General (OIG) estimates that discounts across all 340B providers (hospitals and certain clinics) average 34 percent of ASP, allowing these providers to generate significant profits when they administer Part B drugs (MedPAC March 2016 Report to Congress, page 76). MedPAC further noted the estimate of the aggregate discount was based on all covered entities (hospitals and certain clinics).

Because 340B hospitals accounted for 91 percent of Part B drug spending for all covered entities in 2013, it is reasonable to assume that 340B hospitals received a discount similar to 33.6 percent of ASP (MedPAC March 2016 Report to Congress, page 79).

Further, as we stated in the proposed rule, the GAO reported that the amount of the 340B discount ranges from an estimated 20 to 50 percent discount, compared to what the entity would have otherwise paid to purchase the drug. In addition, voluntary participation in the PVP results in a covered entity paying a subceiling price on certain covered outpatient drugs (estimated to be approximately 10 percent below the ceiling price). (U.S. Department of Health and Human Services, HRSA FY 2018 Budget Justification)

Accordingly, we continue to believe that ASP minus 22.5 percent represents a conservative estimate of the average minimum discount that 340B-enrolled hospitals paid under the OPPS receive for drugs purchased with a 340B Program discount and that hospitals likely receive an even steeper discount on many drugs, especially brand name drugs. We also continue to believe that section 1833(t)(14)(A)(iii)(II) of the Act allows the Secretary to make adjustments, if hospital acquisition cost data is not available, as necessary, so that the Medicare payment rate better represents the acquisition cost for drugs and biologicals that have been acquired with a 340B discount.

With respect to MedPAC's comment regarding targeting the savings to uncompensated care, we refer readers to section XVIII.A.5. of this final rule with comment period.

• Comments Regarding Rural Hospitals

Comment: Commenters representing rural hospitals, particularly RRCs and SCHs, expressed opposition to the proposal, noting that it could be especially harmful to rural hospitals in light of the ''hospital closure crisis.'' One commenter cited a report from a health analytics company and noted that since 2010, 80 rural hospitals have closed and that one-third of remaining rural hospitals are vulnerable to closure, with 41 percent of rural hospitals operating at a financial loss.

Commenters noted that rural hospitals enrolled in the 340B Program depend on the drug discounts to provide access to expensive, necessary care such as labor and delivery and oncology infusions. The commenters stated that rural Americans are more likely to be older, sicker, and poorer than their urban counterparts. The commenter gave examples of rural hospitals that have used profit margins on 340B-acquired drugs to offset uncompensated care and staff emergency departments. In addition, the commenters stated that a portion of rural hospitals are excluded from purchasing orphan drugs through the 340B Program. Therefore, the commenters stated, these hospitals often use their 340B savings to offset the expense of purchasing orphan drugs, which they note comprise a growing number of new drug approvals.

In addition, a commenter representing several 340B-enrolled hospitals stated that multiple hospitals report that the 340B Program is the reason the hospital can provide oncology infusions in their local community and that the chemotherapy infusion centers tend to be small with variation in patients served based on the needs of the community. The commenter stated that, without the 340B Program, many rural hospitals would likely need to stop providing many of the outpatient infusions, thereby forcing patients to either travel 35 miles (in the case of SCHs which must generally be located at least 35 miles from the nearest like hospital) to another facility or receive care in a hospital inpatient setting, which is a more costly care setting. Another commenter, a member of Congress representing a district in the State of Ohio, commented that while the 340B Program is in need of reform, the program remains an important safety net for rural hospitals in Ohio and around the country. The commenter stated that 340B hospitals offer safety-net programs to their communities, including opioid treatment programs, behavioral health science programs, and others. The commenter further stated that the 340B drug payment proposal did not address broader structural issues with the 340B Program itself, including lack of oversight and clear guidance and definitions, and that the proposal could harm the hospitals that the 340B Program was intended to help. In addition, the commenter noted that ''arbitrary cuts'' to the 340B Program for safety-net hospitals could have detrimental impacts on the economic growth and opportunities in the communities those hospitals serve and that the proposal does not advance the larger goals of 340B Program reform.

One commenter noted that SCHs face 47.5 percent higher levels of bad debt and 55 percent lower profit margins. Thus, even with 340B discounts, the commenter argued that rural hospitals like rural SCHs are financially threatened. Commenters also noted that rural hospitals are typically located in lower income economic areas and are not able to absorb the proposed reduction in drug payment for 340B purchased drugs. Moreover, commenters suggested that the proposal disproportionately impacts rural hospitals compared to its effect on urban hospitals.

Finally, commenters requested that, if CMS finalizes the policy as proposed, CMS exempt hospitals with a RRC or SCH designation from the alternative 340B drug payment policy. The commenters asserted that RRCs and SCHs are rural safety-net hospitals that provide localized care for Medicare beneficiaries and also serve as ''economic engines'' for many rural communities.

Response: We share commenters' concerns about access to care, especially in rural areas where access issues may be even more pronounced than in other areas of the country. We note our proposal would not alter covered entities' access to the 340B Program. The alternative 340B drug payment methodology solely changes Medicare payment for 340B-acquired drugs.

Medicare has long recognized the particularly unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006.

In the CY 2018 OPPS/ASC proposed rule, we sought public comment for future policy refinements on whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPPS (for example, rural SCHs or PPS-exempt cancer hospitals) if a policy were adopted to adjust OPPS payments for drugs acquired under the 340B program. Taking into consideration the comments

regarding rural hospitals, we believe further study on the effect of the 340B drug payment policy is warranted for classes of hospitals that receive statutory payment adjustments under the OPPS. In particular, given challenges such as low patient volume, it is important that we take a closer look at the effect of an ASP minus 22.5 percent payment on rural SCHs.

With respect to RRCs, we note that there is no special payment designation for RRCs under the OPPS. By definition, RRCs must have at least 275 beds and therefore are larger relative to rural SCHs. In addition, RRCs are not subject to a distance requirement from other hospitals. Accordingly, at this time, we are not exempting RRCs from the 340B payment adjustment.

For CY 2018, we are excluding rural SCHs (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes) from this policy. We may revisit our policy to exempt rural SCHs, as well as other hospital designations for exemption from the 340B drug payment reduction, in the CY 2019 OPPS rulemaking.

• Children's and PPS-Exempt Cancer Hospitals

Comment: Commenters representing children's hospitals (''children's'') raised objections to the proposal because of the potential impact on the approximate 8,000 children with end-stage renal disease (ESRD) who are eligible for Medicare. One commenter cited that currently 48 children's hospitals participate in the 340B Program and rely on the savings the program provides to enhance care for vulnerable children. According to the commenter, pediatric ESRD patients require high levels of care and rely on life-saving pharmaceuticals that often come at a high cost. Therefore, the commenters posited that it is because children's patients are more expensive to treat and not because of inappropriate drug use that 340B hospitals incur higher drug expenditures. In addition, the commenters expressed concern with the effect the 340B drug payment policy may have on State Medicaid programs, considering Medicaid is the predominant payer type for children's hospitals. The commenters requested that, unless CMS is able to examine the impact on pediatric Medicare beneficiaries, CMS should exempt children's hospitals from the alternative 340B drug payment methodology.

An organization representing PPS-exempt cancer hospitals commented that CMS' proposal would severely harm the hospitals that treat the most vulnerable and underserved patients and communities, undermining these hospitals' ability to continue providing programs designed to improve access to services. The commenter believed that assumptions alluded to in the CY 2018 OPPS/ASC proposed rule, which suggested that providers are abusing the savings generated from the 340B Program or potentially creating incentives to over utilize drugs, are inaccurate and that clinicians provide the care that is necessary to treat a patient's disease. The commenter suggested that CMS work with, or defer to, HRSA to first conduct a complete analysis of how the 340B Program is utilized for the benefit of patients prior to proposing any changes to Medicare payment for drugs purchased through the program.

Response: We share the commenters' views on protecting access to high quality care for all Medicare beneficiaries, including those treated in children's or PPS-exempt cancer hospitals. Further, because of how these classes of hospitals are paid under the OPPS, we recognize that the 340B drug payment proposal may not result in reduced payments for these hospitals in the aggregate.

Specifically, in accordance with section 1833(t)(7)(D)(ii) of the Act, we make transitional outpatient payments (TOPs) to both children's and PPS-exempt cancer hospitals. That is, these hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS. Accordingly, if we were to reduce drug payments to these hospitals on a per claim basis, it is very likely that the reduction in payment would be paid back to these hospitals at cost report settlement, given the TOPs structure.

Accordingly, we believe it is appropriate to exempt children's and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology for CY 2018. Therefore, for CY 2018, we are excluding children's and PPS-exempt cancer hospitals from the alternative 340B drug payment policy. As discussed in a later section in this final rule with comment period, because we are redistributing the dollars in a budget neutral manner within the OPPS through an offsetting increase to the conversion factor, children's hospitals and PPS-exempt cancer hospitals will receive a higher payment when providing a non-drug service.

In summary, we are adopting for CY 2018 an exemption for rural SCHs, children's hospitals, and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology. These three types of hospitals will not be subject to a reduced drug payment for drugs that are purchased under the 340B Program in CY 2018. We may revisit the specific types of hospitals excluded, if any, from the 340B payment policy in CY 2019 rulemaking. However, as discussed in more detail below, it remains important to collect information on which drugs being billed to Medicare were acquired under the 340B Program. Accordingly, these three types of hospitals will still be required to report an informational modifier ''TB'' for tracking and monitoring purposes. We may revisit this 340B drug payment policy, including whether these types of hospitals should continue to be excepted from the reduced Medicare payment rate, in future rulemaking.

• Biosimilar Biological Products

Comment: Some commenters expressed opposing views about applying the proposed 340B payment methodology to biosimilar biological products. One pharmaceutical manufacturer recommended that the Secretary use his equitable adjustment authority at section 1833(t)(2)(E) of the Act to apply a narrow equitable adjustment to biosimilar biological products with pass-through payment status to pay for these drugs at ASP minus 22.5 percent of the reference product rather than ASP+6 percent of the reference product. The commenter asserted that excluding biosimilar biological products from the alternative 340B payment methodology would result in a significant payment differential between biosimilar biological products and reference products which may cause providers to switch patients to different products for financial reasons, rather than clinical factors. The commenter stated that, if the policy is implemented as proposed, the competitive biosimilar marketplace would significantly change because Medicare would pay more for the biosimilar biological product with pass-through payment status and weaken market forces. The commenter estimated that if the 340B drug policy is implemented as proposed, up to $50 million of any savings could be lost due to hospitals switching to the biosimilar biological product on pass-through payment status (that will be paid at ASP+6 percent of the reference product). Moreover, the commenter pointed out that CMS' policy to only provide pass-through payments for the

first eligible biosimilar biological product of any reference biological would also create a similar payment disadvantage for any subsequent biosimilar biological product, which would be ineligible for pass-through payment under CMS' policy.

Another commenter, a different pharmaceutical manufacturer, requested that CMS exclude biosimilar biological products from the proposed payment adjustment until such time as the biosimilar biological product market is better established. The commenter indicated that while a biosimilar biological product is less expensive to the Medicare program, hospitals are incented by the 340B Program to purchase the originator product because of ''the spread'' or payment differential with respect to the originator product. Moreover, the commenter stated that applying the proposed adjustment to payment for biosimilar biological products in certain hospitals will retain market share for the more expensive reference product that is further compounded by market practices of volume-based rebates and exclusionary contracts for the reference product.

Response: We understand the commenters' concerns. As discussed in section V.B.2. of this CY 2018 OPPS/ASC final rule with comment period, we are adopting the biosimilar biological products HCPCS coding established under the CY 2018 MPFS final rule. Briefly, we adopted a final policy to establish separate HCPCS codes for each biosimilar biological product for a particular reference product beginning January 1, 2018. In addition, we also stated in section V.B.2. of this CY 2018 OPPS/ASC final rule with comment period that we are making a conforming amendment to our pass-through payment policy for biosimilar biological products such that each FDA-approved biosimilar biological product will be eligible for transitional pass-through payment instead of only the first biosimilar for a particular reference product.

Therefore, given the policy changes affecting coding and payment for biosimilar biological products that we are adopting in the CY 2018 MPFS final rule and this CY 2018 OPPS/ASC final rule with comment period, we disagree with the commenters that we should exclude biosimilar biological products from the 340B payment policy or use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to adjust payment to ASP minus 22.5 percent of the reference product for biosimilar biological products with pass-through payment status. We believe the statutory provision on transitional drug pass-through payment under section 1833(t)(6)(D)(i) of the Act provides for an explicit payment for drugs eligible for pass-through payment. Therefore, we are unable to accept the commenter's request to pay a biosimilar biological product on pass-through payment status the reduced 340B payment rate. We are adopting a policy that any biosimilar biological product with pass-through payment status will be exempt from the alternative payment methodology for 340B drugs and will continue to be paid at ASP+6 percent of the reference product. Biosimilar biological products that are not on pass-through payment status will be paid ASP minus 22.5 percent of the reference product. We believe it is appropriate to pay this amount for biosimilar biological products as it is consistent with the amount paid for non-340B-acquired biosimilar biological products, which is ASP+6 percent of the reference product. Currently, there are two biosimilar biological products available on the market and both are on pass-through payment status for the entirety of CY 2018. Therefore, no biosimilar biological products currently available will be affected by the alternative payment methodology for 340B-acquired drugs for CY 2018. We recognize the concerns about paying different rates for similar drugs and biologicals and continue to assess the feasibility and practicality of an alternative 340B payment adjustment for biosimilar biological products in the future.

- Nonexcepted Off-Campus Hospital Outpatient Departments

Comment: A few commenters noted that CMS' proposed alternative payment methodology for 340B purchased drugs would not apply to nonexcepted off-campus provider-based departments (PBDs) of a hospital and could result in behavioral changes that may undermine CMS' policy goals of reducing beneficiary cost-sharing liability and undercut the goals of section 603 of the Bipartisan Budget Act of 2015. Commenters recommended that, if CMS adopts a final policy to establish an alternative payment methodology for 340B drugs in CY 2018, CMS also apply the same adjustment to payment rates for drugs furnished in nonexcepted off-campus PBDs of a hospital if such drugs are acquired under the 340B Program. In addition, the commenters believed that because CMS did not propose to limit the expansion of services or volume increases at excepted off-campus PBDs, CMS will create financial incentives for hospitals to shift or reallocate services to the site of care that pays the highest rate for an item or service.

Response: We appreciate the commenter's concerns about potential unintended consequences of our proposal. We will continue to monitor the billing patterns of claims submitted by nonexcepted off-campus outpatient PBDs as we continue to explore whether to pursue future rulemaking on the issues of clinical service line expansion or volume increases, and other related section 603 implementation policies.

In the CY 2017 OPPS/ASC final rule with comment period, we discussed the provision of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 144–74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended the OPPS statute at section 1833(t) by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered outpatient department services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met (81 FR 79699). We issued an interim final rule with comment period along with the CY 2017 OPPS/ASC final rule with comment period to establish the MPFS as the ''applicable payment system,'' which will apply in most cases, and payment rates under the MPFS for non-excepted items and services furnished by nonexcepted off-campus outpatient provider based departments (PBDs) (81 FR 79720). (Other payment systems, such as the Clinical Laboratory Fee Schedule, continue to apply in appropriate cases.) That is, items and services furnished by nonexcepted off-campus outpatient PBDs, are nonexcepted items and services that are not covered outpatient services, and thus, are not payable under the OPPS. Rather, these nonexcepted items and services are paid ''under the applicable payment system,'' which, in this case, is generally the MPFS.

As we discussed in the CY 2017 OPPS/ASC interim final with comment period (81 FR 79718) and reiterated in the CY 2018 MPFS final rule, payment for Part B drugs that would be separately payable under the OPPS (assigned status indicator ''K'') but are not payable under the OPPS because they are furnished by nonexcepted off-campus outpatient PBDs will be paid in accordance with section 1847A of the Act (generally, ASP+6 percent),

consistent with Part B drug payment policy in the physician office. We did not propose to adjust payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018 but may consider adopting such a policy in CY 2019 notice-and-comment rulemaking.

• Data Collection and Modifier

Comment: The vast majority of commenters objected to CMS' intention to require hospitals that *do not* purchase a drug or biological through the 340B program to apply a modifier to avoid a reduced drug payment. A few commenters supported the modifier proposal. The commenters who disagreed with proposal stated that it would place an unnecessary administrative and financial burden on hospitals that do not participate or are not eligible to participate in the 340B Program. Similarly, the commenters stated that the modifier requirement as described in the proposed rule would put a financial and administrative strain on hospitals with fewer resources. In addition, the commenters contended that a requirement for hospitals to report a modifier for drugs that were not acquired under the 340B Program would place hospitals at significant risk for noncompliance if not implemented correctly, which many commenters believe is nearly impossible to do. As an alternative approach, numerous commenters recommended that CMS require hospitals that *do* purchase a drug under the 340B Program to report the modifier, rather than those that do not.

Regarding a January 1, 2018, implementation date for the modifier, some commenters expressed concern and doubted their ability to implement the modifier as described in the proposed rule accurately. The commenters indicated that additional time would be needed to adapt billing systems, allow for testing of claims reported with the modifier, and educate staff. Based on discussion of how the modifier would work in the proposed rule, the commenters stated that hospitals would either have to append the modifier to the claim at the time the drug is furnished, or retroactively apply the modifier, thus delaying claims submission to Medicare.

The commenters provided detailed descriptions on hospital pharmacy set up, including information on software tools to support inventory management of drugs dispensed to 340B and non-340B patients (based on HRSA definition of an eligible patient). One commenter indicated that the drug supply system used for purchasing covered outpatient drugs is completely separate from—and does not necessarily communicate with—the hospital's pharmacy drug dispensing and patient billing systems. While these software tools enable split-billing to distinguish 340B and non-340B patients, the commenters noted that this patient determination is typically not done in real time when a drug is administered. Commenters noted that 340B hospitals that use split-billing software do not receive information on 340B patient status on a daily basis and the proposal could result in delayed billing. The commenters stated that hospitals typically make these determinations retrospectively and it may be 3 to 10 days post-dispensing before the hospital knows whether a drug was replenished under 340B or at regular pricing. The commenters noted that, under this ''replenishment model,'' hospitals track how many 340B-eligible drugs are used, and once enough drugs are dispensed to complete a package, they will replenish the drug at the 340B rate. As such, the commenters argued that hospitals do not know when the drug is dispensed whether it will cost them the 340B rate or the wholesale acquisition cost (WAC). Therefore, the commenters expressed concern that the modifier requirement as described in the proposed rule would result in billing delays and, for some hospitals, may cause a short-term interruption in cash flow.

In addition, the commenters requested that, while the payment reduction would apply to nonpass-through separately payable drugs purchased with a 340B discount, CMS accept the modifier when reported with drug HCPCS codes that are packaged (and for which no separate payment will be made) to reduce or prevent operational burden that may be caused if affected providers have to determine on a claim-by-claim basis whether a drug is eligible for separate payment.

With respect to State Medicaid programs that also require a modifier to identify 340B-purchased drugs on outpatient claims, the commenters noted that CMS' proposal would be counter to Medicaid requirements and would create confusion and add complexity for providers who treat Medicaid recipients in multiple states. The commenters reported that many State Medicaid programs require a modifier to identify drugs that were purchased under 340B to administer their Medicaid drug rebate programs to prevent duplicate discounts on 340B drugs. The commenters suggested that if CMS reversed its position on application of the modifier, it would ensure crossover claims (claims transferred from Medicare to Medicaid) are correctly interpreted by State Medicaid programs so that they can appropriately request manufacturer rebates on drugs not purchased under the 340B Program. Moreover, some commenters believed that if CMS required the modifier to be reported for 340B-purchased drugs, State Medicaid programs would also adopt the modifier, leading to national uniformity in reporting of 340B drugs.

Finally, in the event that CMS required the modifier on claims for 340B drugs, rather than non-340B drugs, commenters sought clarity on whether the modifier applies only to drugs purchased under the 340B Program which are subject to a ceiling price payment from the manufacturer or if the modifier would also apply to drugs purchased by a 340B-registered facility, but purchased under the Prime Vendor Program for which only 340B facilities are eligible. One commenter asked that CMS emphasize that 340B pricing is not available on drugs furnished to hospital inpatients.

Response: We appreciate the detailed comments that were submitted. As noted in the proposed rule, we did not propose to establish the modifier but rather noted our intent to establish the modifier, regardless of whether we adopted the alternative payment methodology for drugs acquired through the 340B Program. However, we are responding to some of the comments submitted in this final rule with comment period with information on this modifier that we believe is important to communicate as soon as possible. We will consider whether additional details will need to be communicated through a subregulatory process, such as information posted to the CMS Web site.

After considering the administrative and financial challenges associated with providers reporting the modifier as described in the CY 2018 OPPS/ASC proposed rule, and in order to reduce regulatory burden, we are reversing our position on how the modifier will be used by providers to effectuate the payment adjustment for 340B-purchased drugs.

Specifically, beginning January 1, 2018, providers who are not excepted from the 340B payment adjustment will report modifier ''JG'' (Drug or biological acquired with 340B Drug Pricing Program Discount) to identify if a drug *was* acquired under the 340B Program. This requirement is aligned with the modifier requirement already mandated in several States under their Medicaid programs. Therefore, we believe that this option will pose less of an administrative burden. Further, having

consistent application of the modifier being required for a drug that was purchased under the 340B Program instead of a drug not purchased under the 340B Program will help improve program integrity by helping ensure that hospitals are not receiving ''duplicate discounts'' through both the Medicaid rebate program and the 340B Program. The phrase ''acquired under the 340B Program'' is inclusive of all drugs acquired under the 340B Program or PVP, regardless of the level of discount applied to the drug. Drugs that were not acquired under the 340B Program should not be reported with the modifier ''JG''. For separately payable drugs (status indicator ''K''), application of modifier ''JG'' will trigger a payment adjustment such that the 340B-acquired drug is paid at ASP minus 22.5 percent. In response to the commenters' request that we allow the 340B modifier to be reported with status indicator ''N'' drugs (that is, drugs that are always packaged), we will accept modifier ''JG'' or ''TB'' to be reported with a packaged drug (although such modifier will not result in a payment adjustment).

In addition, beginning January 1, 2018, providers that are excepted from the 340B drug payment policy for CY 2018, which include rural SCHs, children's hospitals, and PPS-exempt cancer hospitals, should not report modifier ''JG''. Instead, these excepted providers should report the informational modifier ''TB'' (Drug or Biological Acquired With 340B Drug Pricing Program Discount, Reported for Informational Purposes) to identify OPPS separately payable drugs purchased with a 340B discount. The informational modifier ''TB'' will facilitate the collection and tracking of 340B claims data for OPPS providers that are excepted from the payment adjustment in CY 2018. However, use of modifier ''TB'' will not trigger a payment adjustment and these providers will receive ASP+6 percent for separately payable drugs furnished in CY 2018, even if such drugs were acquired under the 340B Program.

For drugs administered to dual-eligible beneficiaries (that is, beneficiaries covered under both Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B Program, the State Medicaid programs should be aware of modifier ''JG'' to help further prevent inappropriate billing of manufacturer rebates.

With respect to comments about timing to operationalize a modifier, we note that hospitals have been on notice since the proposed rule went on display at the Office of the Federal Register on July 13, 2017 that we intended to establish a modifier to implement the policy for payment of drugs acquired under the 340B Program, if finalized. In addition, the modifier will not be required until January 1, 2018, which after display of this final rule with comment period will give hospitals two additional months to operationalize the modifier. Under section 1835(a) of the Act, providers have 12 months after the date of service to timely file a claim for payment. Therefore, for those hospitals that may need more time to ensure that they are in compliance with the modifier requirements, they have 12 months from the date of service to do so.

Further, to the extent many hospitals already report a modifier through their State Medicaid program, we believe that also requiring the modifier on outpatient claims for 340B-acquired drugs paid for under the OPPS would not be a significant administrative burden and would promote consistency between the two programs. With respect to providers in States that are not currently required to report a modifier under the Medicaid program, we note that providers are nonetheless responsible for ensuring that drugs are furnished to ''covered patients'' under the 340B Program and, therefore, should already have a tracking mechanism in place to ensure that they are in compliance with this requirement. Furthermore, modifiers are commonly used for payment purposes; in this case, the presence of the modifier will enable us to pay the applicable 340B drug rate of ASP minus 22.5 percent and track these claims in the Medicare data (in the case of ''JG'' modifier) and will allow us to track other drugs billed on claims that are not subject to the payment reduction (modifier ''TB''). In addition, the presence of the both modifiers will enable Medicare and other entities to conduct research on 340B-acquired drugs in the future.

We remind readers that our 340B payment policy applies to only OPPS separately payable drugs (status indicator ''K'') and does not apply to vaccines (status indicator ''L'' or ''M''), or drugs with transitional pass-through payment status (status indicator ''G'').

Finally, Federal law permits Medicare to recover its erroneous payments. Medicare requires the return of any payment it erroneously paid as the primary payer. Medicare can also fine providers for knowingly, willfully, and repeatedly billing incorrectly coded claims. Providers are required to submit accurate claims, maintain current knowledge of Medicare billing policies, and ensure all documentation required to support the validity of the services reported on the claim is available upon request.

d. Summary of Final Policies for CY 2018

In summary, for CY 2018, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, separately payable Part B drugs (assigned status indicator ''K''), other than vaccines and drugs on pass-through payment status, that meet the definition of ''covered outpatient drug'' as defined in the section 1927(k) of the Act, that are acquired through the 340B Program or through the 340B PVP at or below the 340B ceiling price will be paid at the ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator ''L'' or ''M'') and drugs with OPPS transitional pass-through payment status (assigned status indicator ''G''). Medicare will continue to pay drugs that were not purchased with a 340B discount at ASP+6 percent.

Effective January 1, 2018, biosimilar biological products not on pass-through payment status that are purchased through the 340B program or through the 340B PVP will be paid at ASP minus 22.5 percent of the reference product's ASP, while biosimilar biological products on drug pass-through payment status will continue to be paid ASP+6 percent of the reference product.

To effectuate the payment adjustment for 340B-acquired drugs, CMS is implementing modifier ''JG'', effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as CAHs or those hospitals paid under the Maryland waiver) or excepted from the 340B drug payment policy for CY 2018, are required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural SCHs, children's hospitals and PPS-exempt cancer hospitals will be excepted from the 340B payment adjustment. These hospitals will be required to report informational modifier ''TB'' for 340B-acquired drugs, and will continue to be paid ASP+6 percent.

To maintain budget neutrality within the OPPS, the estimated $1.6 billion in reduced drug payments from adoption of this final alternative 340B drug payment methodology will be redistributed in an equal offsetting amount to all hospitals paid under the OPPS through increased payment rates for non-drug items and services furnished by all hospitals paid under

the OPPS for CY 2018. Specifically, the redistributed dollars will increase the conversion factor across non-drug rates by 3.2 percent for CY 2018.

We may revisit the alternative 340B drug payment methodology in CY 2019 rulemaking.

e. Comment Solicitation on Additional 340B Considerations

As discussed above, we recognize there are data limitations in estimating the average discount for 340B drugs. In the CY 2018 OPPS/ASC proposed rule (82 FR 33634 through 33635), we welcomed stakeholder input with regard to MedPAC's May 2015 analysis and the resulting estimate of ASP minus 22.5 percent as the proposed payment rate for separately payable, nonpass-through OPPS drugs purchased under the 340B Program in CY 2018. We also requested comment on whether we should adopt a different payment rate to account for the average minimum discount of OPPS drugs purchased under the 340B Program. Also, we sought comment on whether the proposal to pay ASP minus 22.5 percent for 340B-acquired drugs should be phased in over time (such as over a period of 2 to 3 years).

In addition, we recognize that the acquisition costs for drugs may vary among hospitals, depending on a number of factors such as size, patient volume, labor market area and case-mix. Accordingly, in the longer term, we are interested in exploring ways to more closely align the actual acquisition costs that hospitals incur rather than using an average minimum discounted rate that would apply uniformly across all 340B hospitals. In the proposed rule, we requested public comment on whether, as a longer term option, Medicare should require 340B hospitals to report their acquisition costs in addition to charges for each drug on the Medicare claim. Having the acquisition cost on a drug-specific basis would enable us to pay a rate under the OPPS that is directly tied to the acquisition costs for each separately payable drug. To the extent that the acquisition costs for some drugs may equal the ceiling price for a drug, we recognize that there may be challenges with keeping the ceiling price confidential as required by section 1927(b)(3)(D) of the Act and we sought comment on this point.

Lastly, for consideration for future policy refinements, we requested public comment on (1) whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPPS (for example, rural SCHs or PPS-exempt cancer hospitals) if a policy were adopted to adjust OPPS payments to 340B participating hospitals (if so, describe how adjusted rates for drugs purchased under the 340B Program would disproportionately affect access in these provider settings); (2) whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment; and (3) whether hospital-owned or affiliated ASCs have access to 340B discounted drugs.

We received feedback on a variety of issues in response to the comment solicitation on additional future considerations. These comments are summarized below.

Comment: One commenter recommended that CMS establish an exemption mechanism for use by stakeholders to request exemptions for certain groups of hospitals. The commenters urged CMS to propose and seek comment on specific guidelines that outline procedures for stakeholders to request an exemption and the criteria CMS would use to determine whether to grant an exception.

Response: We appreciate the comment. As we stated in the summary of final policies, we may revisit the 340B drug payment policy in the CY 2019 rulemaking. For CY 2018, as stated earlier in this section, rural SCHs, children's hospitals and PPS-exempt cancer hospitals will be excepted from the alternative 340B drug payment methodology being adopted in this final rule with comment period. However, each of these excepted providers will report informational modifier ''TB'' on the same claim line as the HCPCS code for their 340B-acquired drugs.

Comment: In response to the solicitation of comments on whether CMS should exclude certain types of drugs from the proposed alternative 340B drug payment methodology, manufacturers of blood clotting factors and radiopharmaceuticals recommended that CMS continue to pay these drug types at ASP+6 percent. With respect to blood clotting factors, the commenters stated that individuals with bleeding disorders have unique needs and are expensive to treat such that the proposed reduced payment could threaten access and/or create unnecessary treatment delays for these patients. With respect to radiopharmaceuticals, the commenters stated that they do not believe that these products are covered outpatient drugs (because it is not possible for the manufacturer to accurately report final dose and pricing information), and therefore these drugs should be excluded as a category of drugs included in the covered drug definition for the 340B Program.

In addition, one commenter recommended that CMS develop a process for stakeholders to request exemptions from the alternative 340B payment methodology that CMS would evaluate using objective patient guidelines designed to ensure patient access.

Response: We appreciate the comments. To the extent that blood clotting factors and radiopharmaceuticals are covered outpatient drugs purchased under the 340B Program, we believe that the OPPS payment rate for these drugs should account for the discounted rate under which they were purchased. Therefore, for CY 2018, OPPS payment for separately payable, nonpass-through drugs, biologicals, and radiopharmaceuticals, including blood clotting factors and radiopharmaceuticals, if purchased through the 340B Program, will be paid at ASP minus 22.5 percent. As we stated in the summary of final policies, we may revisit the 340B drug payment policy in the CY 2019 rulemaking. We will consider these requests for exceptions for certain drug classes in development of the CY 2019 OPPS/ASC proposed rule.

It is unclear to us whether the commenter meant that radiopharmaceuticals are not considered covered outpatient drugs under the OPPS or not considered a covered outpatient drug for purposes of the 340B Program. We assume the commenter was referring to the definition of covered outpatient drug for purposes of the 340B Program and, as such, these comments are outside the scope of the CY 2018 OPPS/ASC proposed rule. We refer commenters to HRSA with questions related to the 340B Program.

Comment: One commenter representing community oncology practices urged CMS not to ''reduce the size of the reimbursement reduction'' or to phase in the adjustment over 2 to 3 years because the commenter believed that hospitals would use that time to ''aggressively strong-arm independent community oncology practices to sell out to them.''

Response: As stated earlier in this section, we are finalizing our proposal to pay ASP minus 22.5 percent for separately payable nonpass-through drugs (other than vaccines). In addition, we agree that it is not necessary to phase in the payment reduction and are implementing the full adjustment for CY 2018.

Comment: Commenters expressed concern about the challenges and costs of implementing acquisition cost billing.

The commenters reported that hospital charge masters are not designed to bill drugs to one payer at a different rate than other payers. The commenters cited a survey response from hospitals that revealed acquisition cost billing would require investment in expensive software upgrades, obtaining a second charge master, or devising burdensome manual workarounds. One commenter stated that hospital cost reports already reflect the 340B acquisition cost based on expenses reported in the pharmacy cost center. The commenter further stated that these lower costs are already reflected in the drug CCR, which will likely be lower because the cost to acquire these drugs is lower. Thus, the commenter asserted, the OPPS ratesetting process already reflects a blend of discounting/lower expenses with respect to 340B drug acquisition in the annual application of CCRs to pharmacy charges.

Response: We thank the commenters for their feedback and will take these comments into consideration for future policymaking. We note that several State Medicaid programs require reporting of actual acquisition cost (AAC) for 340B drugs so the magnitude of the challenges to implement may be less than the commenter suggests.

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate prorata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2018 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2018. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2017 or beginning in CY 2018. The sum of the CY 2018 pass-through spending estimates for these two groups of device categories equals the total CY 2018 pass-through spending estimate for device categories with pass-through payment status. We base the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the CY 2018 OPPS/ASC proposed rule (82 FR 33635), we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2018, we also proposed to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Because we proposed to pay for most nonpass-through separately payable drugs and biologicals under the CY 2018 OPPS at ASP+6 percent, and because we proposed to pay for CY 2018 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of the proposed rule, our estimate of drug and biological pass-through payment for CY 2018 for this group of items was $0, as discussed below. In the proposed rule, we noted that our estimate did not reflect the proposed payment policy for drugs purchased through the 340B program, as we discussed in section V.A. of the proposed rule.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products will not be separately paid. In addition, we policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section II.A.3. of the proposed rule and this final rule with comment period. In the CY 2018 OPPS/ASC proposed rule (82 FR 33635 through 33636), we proposed that all of these policy-packaged drugs and biologicals with pass-through payment status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2018. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2018 was not $0, as discussed below. In section V.A.5. of the proposed rule, we discussed our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs

of the APCs that are associated with the drug receiving pass-through payment, we proposed to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we proposed to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2018. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible in the remaining quarter of CY 2017 or beginning in CY 2018. The sum of the CY 2018 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2018 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Estimate of Pass-Through Spending

In the CY 2018 OPPS/ASC proposed rule (82 FR 33636), we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2018, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2017 (81 FR 79676 through 79678).

For the first group, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2018, there are no active categories for CY 2018. Because there are no active device categories for CY 2018, we proposed an estimate for the first group of devices of $0.

We did not receive any public comments on our proposed estimate for the first group of devices. For this final rule with comment period, using the latest available data, we calculated a CY 2018 spending estimate for this first group of devices of $0.

In estimating our proposed CY 2018 pass-through spending for device categories in the second group, we included: Device categories that we knew at the time of the development of the proposed rule will be newly eligible for pass-through payment in CY 2018; additional device categories that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2018; and contingent projections for new device categories established in the second through fourth quarters of CY 2018. In the CY 2018 OPPS/ASC proposed rule (82 FR 33636), we proposed to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For the proposed rule, the estimate of CY 2018 pass-through spending for this second group of device categories was $10 million.

We did not receive any public comments on our proposed estimate for the second group of devices. For this final rule with comment period, using the latest available data, we calculated a CY 2018 spending estimate for this second group of devices of $10 million.

To estimate proposed CY 2018 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for CY 2018, we proposed to use the most recent Medicare hospital outpatient claims data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals to project the CY 2018 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2018, we estimated the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately paid at ASP+6 percent, which is zero for this group of drugs. Because payment for policy-packaged drugs and biologicals is packaged if the product was not paid separately due to its pass-through payment status, we proposed to include in the CY 2018 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment. For the proposed rule, using the proposed methodology described above, we calculated a CY 2018 proposed spending estimate for this first group of drugs and biologicals of approximately $7.7 million.

We did not receive any public comments on our proposed spending estimate for this first group of drugs and biologicals. For this final rule with comment period, using the latest available data, we calculated a CY 2018 spending estimate for this first group of drugs and biologicals of approximately $9.83 million. We note that this estimate does not reflect drugs purchased with a 340B discount and therefore subject to a payment reduction based on final policy for CY 2018.

To estimate proposed CY 2018 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the proposed rule were newly eligible for pass-through payment in CY 2018, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2017, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2018), we proposed to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2018 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2018 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $8.5 million.

We did not receive any public comments on our proposed methodology or the proposed spending estimate for this second group of drugs.

Therefore, for CY 2018, we are continuing to use the general methodology described earlier. For this final rule with comment period, based on the latest available data, we calculated a CY 2018 spending estimate for this second group of drugs and biologicals of approximately $8.23 million.

In summary, in accordance with the methodology described earlier in this section, for this final rule with comment period, we estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2018 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2018 is approximately $28.06 million (approximately $10 million for device categories and approximately $18.06 million for drugs and biologicals) compared to the proposed $26.2 million (approximately $10 million for device categories and approximately $16.2 million for drugs and biologicals)), which represents 0.04 percent of total projected OPPS payments for CY 2018 (approximately $70 billion). Therefore, we estimate that pass-through spending in CY 2018 will not amount to 2.0 percent of total projected OPPS CY 2018 program spending.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

In the CY 2018 OPPS/ASC proposed rule (82 FR 33637), for CY 2018, we proposed to continue with our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of the current clinic and ED hospital outpatient visits policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also proposed to continue with and not propose any change to our payment policy for critical care services for CY 2018. For a description of the current payment policy for critical care services, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). In the proposed rule, we sought public comments on any changes to these codes that we should consider for future rulemaking cycles. We continued to encourage those parties who comment to provide the data and analysis necessary to justify any suggested changes.

We did not receive any public comments on our proposals for CY 2018. Therefore, we are finalizing our proposal, without modification, to continue our current clinic and ED hospital outpatient visits and critical care services payment policies. We also did not receive any public comments on any changes to these codes that we should consider for future rulemaking cycles.

VIII. Payment for Partial Hospitalization Services

A. Background

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit.

Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the OPD services to be covered under the OPPS. The Medicare regulations that implement this provision specify, at 42 CFR 419.21, that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs as well as Medicare Part B services furnished to hospital outpatients designated by the Secretary, which include partial hospitalization services (65 FR 18444 through 18445).

Section 1833(t)(2)(C) of the Act requires the Secretary, in part, to establish relative payment weights for covered outpatient department (OPD) services (and any groups of such services described in section 1833(t)(2)(B) of the Act) based on median (or, at the election of the Secretary, mean) hospital costs using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we have developed the PHP APCs. Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we established a per diem payment methodology for the PHP APCs, effective for services furnished on or after July 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs were used to calculate the relative payment weights for the PHP APCs. Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

We began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In that final rule with comment period, we made two refinements to the methodology for computing the PHP median: The first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill.

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tier payment approach for partial hospitalization services under which we paid one amount for days with 3 services under PHP APC 0172 (Level 1 Partial

Hospitalization) and a higher amount for days with 4 or more services under PHP APC 0173 (Level 2 Partial Hospitalization) (73 FR 68688 through 68693). We also finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694). Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements under 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). We also revised the partial hospitalization benefit to include several coding updates (73 FR 68695 through 68697).

For CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we established four separate PHP APC per diem payment rates: Two for CMHCs (APC 0172 (for Level 1 services) and APC 0173 (for Level 2 services)) and two for hospital-based PHPs (APC 0175 (for Level 1 services) and 0176 (for Level 2 services)), based on each provider type's own unique data. For CY 2011, we also instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates based solely on CMHC data. Under the transition methodology, CMHC APCs Level 1 and Level 2 per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based PHP median costs and the CY 2011 final CMHC median costs and then adding that number to the CY 2011 final CMHC median costs. A 2-year transition under this methodology moved us in the direction of our goal, which is to pay appropriately for partial hospitalization services based on each provider type's data, while at the same time allowing providers time to adjust their business operations and protect access to care for Medicare beneficiaries. We also stated that we would review and analyze the data during the CY 2012 rulemaking cycle and, based on these analyses, we might further refine the payment mechanism. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion.

In addition, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. In accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth under section 1861(ff)(3)(B) of the Act (75 FR 71990).

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. We established these four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims and cost data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622), we solicited comments on possible future initiatives that may help to ensure the long-term stability of PHPs and further improve the accuracy of payment for PHP services, but proposed no changes. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75050 through 75053), we summarized the comments received on those possible future initiatives. We also continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050).

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on PHP APC geometric mean per diem costs, using the most recent claims and cost data for each provider type.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70465), we described our extensive analysis of the claims and cost data and ratesetting methodology. We found aberrant data from some hospital-based PHP providers that were not captured using the existing OPPS ±3 standard deviation trims for extreme CCRs and excessive CMHC charges resulting in CMHC geometric mean costs per day that were approximately the same as or more than the daily payment for inpatient psychiatric facility services. Consequently, we implemented a trim to remove hospital-based PHP service days that use a CCR that was greater than 5 (CCR5) to calculate costs for at least one of their component services, and a trim on CMHCs with a geometric mean cost per day that is above or below 2 (±2) standard deviations from the mean. We stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70456) that, without using a trimming process, the data from these providers would inappropriately skew the geometric mean per diem cost for Level 2 CMHC services.

In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70459 through 70460), we corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers. We corrected the cost inversion with an equitable adjustment to the actual geometric mean per diem costs by increasing the Level 2 hospital-based PHP APC geometric mean per diem costs and decreasing the Level 1 hospital-based PHP APC geometric mean per diem costs by the same factor, to result in a percentage difference equal to the average percent difference between the hospital-based Level 1 PHP APC and the Level 2 PHP APC for partial hospitalization services from CY 2013 through CY 2015.

Finally, we renumbered the PHP APCs, which were previously 0172, 0173, 0175, and 0176, to 5851, 5852, 5861, and 5862, respectively. For a detailed discussion of the PHP ratesetting process, we refer readers to the CY 2016 OPPS/ASC final rule with

comment period (80 FR 70462 through 70467).

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. However, we finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and to combine the Level 1 and Level 2 APCs for hospital-based PHPs because we believed this would best reflect actual geometric mean per diem costs going forward, provide more predictable per diem costs, particularly given the small number of CMHCs, and generate more appropriate payments for these services, for example by avoiding the cost inversions for hospital-based PHPs addressed in the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70459 and 81 FR 79682). We implemented an 8-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities by limiting the impact of inflated CMHC charges on outlier payments. We will continue to monitor the trends in outlier payments and consider policy adjustments as necessary.

For a comprehensive description on the background of the PHP payment policy, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680).

B. PHP APC Update for CY 2018

1. PHP APC Geometric Mean Per Diem Costs

For CY 2018, in the CY 2018 OPPS/ASC proposed rule (82 FR 33639), we proposed to continue to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. Specifically, we proposed to continue to use CMHC APC 5853 (Partial Hospitalization (3 or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (3 or More Services Per Day)). We proposed to continue to calculate the geometric mean per diem costs for CY 2018 for APC 5853 for CMHCs using only CY 2016 CMHC claims data and the most recent CMHC cost data, and the CY 2018 geometric mean per diem costs for APC 5863 for hospital-based PHPs using only CY 2016 hospital-based PHP claims data and the most recent hospital cost data.

2. Development of the PHP APC Geometric Mean Per Diem Costs

In the CY 2018 OPPS/ASC proposed rule (82 FR 33639), for CY 2018 and subsequent years, we proposed to follow the PHP ratesetting methodology described in section VIII.B.2. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to determine the PHP APCs' geometric mean per diem costs and to calculate the payment rates for APCs 5853 and 5863, incorporating the modifications made in our CY 2017 OPPS/ASC final rule with comment period. As discussed in section VIII.B.1. of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687), we finalized our proposal that, for CY 2017 and subsequent years, the geometric mean per diem cost for hospital-based PHP APC 5863 would be based upon actual hospital-based PHP claims and costs for PHP service days providing 3 or more services. Similarly, we finalized our proposal that, for CY 2017 and subsequent years, the geometric mean per diem cost for CMHC APC 5853 would be based upon actual CMHC claims and costs for CMHC service days providing 3 or more services.

The CMHC or hospital-based PHP APC per diem costs are the provider-type specific costs derived from the most recent claims and cost data. The CMHC or hospital-based PHP APC per diem payment rates are the national unadjusted payment rates calculated from the CMHC or hospital-based PHP APC per diem costs, after applying the OPPS budget neutrality adjustments described in section II.A.4. of this final rule with comment period.

We proposed to apply our established methodologies in developing the CY 2018 geometric mean per diem costs and payment rates, including the application of a ±2 standard deviation trim on costs per day for CMHCs and a CCR≤5 hospital service day trim for hospital-based PHP providers. These two trims were finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70462) for CY 2016 and subsequent years.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For the CY 2018 proposed rule, prior to calculating the proposed geometric mean per diem cost for CMHC APC 5853, we prepared the data by first applying trims and data exclusions, and assessing CCRs as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), so that ratesetting is not skewed by providers with extreme data. For this CY 2018 OPPS/ASC final rule with comment period, we followed the same data preparation steps. Before any trims or exclusions, there were 50 CMHCs in the final PHP claims data file (compared to 47 CMHCs in the CY 2018 OPPS/ASC proposed rule). Under the ±2 standard deviation trim policy, we excluded any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day was more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. By applying this trim for CY 2018 ratesetting, in this final rule with comment period, we excluded 3 CMHCs with geometric mean per diem costs per day below the trim's lower limit of $47.44 and 1 CMHC above the trim's upper limit of $427.72 from the final ratesetting for CY 2018. This standard deviation trim removed 4 providers from ratesetting whose data would have skewed the calculated final geometric mean per diem cost.

In accordance with our PHP ratesetting methodology, in the proposed rule, we also removed service days with no wage index values because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). In this CY 2018 final rule ratesetting, no CMHCs were missing wage index data for all of their service days. Therefore, we did not exclude any CMHCs due to lack of wage index data.

In addition to our trims and data exclusions, before determining the PHP APC geometric mean per diem costs, we also assess CCRs (80 FR 70463). Our longstanding PHP OPPS ratesetting methodology defaults any CMHC CCR>1 to the statewide hospital ancillary CCR (80 FR 70457). In this CY 2018 final rule ratesetting, we identified one CMHC that had a CCR>1. This CMHC's CCR was 1.002, and it was defaulted to its appropriate statewide hospital ancillary CCR for CY 2018 ratesetting purposes.

In summary, these data preparation steps adjusted the CCR for 1 CMHC and excluded 4 CMHCs, resulting in the inclusion of a total of 46 CMHCs in our CY 2018 final rule ratesetting modeling (compared to 39 CMHCs in our proposed rule ratesetting modeling in the CY 2018 OPPS/ASC proposed rule). The trims removed 864 CMHC claims from the 16,242 total CMHC claims, resulting in 15,378 CMHC claims used in ratesetting. We believe that excluding providers with extremely low or high geometric mean costs per day or extremely low or high CCRs protects CMHCs from having that data inappropriately skew the calculation of

the CMHC APC geometric mean per diem cost. Moreover, we believe that these trims, exclusions, and adjustments help prevent inappropriate fluctuations in the PHP APC geometric mean per diem payment rates.

After applying all of the above trims, exclusions, or adjustments, the final CY 2018 geometric mean per diem cost for all CMHCs for providing 3 or more services per day (APC 5853) is $143.22 (compared to the proposed geometric mean per diem cost of $128.81).

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For the CY 2018 proposed rule and for this CY 2018 final rule with comment period, we followed a data preparation process for hospital-based PHP providers that is similar to that used for CMHCs by applying trims and data exclusions as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) so that our ratesetting is not skewed by providers with extreme data. Before any trimming or exclusions, there were 424 hospital-based PHP providers in the CY 2016 final PHP claims data used in this CY 2018 OPPS/ASC final rule with comment period (compared to 420 hospital-based PHPs in the CY 2018 OPPS/ASC proposed rule).

For hospital-based PHP providers, we applied a trim on hospital service days when the CCR was greater than 5 at the cost center level. The CCR>5 hospital service day trim removed hospital-based PHP service days that use a CCR>5 to calculate costs for at least one of their component services. Unlike the ±2 standard deviation trim, which excluded CMHC providers that failed the trim, the CCR>5 trim excluded any hospital-based PHP service day where any of the services provided on that day were associated with a CCR>5. Applying this trim removed from our final rule ratesetting service days from 8 hospital-based PHP providers with CCRs ranging from 5.2024 to 17.5702. However, all of the service days for these 8 hospital-based PHP providers had at least one service associated with a CCR>5, so the trim removed these providers entirely from our final rule ratesetting. In addition, 16 hospital-based PHPs reported zero daily costs, and therefore were removed for having no days with PHP payment; 1 hospital-based PHP was removed for missing wage index data; and 1 hospital-based PHP was removed by the OPPS ±3 standard deviation trim on costs per day.

Therefore, we excluded 26 hospital-based PHP providers, resulting in 398 hospital-based PHP providers in the data used for final rule ratesetting (compared to 393 hospital-based PHPs in the CY 2018 OPPS/ASC proposed rule). In addition, 2 hospital-based PHP providers were defaulted to using their overall hospital ancillary CCR due to outlier cost center CCR values (72.7362 and 117.1943). After completing these data preparation steps, we calculated the final geometric mean per diem cost for hospital-based PHP APC 5863 for hospital-based PHP services. The final geometric mean per diem cost for hospital-based PHP providers that provide 3 or more services per service day (hospital-based PHP APC 5863) is $208.09 (compared to $213.60 from the CY 2018 OPPS/ASC proposed rule).

We received a few public comments relating to our proposal to use our established methodology and policies in developing the PHP geometric mean per diem costs.

Comment: One commenter opposed CMS continuing to use the single-tier payment system implemented in CY 2017 OPPS/ASC rulemaking because the commenter believed this system punished CMHCs for the cost inversion in the hospital-based PHP data. The commenter suggested that CMS return to the two-tier payment system. Another commenter was concerned that the single-tier payment system could have unintended consequences, including reducing the number of PHPs or the number of services provided per day, and urged CMS to monitor the data.

One commenter disagreed with CMS paying CMHCs and hospital-based PHPs differently for providing the exact same services and believed that the APCs distinguished by provider type hurts rather than rewards CMHCs for being more cost effective than hospital-based PHPs. The commenter referred to a 2011 bill introduced in the Congress to address the ''inequity'' of the current payment system and stated that CMHCs should be paid the same rate as hospital-based PHPs. This commenter also stated that setting CMHCs' payment rates based on a small number of CMHCs does not reflect the actual cost of providing these services and expressed concern that basing payments at the mean or median level would result in half of CMHCs receiving payments less than their costs, which would guarantee that more CMHCs would close, further limiting access to care.

Response: We thank the commenters for their input. We reiterate our single-tier payment policy and rationale. In the CY 2017 OPPS/ASC final rule with comment period, we combined the Level 1 and Level 2 PHP APCs into a single tier PHP APC for CMHCs, and we did the same for hospital-based PHPs. We cited several reasons for implementing the single-tier payment system (81 FR 79682 through 79686) and noted that one primary reason for combining the two-tier system into a single tier, by provider type, was the decrease in the number of CMHCs (81 FR 79683). With a small number of providers, data from large providers with a high percentage of all PHP service days and unusually high or low geometric mean costs per day would have a more pronounced effect on the PHP APCs geometric mean per diem costs, skewing costs up or down. The effect would be magnified by continuing to split the geometric mean per diem costs further by distinguishing between Level 1 and Level 2 PHP services. We believed that creating a single PHP APC for each provider type for providing 3 or more PHP services per day would reduce these cost fluctuations and provide more stability in the PHP APC geometric mean per diem costs.

We do not believe that the single-tier payment system will lead to a reduction in the number of PHPs, but rather that the increased stability in CMHC and hospital-based PHP payment rates will provide more stability for the PHP APCs. In addition, the calculated rates for APCs 5853 and 5863 continue to be based upon the actual costs of CMHCs and hospital-based PHPs, respectively. Therefore, we believe that the payment rates for the single-tier PHP APCs should be an appropriate approximation of provider costs, and should not result in reduced access to care.

Because the single-tier PHP APCs 5853 and 5863 became effective January 1, 2017, we will have to wait until our CY 2017 claims data are available to determine any effect of the payment rates for these APCs on the provision of services per day. We will continue to monitor PHP data for any unintended consequences resulting from the single-tier APC policy.

The OPPS pays for hospital outpatient services, including partial hospitalization services. This system bases payment on the geometric mean per diem costs of providing services using provider data from claims and cost reports. We calculate the PHP APC geometric mean per diem costs based on the data provided for each type of provider to determine payment for these services. We believe that this system provides appropriate payment for partial hospitalization services based on actual provider costs. The final PHP APC geometric mean per diem costs for CY 2018 reflect these actual provider costs.

Regarding the 2011 bill introduced in the Congress that would have required CMHCs and hospital-based PHPs to be paid at the same rate, we note that this bill was not enacted.

The difference in payment between CMHCs and hospital-based PHPs is based upon differences in resource use (or costs). When Congress required the Secretary to implement an outpatient prospective payment system, it generally required that this payment system group clinically similar covered services with respect to resource use (section 1833(t)(2) of the Act). Because the resource uses of CMHCs and hospital-based PHPs are different, these two provider types are paid under different APCs, based on their actual resource use.

Because the cost of providing partial hospitalization services differs significantly by site of service, we established different PHP APC payment rates for hospital-based PHPs and CMHCs in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). However, we allowed a 2-year transition to the CMHC payment rates based solely on CMHC data. With respect to the continued use of PHP APC geometric mean per diem costs for determining payment rates by provider, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412) for a discussion of the implementation of this policy. The resulting payment rates reflect the geometric mean cost of what providers expend to maintain such programs, based on data provided by CMHCs and hospital-based PHPs, which we believe are an improvement over the payment rates under the two-tier methodology calculated based on median costs using only hospital-based data.

Comment: One commenter was concerned that the PHP trim methodologies could cause changes to the payment rates which could lead to a reduction in the number of PHPs. The commenter urged CMS to monitor the data to ensure that there are no unintended consequences, such as a reduction in the number of PHPs.

Response: We thank the commenter for sharing these concerns. We are continuing to monitor PHP data, including the number of PHPs that provide care to Medicare beneficiaries. Our trim methodologies should protect PHP ratesetting from skewing by aberrant data, such as extremely low or extremely high costs per day. We do not believe that our PHP trim methodologies will lead to a reduction in PHPs, but rather that the trims we apply will provide stability to PHPs by reducing fluctuations in their payment rates due to aberrant data.

Comment: One commenter suggested that CMS consider paying PHPs using a quality-based payment system, and that CMS use a value-based purchasing program for PHPs.

Response: Currently, there is no statutory language explicitly authorizing a value-based purchasing program for PHPs. We responded to a similar public comment in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462) and refer readers to a summary of that comment and our response. To reiterate, sections 1833(t)(2) and 1833(t)(9) of the Act set forth the requirements for establishing and adjusting OPPS payment rates, which include PHP payment rates. Section 1833(t)(17) of the Act authorizes the Hospital OQR Program, which applies a payment reduction to subsection (d) hospitals that fail to meet program requirements. In the CY 2015 OPPS/ASC proposed rule (79 FR 41040), we considered future inclusion of, and requested comments on, the following quality measures addressing PHP issues that would apply in the hospital outpatient setting: (1) 30-day Readmissions; (2) Group Therapy; and (3) No Individual Therapy. We also refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66957 through 66959) for a detailed discussion of PHP measures considered for inclusion in the Hospital OQR Program in future years. The Hospital OQR Program does not apply to CMHCs.

Comment: One commenter presented a number of suggestions for a more holistic approach to the way Medicare (or Medicaid) pays for and covers PHP services, including coverage for case management, and assistance with medication compliance, proper housing, and work and training facilities.

Response: We appreciate these suggestions. As we noted in the preceding comment response, the payment methodology for PHP services is governed by sections 1833(t)(2) and 1833(t)(9) of the Act. PHP services are defined in section 1861(ff) of the Act and do not include those services described by the commenter. We do not have the authority to cover and pay for services beyond those described in the Act, or to pay outside of the statutory methodology.

Comment: One commenter stated that the CMHC PHP payment rate is too low, which can affect access to care by some of the most disadvantaged Medicare beneficiaries. This commenter expressed concern about the closure of CMHCs, which the commenter attributed to low CMHC PHP payment rates. The commenter noted that declining payment rates are occurring at a time when CMHCs have experienced higher costs due to the establishment of CMHC conditions of participation (CoPs) and higher bad debt expenses. The commenter believed that CMS is only concerned about protecting access to hospital-based PHPs, and not to CMHCs PHPs.

Response: The final CY 2018 CMHC geometric mean per diem costs are 11 percent higher than the proposed geometric mean per diem costs, and are approximately 15 percent higher than those costs finalized in the CY 2017 rulemaking. These final CY 2018 CMHC geometric mean per diem costs are based upon the most recent CMHC claims and cost data reported by providers. Therefore, we believe the payment rate derived from these geometric mean per diem costs represents an appropriate payment to CMHCs and should not result in provider closures or affect beneficiary access to care.

Most (if not all) of the costs associated with adhering to CoPs should be captured in the cost report data used in ratesetting and, therefore, are accounted for when computing the geometric mean per diem costs. The reduction to bad debt reimbursement was a result of provisions of section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96). The reduction to bad debt reimbursement impacted all providers eligible to receive bad debt reimbursement, as discussed in the CY 2013 End-Stage Renal Disease final rule (77 FR 67518). Medicare currently reimburses bad debt for eligible providers at 65 percent.

We appreciate the commenter's input regarding the effect any reduction in PHP payment rates would have on access to care, but we disagree with the commenter's assertion that CMS is only concerned about access to hospital-based PHPs. We are working to strengthen continued access to *both* CMHCs and hospital-based PHPs for eligible Medicare beneficiaries. For example, for the CY 2016 ratesetting, we conducted an extensive analysis of the ratesetting process, and discovered errors providers had made in claims coding of revenue and HCPCS codes that were leading to lower geometric mean per diem costs. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466), we also included a detailed description of the ratesetting process to help all PHPs record costs correctly so that we can more fully capture PHP costs in ratesetting. In that same final rule with comment period, we also addressed

fluctuations in payments and protected ratesetting from aberrant data by implementing trims on all PHP data used in ratesetting (80 FR 70455 through 70457). For example, the CMHC ±2 standard deviation trim has protected CMHCs by removing from ratesetting those providers with aberrantly low costs per day, which would have lowered total CMHC geometric mean per diem costs, and thus lowered CMHC per diem payment rates. In this CY 2018 final rule with comment period ratesetting, that ±2 standard deviation trim resulted in our removing 4 CMHCs from the ratesetting data, 3 of which had costs per day that were extremely low.

We agree that both CMHCs and hospital-based PHPs serve some of the most disadvantaged Medicare beneficiaries, and appreciate the care that these providers give. We remain concerned about access to all PHP services, and particularly about the small numbers of CMHCs. The CY 2016 PHP data file of claims used for CY 2018 ratesetting showed only 50 CMHCs before we applied our data trims. We want to ensure that CMHCs remain a viable option as providers of mental health care, and will continue to explore policy options for strengthening the PHP benefit and increasing access to the valuable services provided by CMHCs and hospital-based PHPs.

We did not receive any public comments on the hospital-based PHP geometric mean per diem costs.

After consideration of the public comments we received, we are finalizing our proposals to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. Specifically, we are finalizing our proposal to continue to pay CMHCs using APC 5853 (Partial Hospitalization (3 or More Services Per Day)) and to continue to pay hospital-based PHPs using APC 5863 (Partial Hospitalization (3 or More Services Per Day)). We calculated the geometric mean per diem costs for CY 2018 for APC 5853 for CMHCs using only CY 2016 CMHC claims data and the most recent CMHC cost data, and the CY 2018 geometric mean per diem costs for APC 5863 for hospital-based PHPs using only CY 2016 hospital-based PHP claims data and the most recent hospital cost data. We also are finalizing our proposal to continue applying our established trim methodologies, including the application of a ±2 standard deviation trim on costs per day for CMHCs and a CCR>5 hospital service day trim for hospital-based PHP providers.

The final CY 2018 PHP APC geometric mean per diem costs for CMHC PHP APC 5853 are $143.22 and for hospital-based PHP APC 5863 are $208.09, as shown in Table 74 below. The final PHP APC payment rates are included in Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 74—CY 2018 PHP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2018 APC	Group title	Final PHP APC geometric mean per diem costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$143.22
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	208.09

3. PHP Service Utilization Updates

In the CY 2016 OPPS/ASC final rule with comment period (81 FR 79684 through 79685), we expressed concern over the low frequency of individual therapy provided to beneficiaries. The final CY 2016 claims data used for this CY 2018 final rule with comment period revealed some increases in the provision of individual therapy compared to CY 2015 claims data. In the CY 2016 final claims data, hospital-based PHPs provided individual therapy on 4.7 percent of days with only 3 services and 5.8 percent of days with 4 or more services (compared to 4.0 percent and 6.2 percent, respectively, in CY 2015). Similarly, in the CY 2016 final claims data, CMHCs provided individual therapy on 8.5 percent of days with only 3 services provided and 5.0 percent of days with 4 or more services provided (compared to 7.9 percent and 4.4 percent, respectively, in CY 2015 claims).

In the CY 2018 OPPS/ASC proposed rule (82 FR 33640), we stated that we are aware that our single-tier payment policy may influence a change in service provision because providers are able to obtain payment that is heavily weighted to the cost of providing 4 or more services when they provide only 3 services. We indicated that we are interested in ensuring that providers furnish an appropriate number of services to beneficiaries enrolled in PHPs. Therefore, with the CY 2017 implementation of APC 5853 and APC 5863 for providing 3 or more PHP services per day, we are continuing to monitor utilization of days with only 3 PHP services.

For this CY 2018 final rule with comment period, we used the final update of the CY 2016 claims data. The final CY 2016 claims data showed that PHPs maintained an appropriately low utilization of 3 service days compared to CY 2015. Hospital-based PHPs have increased their provision of services since CY 2015 by providing fewer days with 3 services only, and more days with 5 or more services. CMHCs have remained steady in providing an appropriately low level of 3 service days.

TABLE 75—PERCENTAGE OF PHP DAYS BY SERVICE UNIT FREQUENCY

	CY 2015 (%)	CY 2016 * (%)	Change (%)
CMHCs:			
Percent of Days with 3 services	4.7	4.8	2.1
Percent of Days with 4 services	62.9	70.3	11.8
Percent of Days with 5 or more services	32.4	24.9	−23.1
Hospital-based PHPs:			
Percent of Days with 3 services	12.4	10.9	−12.1
Percent of Days with 4 services	69.8	64.9	−7.0

TABLE 75—PERCENTAGE OF PHP DAYS BY SERVICE UNIT FREQUENCY—Continued

	CY 2015 (%)	CY 2016 * (%)	Change (%)
Percent of Days with 5 or more services	17.8	24.1	35.4

* May not sum to 100 percent by provider type due to rounding.

As we noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79685), we will continue to monitor the provision of days with only 3 services, particularly now that the single-tier PHP APCs 5853 and 5863 are in place for providing 3 or more services per day to CMHCs and hospital-based PHPs, respectively.

It is important to reiterate our expectation that days with only 3 services are meant to be an exception and not the typical PHP day. In the CY 2009 OPPS/ASC final rule with comment period, we clearly stated that we consider the acceptable *minimum* units of PHP services required in a PHP day to be 3 and explained that it was never our intention that 3 units of service represent the number of services to be provided in a typical PHP day. PHP is furnished in lieu of inpatient psychiatric hospitalization and is intended to be more intensive than a half-day program. We further indicated that a typical PHP day should include 5 to 6 hours of services (73 FR 68687 through 68694). We explained that days with only 3 units of services may be appropriate to bill in certain limited circumstances, such as when a patient might need to leave early for a medical appointment and, therefore, would be unable to complete a full day of PHP treatment. At that time, we noted that if a PHP were to only provide days with 3 services, it would be difficult for patients to meet the eligibility requirement in 42 CFR 410.43, that patients must require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care (73 FR 68689).

4. Minimum Service Requirement: 20 Hours Per Week

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68694), we codified patient eligibility criteria to reflect the intensive nature of a PHP. At that time, we noted that many of the patient eligibility criteria had been longstanding policy requirements that did not reflect a change in policy. The added regulatory text was intended to strengthen and enhance the integrity of the PHP benefit. We further stated that because PHP is provided in lieu of inpatient care, it should be a highly structured and clinically intensive program. Our goal was to improve the level of service furnished in a day of PHP, while also ensuring that the appropriate population utilizes the PHP benefit (73 FR 68695).

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33641 through 33642), when we codified these eligibility criteria, we acknowledged commenters' concerns related to the eligibility requirement that a patient must require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care. For example, we recognized commenters' concerns that it may sometimes be difficult for patients to receive 20 hours per week of therapeutic services, such as when transitioning into or out of a PHP program (73 FR 68695). Therefore, to permit flexibility in treating PHP patients, we require a minimum of 20 hours per week of therapeutic services, with the understanding that patients may not always meet this minimum, and qualified the requirement by adding ''as evidenced in their plan of care.'' This eligibility requirement only addresses the minimum amount of PHP services beneficiaries must require as evidenced in their plan of care. It does not address whether or not beneficiaries *receive* a particular number of therapeutic services per week. However, we have noted in multiple prior OPPS/ASC final rules with comment period that a typical PHP day would include 5 to 6 hours per day of PHP services (70 FR 68548, 71 FR 67999, 72 FR 66671, and 73 FR 68687).

Most recently, we discussed the 20 hours of services requirement in the CY 2017 rulemaking when we reminded providers that our regulations at §§ 410.43(a)(3) and (c)(1) continue to require that PHP beneficiaries must require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care, and that PHP services must be furnished in accordance with a physician certification and the beneficiary's plan of care reflecting that need.

We analyzed CY 2015 and CY 2016 PHP claims data to assess the intensity of PHP services provided, using PHP-allowable HCPCS codes and provider and service date information. To calculate the number of hours of PHP services provided to each beneficiary each day, we assumed each unit of service equaled 1 hour of time. Each service day was then mapped to its Sunday through Saturday calendar week, and the number of PHP hours per week was calculated for each beneficiary. Next, the service weeks for each beneficiary were sorted chronologically and assessed: The first service week in a continuous series of service weeks was flagged as an ''Admission'' week, and the last service week in a continuous series of service weeks was flagged as a ''Discharge'' week. We removed from the analysis the admission and discharge weeks for each beneficiary to permit us to assess the intensity of services provided to beneficiaries fully engaged in PHPs (that is, those in ''nontransitional'' weeks). We then calculated the total number of service weeks and the number of service weeks with at least 20 PHP hours for each beneficiary. These two values were then used to determine the percentage of nontransitional service weeks that met the 20-hour PHP threshold for each beneficiary.

As stated in the CY 2018 OPPS/ASC proposed rule (82 FR 33641), we found that a majority of PHP patients did not receive at least 20 hours of PHP services per week. Approximately half of Medicare beneficiaries receiving PHP services received 20 hours or more of services in 50 percent or more of nontransitional weeks. In CY 2016 claims data, only 16.4 percent of Medicare beneficiaries in CMHCs and 34.8 percent of Medicare beneficiaries in hospital-based PHPs received at least 20 hours of PHP services in 100 percent of nontransitional weeks.

TABLE 76—NUMBER AND PERCENTAGE OF MEDICARE BENEFICIARIES RECEIVING AT LEAST 20 HOURS OF PHP SERVICES PER WEEK—CY 2015 THROUGH CY 2016

Type	Beneficiaries Receiving 20 or more hours of PHP services per nontransitional week *	CY 2015		CY 2016	
		Number	Percentage	Number	Percentage
CMHC PHP Beneficiaries	In 50 percent or more of weeks	1,205	53.1	1,016	57.3
	In 100 percent of weeks	319	14.1	291	16.4
Hospital-Based PHP Beneficiaries	In 50 percent or more of weeks	8,610	51.0	8,333	56.7
	In 100 percent of weeks	5,003	29.6	5,115	34.8

* Weeks are trimmed to exclude admission and discharge weeks based on a Sunday through Saturday week. Nontransitional weeks are weeks that are not admission or discharge weeks.

Overall, the data suggest that some PHP beneficiaries may not be receiving the intensive services that eligible beneficiaries actually need. In the CY 2018 OPPS/ASC proposed rule, we stated that we were concerned about these findings, and encouraged PHPs to review their admission practices and ensure they are providing the services beneficiaries need.

Given similar concerns, in the CY 2017 OPPS/ASC final rule with comment period, we solicited public comments on potential future editing of PHP claims for the 20 hours per week minimum eligibility requirement and on strengthening the tie between a beneficiary's receipt of 20 hours per week of PHP services and payment for those services (81 FR 79686). We received a number of public comments in response to our solicitation, which we addressed in the CY 2018 OPPS/ASC proposed rule (82 FR 33641 through 33642).

In the CY 2018 OPPS/ASC proposed rule, we solicited public comments on the advisability of applying a payment requirement conditioned on a beneficiary's receipt of a minimum of 20 hours of therapeutic services per week. We also solicited public comments addressing the need for exceptions to such a policy. Specifically, we wanted to know and understand the type of occurrences or circumstances that would cause a PHP patient to not receive at least 20 hours of PHP services per week, particularly where payment would still be appropriate.

Comment: Many commenters agreed it is critical that beneficiaries requiring PHP services receive the appropriate intensity of services, but suggested that CMS work with industry to define ''intensity'' more broadly than total hours of services received per week. A few commenters suggested that CMS check the Local Coverage Determinations (LCDs) when evaluating intensity. One commenter provided a history of the PHP benefit, and noted that, historically, day programs similar to PHPs were required to offer 20 hours per week in programming, but the patient and the treatment team determined the amount of time in treatment.

A few commenters suggested that CMS forego editing, and instead implement a targeted medical review of those providers whose data are problematic. These and other commenters suggested that CMS educate the PHP provider community about a 20-hour per week minimum service requirement. A number of commenters suggested that CMS reissue the rescinded Special Edition 1607 MedLearn Matters article and its associated Change Request 9880, about messaging on the remittance advice to providers. One commenter suggested that CMS include beneficiaries in any communications about a 20-hour per week minimum service requirement.

Several commenters believed that it would be premature to edit claims until CMS could determine the effect of the single-tier payment system on provision of services. These commenters urged a delay in editing until the CY 2019 rulemaking when CMS could analyze the CY 2017 data (the first year that could show the effect of the single-tier payment system on provision of services) and monitor utilization in the meantime. A few commenters stated that CMS should not require weekly billing of claims in order to implement payment editing of the 20-hour requirement, as it would increase providers' administrative burden because it would increase the number of claims providers would be required to submit.

Some commenters cited language from the CY 2009 OPPS/ASC final rule with comment period which implemented this eligibility requirement: That CMS stated it is to be documented in the plan of care and the language did not require PHP patients to *receive* 20 hours of care. One commenter believed that an edit limiting payment would be unduly burdensome, particularly given the PHP preamble language in the CY 2009 final rule with comment period. One commenter suggested that allowing nurse practitioners to create the treatment plan, and supervise and direct patients in PHPs, would give providers more flexibility in providing services to meet the minimum requirements.

One commenter was concerned that a 20-hour minimum service requirement, combined with limiting payment to essentially a 3-service encounter, would not fully serve the patients and would push patients out of PHPs and into ''Intensive Outpatient Programs (IOPs).'' One commenter stated that if there were editing for a 20-hour requirement, the PHP revenue for one provider, for example, would decline by $100,000 at a time when the provider is struggling to find nursing staff, and its psychiatry and nursing costs are rising.

Multiple commenters described reasons why PHP patients are sometimes unable to attend the program for 20 hours per week. Commenters suggested exceptions for weather, acute illness or comorbid disease, family or childcare issues, holidays, transportation problems, other medical or social service appointments, court or legal appointments, and local emergencies or disasters. Several commenters discussed problems with medication compliance and medication adjustments, the cognitive effects of which could make attending for 20 hours per week clinically suboptimal. Several commenters noted that an overly strict edit could result in inappropriate changes and reduce access to PHP services.

Response: We thank the commenters for their insights and suggestions. We will consider these comments in future rulemaking and in developing subregulatory guidance.

We wish to correct two erroneous assumptions included in the comments. First, we have not rescinded Change Request 9880 about messaging on the provider remittance advice. This Change Request is available online at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017-*

Transmittals-Items/R1833OTN.html?DLPage=1&DLEntries=10&DLFilter=9880&DLSort=1&DLSortDir=ascending. However, we did rescind MLN Special Edition (SE) article 1607, partly because it referred to requiring weekly billing. We do not currently require PHPs to bill weekly, although PHPs may do so if they wish. Second, regarding the comment about limiting payment to a 3-service encounter, it was unclear if the commenter believed that PHP per diem payment was limited to that for 3 services. We note that the single-tier APCs for CMHCs and for hospital-based PHPs are based upon the geometric mean per diem costs for providing 3 *or more* PHP services per day. PHP APCs 5853 and 5863 do not limit PHP services to 3 per day.

Our goal is for PHP providers to continue to have flexibility in providing PHP services. However, we must ensure that Medicare beneficiaries enrolled in PHPs are legitimately eligible for PHP services and receive appropriately intensive treatment. As we seek to understand the usage of PHP services by Medicare beneficiaries, we also will continue to monitor the intensity of services provided on a weekly basis.

C. Outlier Policy for CMHCs

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), after examining the costs, charges, and outlier payments for CMHCs, we concluded that establishing a separate OPPS outlier policy for CMHCs would be appropriate. Beginning in CY 2004, we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

The separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004, and $0.5 million in outlier payments to CMHCs in CY 2005. In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments. We note that, in the CY 2009 OPPS/ASC final rule with comment period, we also established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments (73 FR 68594 through 68599). In CY 2017, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). This outlier payment cap only affects CMHCs, and does not affect other provider types. This outlier payment cap is in addition to and separate from the current outlier policy and reconciliation policy in effect. We finalized the CMHC outlier payment cap to be set at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695).

In the CY 2018 OPPS/ASC proposed rule (82 FR 33642), we proposed to continue to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS in CY 2018, excluding outlier payments. This policy results in CMHC outliers being paid under limited circumstances associated with costs from complex cases, rather than as a substitute for the standard PHP payment to CMHCs. In the CY 2018 OPPS/ASC proposed rule, we also noted that CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2018, excluding outlier payments. Therefore, we proposed to designate approximately 0.0027 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs. As we do for each rulemaking cycle, we have updated the CMHC CCRs and claims data used to model the PHP payments rates for this final rule with comment period.

Based on our simulations of CMHC payments for CY 2018, in the proposed rule, we proposed to continue to set the cutoff point for outlier payments for CY 2018 at 3.4 times the highest CMHC APC payment rate implemented for that calendar year, which for CY 2018 is the payment rate for CMHC APC 5853. In addition, we proposed to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2018, we proposed to continue to pay 50 percent of CMHC APC geometric mean per diem costs over the cutoff point. For example, for CY 2018, if a CMHC's cost for partial hospitalization services paid under CMHC APC 5853 exceeds 3.4 times the proposed payment rate for CMHC APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the payment rate for CMHC APC 5853.

In section II.G. of the proposed rule, for the hospital outpatient outlier payment policy, we proposed to set a fixed dollar threshold in addition to an APC multiplier threshold. APC 5853 is the only APC for which CMHCs may receive payment under the OPPS, and is for providing a defined set of services that are relatively low cost when compared to other OPPS services. As such, it is not necessary to also impose a fixed dollar threshold on CMHCs. Therefore, we did not propose to set a dollar threshold for CMHC outlier payments.

In summary, we proposed to continue to calculate our CMHC outlier threshold and CMHC outlier payments according to our established policies.

We did not receive any public comments on these proposals. Therefore, we are finalizing our proposals to continue to calculate CMHC outlier threshold and CMHC outlier payments according to our established policies. Using the updated data for this final rule with comment period, CMHCs are projected to receive 0.03 percent of total hospital outpatient payments in CY 2018, excluding outlier payments. Therefore, for CY 2018 we are designating approximately 0.02 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs.

IX. Procedures That Will Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full historical discussion of our longstanding policies on how we identify procedures that are typically provided only in an inpatient setting (referred to as the inpatient only (IPO) list) and, therefore, will not be paid by Medicare under the OPPS, and on the criteria that we use to review the IPO list each year to determine whether or not any procedures should be removed from the list. The complete list of codes that will be paid by Medicare in CY 2018 as inpatient only procedures is included as Addendum E to this final rule with comment period (which is available via the Internet on the CMS Web site).

B. Changes to the Inpatient Only (IPO) List

1. Methodology for Identifying Appropriate Changes to IPO List

In the CY 2018 OPPS/ASC proposed rule (82 FR 33642 through 33645), for CY 2018, we proposed to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65834)) of reviewing the current list of procedures on the IPO list to identify any procedures that may be removed from the list. We have established five criteria that are part of this methodology. As

noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we utilize these criteria when reviewing procedures to determine whether or not they should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We note that a procedure is not required to meet all of the established criteria to be removed from the IPO list. The criteria include the following:

1. Most outpatient departments are equipped to provide the services to the Medicare population.

2. The simplest procedure described by the code may be performed in most outpatient departments.

3. The procedure is related to codes that we have already removed from the IPO list.

4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.

5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

Using the above-listed criteria, in the CY 2018 OPPS/ASC proposed rule (82 FR 33643 and 33644), we identified the procedures described by the following codes that we proposed to remove from the IPO list for CY 2018: CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)) and CPT code 55866 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed). The procedures that we proposed to remove from the IPO list for CY 2018 and subsequent years, including the HCPCS code, long descriptors, and the CY 2018 payment indicators, were displayed in Table 29 of the proposed rule.

We note that we address the public comments we received on removing the procedure described by CPT code 55866 from the IPO list under section IX.B.2. of this final rule with comment period. We address the public comments we received on removing CPT code 27447 from the IPO list under section IX.B.3. of this final rule with comment period.

2. Removal of Procedure Described by CPT Code 55866

In the CY 2018 OPPS/ASC proposed rule, we proposed to remove CPT code 55866 from the IPO list and to assign it to C–APC 5362 (Level 2 Laparoscopy & Related Services) with status indicator ''J1''. We stated in the proposed rule that after consulting with stakeholders and our clinical advisors regarding the procedure described by CPT code 55866, we believe that this procedure meets criteria 1 and 2. We sought comment on whether the public believes that these criteria are met and whether CPT code 55866 meets any other of the five criteria cited earlier.

Comment: Commenters, including cancer centers, physicians, and individual stakeholders, supported the proposal to remove CPT code 55866 from the IPO list. These commenters believed this procedure could be safely performed on hospital outpatients and noted that many hospital outpatient departments are equipped to do so.

Response: We appreciate the commenters' support.

Comment: One commenter opposed the removal of CPT code 55866 from the IPO list, stating that the procedure cannot be safely performed as an outpatient procedure for a majority of patients.

Response: We continue to believe that the procedure described by CPT code 55866 can be safely performed in the hospital outpatient setting on patients who are appropriate candidates to receive the procedure in that setting. Because the procedure meets several of the criteria for removal from the IPO list, we believe it is appropriate to remove it.

3. Removal of the Total Knee Arthroplasty (TKA) Procedure Described by CPT Code 27447

For a number of years, total knee arthroplasty (TKA) has been a topic of discussion for removal from the IPO list with both stakeholder support and opposition. Most recently, in the CY 2017 OPPS/ASC proposed rule (81 FR 45679 through 45681), we sought public comments on the removal of the TKA procedure from the IPO list from interested parties, including specifically: Medicare beneficiaries and advocate associations for Medicare beneficiaries; orthopedic surgeons and physician specialty societies that represent orthopedic surgeons who perform TKA procedures; hospitals and hospital trade associations; and any other interested stakeholders. In the CY 2017 proposed rule comment solicitation, we requested stakeholder input on whether the TKA procedure met the established criteria used to identify procedures to remove from the IPO list. We also requested input regarding how to modify current Medicare payment models that include TKA, such as the Bundled Payments for Care Improvement (BPCI) and the Comprehensive Care for Joint Replacement (CJR) initiatives, if the procedure was removed from the IPO list.

Below is a summary of the public comments we received in response to the comment solicitation in the CY 2017 OPPS/ASC proposed rule. These public comments were varied and nuanced.

- A number of commenters believed that continued refinements to the TKA surgical procedure allowed it to be performed safely on properly selected Medicare beneficiaries in the outpatient setting. A number of facilities indicated that they were currently performing TKA procedures on an outpatient basis in both the HOPD and ASC on non-Medicare patients. Commenters who supported removing the TKA procedure from the IPO list also noted recent peer-reviewed publications that reported on investigations of the feasibility of outpatient TKA with positive results; that is, TKA outpatients did not experience higher rates of complications or readmissions in comparison to TKA inpatients.
- A minority of commenters (including teaching hospital stakeholders and some professional organizations representing orthopedic surgeons) stated that the risk of postsurgical complications was too high for patients with the TKA procedure performed in the outpatient setting for the Medicare population and noted that patients appropriate for the TKA procedure performed on an outpatient basis tend to be younger, more active, have fewer complications, and have more at home support than most Medicare beneficiaries. These commenters also believed there was insufficient research on the TKA procedure performed on an outpatient basis to definitively claim that the procedure could be safely performed in the outpatient setting.
- Some commenters noted that if the TKA procedure was removed from the IPO list, inpatient TKA cases should not be subject to Recovery Audit Contractor (RAC) review for appropriate site-of-service. In addition, some commenters expressed concerns about the effect that removing the TKA procedure from the IPO list could have on the BPCI and CJR Medicare payment models. We stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699) that we would consider all public comments received in future policymaking.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33643), we stated that we have reviewed the clinical characteristics of the TKA procedure and related evidence, including current

length-of-stay (LOS) data for inpatient TKA procedures and peer-reviewed literature related to outpatient TKA procedures. We also stated that we have considered input from the comment solicitation in the CY 2017 OPPS/ASC proposed rule (as summarized earlier) and the professional opinions of orthopedic surgeons and CMS clinical advisors. In addition, we stated that we have taken into account the recommendation from the summer 2016 meeting of the HOP Panel to remove the TKA procedure from the IPO list. Based on this information, we stated in the CY 2018 OPPS/ASC proposed rule that we have determined that the TKA procedure would be an appropriate candidate for removal from the IPO list. We stated that we expect providers to carefully develop evidence-based patient selection criteria to identify patients who are appropriate candidates for an outpatient TKA procedure as well as exclusionary criteria that would disqualify a patient from receiving an outpatient TKA procedure. We believe that the subset of Medicare beneficiaries who meet patient selection criteria for performance of the TKA procedure on an outpatient basis may have the procedure performed safely in the outpatient setting.

In the CY 2018 OPPS/ASC proposed rule, we stated that we believe that the TKA procedure described by CPT code 27447 meets a number of criteria for removal from the IPO list, including criteria 1, 2, and 4. We sought comments on whether the public believes that these criteria are met and whether the TKA procedure meets any other of the five criteria stated in the beginning of this section. In the proposed rule, we also proposed that CPT code 27447 would be assigned to C–APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator ''J1''.

Comment: Numerous commenters, including individual stakeholders, orthopedic surgeons, clinical specialty societies, national and State-level hospital associations, hospital systems, device manufacturers, and private insurance providers responded to this proposal. Some commenters, including some orthopedic specialty societies and surgeons, private insurance providers, ambulatory surgical centers, hospital systems, and beneficiaries supported the proposal to remove CPT code 27447 from the IPO list. Many of these commenters believed that TKA met CMS' established criteria for removing a procedure from the IPO list and stated that appropriately selected patients who were in excellent health and with no or limited medical comorbidities and sufficient caregiver support could be successful candidates for outpatient TKA. Several commenters referenced their personal, positive experiences with outpatient TKA. Other commenters supported the proposal, but with certain caveats regarding patient safety, including requests that CMS develop, with input from stakeholders, patient selection criteria and risk stratification protocols for TKA to be performed in an outpatient setting. Two orthopedic specialty societies stated that their organization was in the process of developing these patient selection and protocol tools.

In addition, some commenters requested that CMS explicitly state that the surgeon is the final arbiter of the appropriate site for the surgical procedure, that CMS provide an incentive for outpatient and ambulatory settings performing TKA, PHA, and THA to be a part of a registry such as the American Joint Replacement Registry, and that CMS confirm that surgeons will continue to have the option to select the appropriate setting (inpatient or outpatient) for the procedure.

Some commenters expressed concerns that removal of TKA from the IPO list may lead commercial payers to implement coverage policies that would drive these surgeries from the inpatient setting to lower cost outpatient settings that may not be sufficiently prepared to handle the complexities or risks associated with some outpatient TKA procedures. Further, some commenters stated that removing TKA from the IPO list could drive TKA to specific facilities based on cost alone, which could result in significant further stresses in isolated rural care settings.

Response: We appreciate the commenters' support of our proposal. As previously stated in the discussion of the CY 2018 OPPS/ASC proposed rule, we continue to believe that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary. We also reiterate our previous statement that the removal of any procedure from the IPO list does *not* require the procedure to be performed only on an outpatient basis.

While we continue to expect providers who perform outpatient TKA on Medicare beneficiaries to use comprehensive patient selection criteria to identify appropriate candidates for the procedure, we believe that the surgeons, clinical staff, and medical specialty societies who perform outpatient TKA and possess specialized clinical knowledge and experience are most suited to create such guidelines. Therefore, we do not expect to create or endorse specific guidelines or content for the establishment of providers' patient selection protocols. However, we remind commenters that the ''2-midnight'' rule continues to be in effect and was established to provide guidance on when an inpatient admission would be appropriate for payment under Medicare Part A (inpatient hospital services). In general, this guidance provides that if the physician expects the beneficiary to require hospital care that spans at least 2 midnights and admits the beneficiary based upon that expectation, the case is appropriate for payment under the IPPS (80 FR 70539). For stays for which the physician expects the patient to need less than 2 midnights of hospital care, an inpatient admission is payable under Medicare Part A on a case-by-case basis if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care. This documentation and the physician's admission decision are subject to medical review, which is discussed in greater detail below (80 FR 70541). The 2-midnight rule does not apply to procedures on the IPO list; that is, medically necessary procedures that are on the IPO list are appropriate for Medicare Part A payment without regard to the actual or expected length of stay (80 FR 70539).

With regard to the behavior of commercial insurance providers and site selection for outpatient TKA, while we believe that these comments are out of the scope of the proposed rule, we note that commercial providers are responsible for establishing their own rules governing payment for services.

Comment: Several commenters opposed the proposal to remove the TKA procedure from the IPO list, including national and State-level hospital associations, hospital systems, and individual stakeholders. Some of these commenters expressed concerns that TKA was not clinically appropriate for the outpatient setting. The commenters stated that the TKA procedure is invasive and Medicare beneficiaries are more likely to have comorbidities that could make pain more difficult to control. The commenters also stated that, because of these comorbidities, Medicare beneficiaries will face greater complications, recovery times, and rehabilitation needs than non-Medicare populations to recover from TKA procedures.

Response: We continue to believe that the TKA procedure meets a number of our established criteria for removal from the IPO list, including criteria 1, 2, and 4. We also continue to believe that there are a subset of Medicare beneficiaries with less medical complexity who are able to receive this procedure safely on a hospital outpatient basis and that providers should adopt evidence-based patient selection protocols to appropriately identify these patients. As previously noted, removal of a procedure from the IPO list does not require the procedure to be performed only on an outpatient basis. Rather, it allows payment to be made under the OPPS when the procedure is performed on a hospital outpatient. In addition, we expect that physicians will continue to exercise their complex medical judgment, based on a number of factors, including the patient's comorbidities, the expected length of stay in the hospital (in accordance with the 2-midnight rule), the patient's anticipated need for postoperative skilled nursing care, and other factors.

Comment: Several commenters stated their concerns regarding the ability of beneficiaries to access postacute care for a TKA procedure at an SNF. By statute, beneficiaries must have a prior inpatient hospital stay of no fewer than 3 consecutive days to be eligible for Medicare coverage of inpatient SNF care. The commenters stated that discharging outpatient TKA patients without a 3-day stay and access to adequate rehabilitation would increase the likelihood of further medical concerns that may result in readmissions, which will result in higher expenses for the beneficiary, the Medicare program, and the hospital. These commenters stated that if there is no commensurate waiver of the SNF 3-day stay requirement, all outpatient TKA patients would need to be appropriate for discharge to home or home health care. One commenter questioned beneficiaries' ability to access the SNF benefit if a beneficiary has outpatient TKA surgery and is then admitted as an inpatient after being discharged from the hospital outpatient department. Other commenters noted that the vast majority of beneficiaries who fit the criteria for an outpatient TKA or THA procedure would not need institutional postacute care services. Commenters also stated that a large percentage of TKA inpatients do not require a 3-day length of stay, and that removing TKAs from the IPO list would not preclude these patients from meeting the 3-day qualifying stay requirement when warranted.

Response: We reiterate that removal of the TKA procedure from the IPO list does not require the procedure to be performed only on an outpatient basis. Removal of the TKA procedure from the IPO list allows for payment of the procedure in either the inpatient setting or the outpatient setting. The commenter is correct that a prior inpatient hospital stay of at least 3 consecutive days is required by law under Medicare FFS as a prerequisite for SNF coverage. We note that Medicare Advantage plans may elect, pursuant to 42 CFR 409.30 and 422.101(c), to provide SNF coverage without imposing the SNF 3-day qualifying stay requirement and that CMS has issued conditional waivers of the 3-day qualifying stay requirement as necessary to carry out the Medicare Shared Savings Program and to test certain Innovation Center payment models, including the Next Generation ACO Model.

We agree that the physician should take the beneficiaries' need for post-surgical services into account when selecting the site of care to perform the surgery. We would expect that Medicare beneficiaries who are selected for outpatient TKA would be less medically complex cases with few comorbidities and would not be expected to require SNF care following surgery. Instead, we expect that many of these beneficiaries would be appropriate for discharge to home (with outpatient therapy) or home health care. We believe that comprehensive patient selection protocols should be implemented to properly identify these beneficiaries. However, we do not believe that Medicare should establish such protocols and believe that physicians and providers should select an appropriate patient selection protocol.

Comment: Numerous commenters from stakeholders addressed the effect that removing TKA from the IPO list could potentially have on two Medicare payment models currently being administered by the Center for Medicare and Medicaid Innovation: BPCI and the CJR model. The commenters were concerned that the proposal to remove TKA from the IPO list could significantly alter the composition of BPCI and CJR participant hospitals' patient populations. Specifically, the commenters believed that younger and healthier patients would be more likely to receive outpatient TKAs and that a higher proportion of patients receiving inpatient TKAs would be high risk and/or more likely to require additional postacute care support. As a result, the commenters believed that a change in patient-mix could increase the average episode payment of the remaining inpatient TKA BPCI and CJR episodes when compared to current payment levels and affect a hospital's ability to fall below the established target price for the episode, thereby hindering the hospital's ability to generate savings under the BPCI or CJR model. The commenters presented several proposed refinements to the BPCI and CJR models to mitigate these effects, including adjusting the target price for BPCI and CJR episodes involving TKA to exclude procedures that could have been performed in the HOPD or allowing BPCI Model 2 and CJR episodes to be initiated by TKA performed in the hospital outpatient department.

Response: As mentioned earlier, we believe that there is a subset of less medically complex TKA cases that could be appropriately and safely performed on an outpatient basis. However, we do not expect a significant volume of TKA cases currently being performed in the hospital inpatient setting to shift to the hospital outpatient setting as a result of removing this procedure from the IPO list. At this time, we expect that a significant number of Medicare beneficiaries will continue to receive treatment as an inpatient for TKA procedures. As providers' knowledge and experience in the delivery of hospital outpatient TKA treatment develops, there may be a greater migration of cases to the hospital outpatient setting. However, we do not expect a significant shift in TKA cases from the hospital inpatient setting to the hospital outpatient setting between January 1, 2018 (the effective date for the removal of TKA from the IPO list) and the current end dates of the performance periods for the BPCI and CJR models, September 30, 2018 and December 31, 2020, respectively. Accordingly, we do not expect a substantial impact on the patient-mix for the BPCI and CJR models. We intend to monitor the overall volume and complexity of TKA cases performed in the hospital outpatient department to determine whether any future refinements to these models are warranted.

Comment: Some commenters asked CMS to reconsider the proposed assignment of CPT code 27447 to C–APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator ''J1''. The commenters presented an analysis of OPPS claims data which indicated that approximately one-third of the TKA claims reported no joint implant HCPCS C-code on the claim. Some of these commenters asserted that the claims that did not include a joint implant had a geometric mean cost of approximately

$3,808 and the claims that did include a joint implant had a geometric mean cost of approximately $13,843, while the overall geometric mean cost for claims with CPT code 27447 was approximately $8,602. The commenters requested that CMS only use claims for ratesetting for CPT 27447 that include a joint implant and to assign the procedure to APC 5116 (Level 6 Musculoskeletal Procedures). One commenter also stated that CMS failed to provide the general public with an explanation of the source of the geometric mean cost of the TKA procedure, which was CMS' basis for assigning the TKA procedure to a C–APC.

Response: Since the assignment of CPT code 27447 to the IPO list, no payment for claim lines billing this procedure code were made. Based on clinical similarity with other musculoskeletal procedures, we continue to believe that C–APC 5115 is an appropriate APC assignment for CPT code 27447. Further, we note that the 50th percentile IPPS payment for TKA without major complications or comorbidities (MS–DRG 470) is roughly $11,760 for FY 2018. We note that the geometric mean cost for C–APC 5116 is over $15,000. As previously stated, we would expect that beneficiaries selected for outpatient TKA would generally be expected to be less complex and to not have major complications or comorbidities. Therefore, we do not believe that it would be appropriate for the OPPS payment rate to exceed the IPPS payment rate for TKA without major complications/comorbidities because IPPS cases would generally be expected to be more complicated and complex than those selected for performance in the hospital outpatient setting and because inpatient cases would include room and board as well as more time in the hospital.

With respect to the billing concern, we rely on hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report charges on claims and charges and costs on their Medicare hospital cost reports appropriately (77 FR 68324). As we do every year, we will review and evaluate the APC groupings based on the latest available data in the next rulemaking cycle.

After consideration of the public comments we received, we are finalizing our proposal to remove the TKA procedure described by CPT code 27447 from the IPO list beginning in CY 2018 and to assign the TKA procedure to C–APC 5115 with status indicator ''J1''.

4. Recovery Audit Contractor (RAC) Review of TKA Procedures

In the CY 2018 OPPS/ASC proposed rule (82 FR 33643 and 33644), we proposed that if we finalized our proposal to remove the TKA procedure described by CPT code 27447 from the IPO list, we would also prohibit RAC review of patient status for TKA procedures performed in the inpatient setting for a period of 2 years to allow providers time to gain experience with these procedures in the outpatient setting. We believe this approach will help ensure that hospitals can determine whether to perform the procedure on a hospital outpatient or hospital inpatient basis without taking into account the possibility of an inpatient TKA claim being denied upon a patient status review by a RAC. That is, given that this surgical procedure is newly eligible for payment under either the IPPS or the OPPS, we proposed that RAC patient status reviews of a hospital claim is prohibited for a period of 2 years. We note that RAC reviews of TKA procedures described by CPT code 27447 will continue to be permitted for issues other than patient status as an inpatient or outpatient, including those for underlying medical necessity.

Comment: Many commenters supported a prohibition on RAC review for patient status for TKA procedures performed in the inpatient setting for a period of 2 years. Some commenters suggested that CMS prohibit RAC review for a period of at least 36 months to allow consensus to develop around appropriate evidence-based patient selection criteria. One commenter requested that CMS impose a permanent moratorium on RAC reviews of patient status for TKA or confirm that after any moratorium is lifted, a RAC will only be permitted to undertake such a review upon a referral by a Quality Improvement Organization (''QIO''). One commenter also requested that CMS also clarify that its current 2-midnight policy will apply to the TKA procedure if it were to be removed from the IPO, as it does for other inpatient admissions.

Response: We continue to believe that a 2-year prohibition on RAC review for TKA procedures performed in the inpatient setting is an adequate amount of time to allow providers to gain experience with determining the most appropriate setting to perform these procedures and establishing patient selection criteria to assist in the determination. As stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70538 through 70549), under the 2-midnight rule, an inpatient admission is generally appropriate for Medicare Part A payment if the physician (or other qualified practitioner) admits the patient as an inpatient based upon the expectation that the patient will need hospital care that crosses at least 2 midnights. However, Medicare Part A payment is allowed on a case-by-case basis for inpatient admissions that do not satisfy the 2-midnight benchmark, if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than 2 midnights. The initial medical reviews of claims for short-stay inpatient admissions are conducted by QIOs, which may refer providers to the RACs due to exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to: Having high denial rates and consistently failing to adhere to the 2-midnight rule, or failing to improve their performance after QIO educational intervention. The 2-midnight rule and this medical review policy do not apply to procedures that are included on the IPO list. However, these policies do apply to other inpatient admissions for procedures that are not included on the IPO list and would also generally apply to TKA procedures performed in the hospital inpatient setting. As mentioned previously, however, RAC patient status reviews for TKA procedures performed in the hospital inpatient setting is prohibited for a period of 2 years.

5. Public Requests for Additions to or Removal of Procedures on the IPO List

Commenters who responded to the CY 2018 OPPS/ASC proposed rule also requested that CMS remove several additional procedures from the IPO list. These additional procedures are listed in Table 77 below.

TABLE 77—PROCEDURES REQUSTED BY COMMENTERS TO BE REMOVED FROM THE CY 2018 INPATIENT ONLY LIST

CY 2018 PT code	CY 2018 long descriptor
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty.
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder)).
27125	Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty).
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft.
27702	Arthroplasty, ankle; with implant (total ankle).
27703	Arthroplasty, ankle; revision, total ankle.
43282	Laparoscopy, surgical, repair of paraesophageal hernia with implantation of mesh.
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only.
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only.
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components.

After evaluating the above list of codes that commenters requested to be removed from the IPO list against our established criteria, we believe that CPT codes 43282, 43772, 43773, 43774 meet several criteria to be removed from the IPO list, including criteria 3. Accordingly, we are removing these four CPT codes from the IPO list for CY 2018 and assigning them to APCs in this final rule with comment period.

For the remaining CPT codes requested to be removed from the IPO list that describe joint replacement procedures, because of the strong public interest and numerous comments that we have received from stakeholders regarding our proposals to remove other joint replacement procedures, namely the TKA procedure, from the IPO list, we are not removing these procedures from the IPO list at this time to allow for further discussion. We will take these requests into consideration and any proposed policy changes regarding these procedures will be announced in future rulemaking. A further discussion of the comment solicitation of the possible removal of partial hip arthroplasty (PHA) and total hip arthroplasty (THA) procedures from the IPO list is included under section IX.C. of this final rule with comment period.

One commenter requested that CMS add the procedure described by CPT code 92941 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, artherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel) to the IPO list because this procedure is performed emergently to treat acute myocardial infarction patients.

We evaluated the procedure described by CPT code 92941 against our criteria, and we agree with the commenter that CPT code 92941 should be added to the IPO list.

6. Summary of Changes to the IPO List for CY 218

After consideration of the public comments we received and for the reasons discuss previously, we are removing the following procedures from the IPO list for CY 2018: CPT codes 27447, 43282, 43772, 43773, 43774, and 55866. We also are adding CPT code 92941 to the IPO list for CY 2018. The specific procedures, including the CPT code, long descriptors, and the CY 2018 status indicators, are displayed in Table 78 below.

TABLE 78—CHANGES TO THE INPATIENT ONLY LIST FOR CY 2018

CY 2018 CPT code	CY 2018 long descriptor	Status	CY 2018 OPPS APC assignment	CY 2018 OPPS status indicator
27447	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty).	Removed	5115	J1
43282	Laparoscopy, surgical, repair of paraesophageal hernia with implantation of mesh.	Removed	5362	J1
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only.	Removed	5303	J1
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only.	Removed	5361	J1
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components.	Removed	5303	J1
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed.	Removed	5362	J1
92941	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, artherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel.	Added	N/A	C

The complete list of codes (the IPO list) that will be paid by Medicare in CY 2018 as inpatient only procedures is included as Addendum E to this final rule with comment period (which is available via the Internet on the CMS Web site).

C. Discussion of Solicitation of Public Comments on the Possible Removal of Partial Hip Arthroplasty (PHA) and Total Hip Arthroplasty (THA) Procedures From the IPO List

1. Background

Partial hip arthroplasty (PHA), CPT code 27125 (Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)), and total hip arthroplasty (THA) or total hip replacement, CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft), have traditionally been considered inpatient surgical procedures. The procedures were placed on the original IPO list in the CY 2001 OPPS final rule (65 FR 18780). In 2000, the primary factors that were used to determine the assignment of a procedure to the IPO list were as follows: (1) The invasive nature of the procedure; (2) the need for at least 24 hours of postoperative care; and (3) the underlying physical condition of the patient who would require the surgery (65 FR 18455). In 2000, the geometric mean average length of stay for the DRG to which uncomplicated PHA and THA procedures were assigned was 4.6 days, and in 2016, the average length of stay for current uncomplicated PHA and THA procedures for the MS–DRG was 2.7 days.

In the CY 2017 OPPS/ASC proposed rule, we solicited public comments on the possible removal of total knee arthroplasty (TKA) from the IPO list (81 FR 45679 through 45681). Included in the public comments received related to the removal of TKA from the IPO list were several comments in support of removal of THA from the IPO list as well. Among those commenters expressing support for removal of THA from the IPO list were several surgeons and other stakeholders who believed that, given thorough preoperative screening by medical teams with significant experience and expertise involving hip replacement procedures, the THA procedure could be provided on an outpatient basis for some Medicare beneficiaries. These commenters noted significant success involving same day discharge for patients who met the screening criteria and whose experienced medical teams were able to perform the procedure early enough in the day for the patients to achieve postoperative goals, allowing home discharge by the end of the day. The commenters believed that the benefits of providing the THA procedure on an outpatient basis will lead to significant enhancements in patient well-being, improved efficiency, and cost savings to the Medicare program, including shorter hospital stays resulting in fewer medical complications, improved results, and enhanced patient satisfaction.

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33644 and 33645), recent innovations have enabled surgeons to perform the PHA and THA procedures on an outpatient basis on non-Medicare patients (both in the HOPD and in the ASC). These innovations in PHA and THA care include minimally invasive techniques, improved perioperative anesthesia, alternative postoperative pain management, and expedited rehabilitation protocols. Patients undergoing minimally invasive surgical procedures instead of open surgical techniques generally benefit from a shorter hospital stay. However, not all patients are candidates for minimally invasive PHA or THA. Commenters on the CY 2017 OPPS/ASC proposed rule comment solicitation on the TKA procedure have stated that benefits of outpatient PHA and THA procedures include a likelihood of fewer complications, more rapid recovery, increased patient satisfaction, recovery at home with the assistance of family members, and a likelihood of overall improved outcomes. On the contrary, unnecessary inpatient hospitalization exposes patients to the risk of hospital-acquired conditions such as infections and a host of other iatrogenic mishaps.

We stated in the CY 2018 OPPS/ASC proposed rule that, like most surgical procedures, both PHA and THA need to be tailored to the individual patient's needs. Patients with a relatively low anesthesia risk and without significant comorbidities who have family members at home who can assist them may likely be good candidates for an outpatient PHA or THA procedure. These patients may be determined to also be able to tolerate outpatient rehabilitation in either an outpatient facility or at home postsurgery. On the other hand, patients with multiple medical comorbidities, aside from their osteoarthritis, would more likely require inpatient hospitalization and possibly postacute care in a skilled nursing facility or other facility. Surgeons who have discussed outpatient PHA and THA procedures in public comments in response to our CY 2017 OPPS/ASC proposed rule comment solicitation on the TKA procedure have emphasized the importance of careful patient selection and strict protocols to optimize outpatient hip replacement outcomes. These protocols typically manage all aspects of the patient's care, including the at-home preoperative and postoperative environment, anesthesia, pain management, and rehabilitation to maximize rapid recovery, ambulation, and performance of activities of daily living.

We also noted in the proposed rule that not uncommonly we receive questions from the public about the IPO list that lead us to believe that some members of the public may misunderstand certain aspects of the IPO list. Therefore, two important principles of the IPO list must be reiterated at the outset of this discussion. First, just because a procedure is not on the IPO list does not mean that the procedure cannot be performed on an inpatient basis. IPO list procedures must be performed on an inpatient basis (regardless of the expected length of the hospital stay) in order to qualify for Medicare payment, but procedures that are not on the IPO list can be and very often are performed on individuals who are inpatients (as well as individuals who are hospital outpatients and ASC patients). Second, the IPO list status of a procedure has no effect on the MPFS professional payment for the procedure. Whether or not a procedure is on the IPO list is not in any way a factor in the MPFS payment methodology.

2. Topics and Questions for Public Comments

In the CY 2018 OPPS/ASC proposed rule (82 FR 33645), we sought public comments on whether we should remove the procedures described by CPT codes 27125 and 27130 from the IPO list from all interested parties, including the following groups or individuals: Medicare beneficiaries and advocate associations for Medicare beneficiaries; orthopedic surgeons and physician specialty societies that represent orthopedic surgeons who perform PHA and/or THA procedures; hospitals and hospital trade associations; and any other interested stakeholders. We sought public comments on the following questions:

- Are most outpatient departments equipped to provide PHA and/or THA to some Medicare beneficiaries?
- Can the simplest procedure described by CPT codes 27125 and 27130 be performed in most outpatient departments?
- Are the procedures described by CPT codes 27125 and 27130 sufficiently related to or similar to other procedures we have already removed from the IPO list?
- How often is the procedure described by CPT codes 27125 and 27130 being performed on an outpatient

basis (either in an HOPD or ASC) on non-Medicare patients?

• Would it be clinically appropriate for some Medicare beneficiaries in consultation with his or her surgeon and other members of the medical team to have the option of either a PHA or THA procedure as a hospital outpatient, which may or may not include a 24-hour period of recovery in the hospital after the operation?

In addition, we sought public comments on whether the PHA and THA procedures may meet the criteria to be added to the ASC Covered Procedures List. We refer readers to section XII.C.1.d. of this final rule with comment period for a complete discussion of the ASC Covered Procedures List.

Finally, as noted when we solicited public comment on removing the TKA procedure from the IPO list in the CY 2017 rulemaking, we solicited public comment on the effect of removing the TKA procedure from the IPO list on the CJR Model and the BPCI Model. We refer readers to the CY 2017 OPPS/ASC proposed rule for a discussion of questions we raised for public comments, and we again sought public comment on the effect of removing the PHA and THA procedures from the IPO list on these models. For a discussion of these models in the CY 2017 rulemaking, we refer readers to 81 FR 79698 through 79699.

Comment: Numerous commenters representing a variety of stakeholders, including physicians and other care providers, individual stakeholders, specialty societies, hospital associations, hospital systems, ASCs, device manufacturers, and beneficiaries responded to our solicitation of comments regarding the removal of PHA and THA from the IPO list. The comments were diverse and some were similar to the comments we received on our proposal to remove TKA from the IPO list. Some commenters, including hospital systems and associations, as well as specialty societies and physicians, stated that it would not be clinically appropriate to remove PHA and THA from the IPO list, indicating that the patient safety profile of outpatient THA and PHA in the non-Medicare population is not well-established. Commenters representing orthopedic surgeons also stated that patients requiring a hemiarthroplasty (PHA) for fragility fractures are by nature higher risk, suffer more extensive comorbidities and require closer monitoring and preoperative optimization; therefore, it would not be medically appropriate to remove the PHA procedure from the IPO list.

Other commenters, including ambulatory surgery centers, physicians, and beneficiaries, supported the removal of PHA and THA from the IPO list. These commenters stated that the procedures were appropriate for certain Medicare beneficiaries and most outpatient departments are equipped to provide THA to some Medicare beneficiaries. They also referenced their own personal successful experiences with outpatient THA.

Finally, commenters stated concerns regarding the effect of removing THA on the pricing methodologies, target pricing, and reconciliation process of the procedure in certain Medicare payment models (that is, the CJR and the BPCI models). They requested modifications to these models if the THA procedure is removed from the IPO list and requested that these procedures be suspended from quality programs such as the Hospital Readmissions Reduction Program, the Hospital Value-Based Purchasing Program, and Hospital Inpatient Quality Reporting Program if they are removed from the IPO list.

Response: We thank the commenters for their detailed responses. We will consider these comments in future policymaking.

X. Nonrecurring Policy Changes

A. Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

1. Background

Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off campus outpatient departments of a provider on or after January 1, 2017, will not be considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and will instead be paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met. To be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. The implementation of section 603 of the Bipartisan Budget Act of 2015 was finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (79720 through 79729).

2. Expansion of Services by Excepted Off-Campus Hospital Outpatient Departments

In the CY 2018 OPPS/ASC proposed rule (82 FR 33645 through 33648), we did not propose any policies to limit clinical service line expansion or volume increases at excepted off-campus provider-based departments (PBDs). However, we stated that we would continue to monitor claims data for changes in billing patterns and utilization, and continue to invite public comments on the issue of service expansion.

We received a number of comments from various stakeholders regarding both clinical service line expansion and volume increases, as well as other topics not discussed in the CY 2018 OPPS/ASC proposed rule, including relocation and change of ownership. We appreciate all of the comments received, and we will consider them as we consider whether to pursue future rulemaking on these issues.

We also received some public comments regarding issues that are outside the scope of the policies addressed in the CY 2018 OPPS/ASC proposed rule, including comments related to the proposed payment adjustment applied for nonexcepted items and services furnished by nonexcepted off-campus PBDs, which are addressed in the CY 2018 MPFS final rule, and comments regarding technical billing questions. With respect to the payment adjustment for nonexcepted items and services furnished by nonexcepted off-campus PBDs and changes to the payment relativity adjuster, we refer readers to the CY 2018 MPFS final rule for that information and, more broadly, for the payment rates under the MPFS that will apply to nonexcepted items and services furnished by nonexcepted off-campus PBDs for CY 2018. We expect the CY 2018 MPFS final rule to be issued on or about the same date as this OPPS/ASC final rule with comment. Comments submitted regarding technical billing questions are addressed through applicable program instructions.

3. Section 16002 of the 21st Century Cures Act (Treatment of Cancer Hospitals in Off-Campus Outpatient Department of a Provider Policy)

As discussed in the CY 2018 OPPS/ACS proposed rule (82 FR 33648), in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699), we finalized a number of proposals to implement section 603 of the Bipartisan Budget Act of 2016 (Pub. L. 114–74), enacted on November 2, 2015, which

amended section 1833(t) of the Act. Specifically, this provision amended the OPPS statute to require that certain items and services furnished by certain off-campus PBDs on or after January 1, 2017 will not be considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS, and instead will be paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699), we established the Medicare Physician Fee Schedule as the ''applicable payment system'' for the majority of the nonexcepted items and services furnished by nonexcepted off-campus PBDs.

Section 16002(a) of the 21st Century Cures Act (Pub. L. 114–255) amended the Act at section 1833(t)(20)(B) and provided that, with respect to applicable items and services furnished during 2017 or a subsequent year, the term ''off-campus outpatient department of a provider'' excludes certain cancer hospitals. To meet this exclusion, section 16002(a) requires that such cancer hospitals (1) be described in section 1886(d)(1)(B)(v) of the Act; and (2) for hospital outpatient departments that meet the requirements for 42 CFR 413.65, after November 1, 2015 and before December 15, 2016, that the Secretary has received from the provider an attestation that the department met such requirements not later than 60 days after the date of enactment of section 16002 (December 13, 2016), or, for departments that meet the requirements after December 13, 2016, the Secretary has received from the provider an attestation that the department met the requirements not later than 60 days after the date the department first met the requirements of 42 CFR 413.65. As we stated in the CY 2018 OPPS/ASC proposed rule, through operational guidance, we have provided direction to all MACs regarding this provision. We also have provided guidance on this provision to hospital providers, which can be found on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Sections-16001-16002.pdf*.

Section 16002(b) of Public Law 114–255 amended section 1833(t)(18) of the Act by adding a new subparagraph (C) that requires the Secretary, in applying 42 CFR 419.43(i) for services furnished on or after January 1, 2018, to use a target payment-to-cost ratio (PCR) that is 1 percentage point less than the target PCR that would otherwise apply. In addition to the 1 percentage point reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described in section 1833(t)(21)(C) of the Act other than for services furnished by certain cancer hospitals. Further, in making any budget neutrality adjustments under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act. We refer readers to section II.F. of this final rule with comment period for a discussion on the calculation of the target PCR for cancer hospitals for CY 2018.

B. Medicare Site-of-Service Price Transparency (Section 4011 of the 21st Century Cures Act)

Section 4011 of the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016, amended section 1834 of the Act by adding a new subsection (t). New section 1834(t) of the Act provides that, in order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under Title XVIII, the Secretary shall, for 2018 and each year thereafter, make available to the public via a searchable Web site, with respect to an appropriate number of items and services, the estimated payment amount for the item or service under the OPPS and ASC payment system and the estimated beneficiary liability applicable to the item or service. In the CY 2018 OPPS/ASC proposed rule (82 FR 33648), we announced our plan to establish the searchable Web site required by section 1834(t) of the Act. We indicated that details regarding the Web site will be issued through our subregulatory process. We stated in the proposed rule that we anticipate that the Web site will be made available in early CY 2018.

Comment: One commenter requested that CMS ensure that the Web site is designed in a user-friendly manner, and err on the side of including services for display. Another commenter requested that Web site users be provided with the proper context for understanding some of the reasons for potential cost differences.

Response: We appreciate these comments and will take them into consideration as we develop the Web site.

C. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) added subsection (q) to section 1834 of the Act, which directs the Secretary to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services (the AUC program). Section 1834(q)(1)(B) of the Act defines AUC as criteria that are evidence-based (to the extent feasible) and assist professionals who order and furnish applicable imaging services to make the most appropriate treatment decisions for a specific clinical condition. The current policies for the AUC program for advanced diagnostic imaging services are codified in the regulations at 42 CFR 414.94.

There are four components of the AUC program for advanced diagnostic imaging services program. In the CY 2016 MPFS final rule with comment period (80 FR 71102 through 71116 and 80 FR 71380 through 71382), we addressed the first component of the Medicare AUC program. The first component includes the requirements and process for the establishment and specification of the AUC. In the CY 2017 MPFS final rule (81 FR 80403 through 80428 and 81 FR 80554 through 80555), we addressed the second component of the AUC program. The second component includes the specification of qualified clinical decision support mechanisms (CDSMs). A CDSM is the electronic tool through which the ordering practitioner consults AUC. In the CY 2018 OPPS/ASC proposed rule (82 FR 33648 and 33649), we stated that we had proposed in the CY 2018 MPFS proposed rule to address the third component of the AUC program. The third component includes the requirements for an ordering professional to consult with a qualified CDSM when ordering an applicable imaging service, and for the furnishing professional to include that consultation information on claims for the service that is furnished in an applicable setting and paid under an applicable payment system. Based on the statutory language of section 1834(q)(4)(B) of the Act, the AUC program applies to advanced imaging services for which payment is made under the following applicable payment systems: The MPFS; the OPPS; and the ASC payment system. The fourth component of the program is prior authorization for outlier ordering professionals. This component will be discussed in future rulemaking.

We indicated in the CY 2018 OPPS/ASC proposed rule that public

comments related to the requirements for the AUC program should be addressed in response to the CY 2018 MPFS proposed rule. Therefore, we refer readers to the CY 2018 MPFS final rule for further information governing the Medicare AUC program and the finalized policies for CY 2018, including summaries of any public comments we received on the proposals in the CY 2018 MPFS proposed rule and our responses to those comments.

D. Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in Critical Access Hospitals (CAHs) and Certain Small Rural Hospitals

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33649), in the CY 2009 OPPS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, respectively), we clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals as well as in PBDs of hospitals, as set forth in the CY 2000 OPPS final rule with comment period (65 FR 18525). In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60575 through 60591), we finalized a technical correction to the title and text of the applicable regulation at 42 CFR 410.27 to clarify that this standard applies in CAHs as well as hospitals. In response to concerns expressed by the hospital community, in particular CAHs and small rural hospitals, that they would have difficulty meeting this standard, on March 15, 2010, we instructed all MACs not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs from January 1, 2010 through December 31, 2010, while the agency revisited the supervision policy during the CY 2011 OPPS/ASC rulemaking cycle.

Due to continued concerns expressed by CAHs and small rural hospitals, we extended this notice of nonenforcement (''enforcement instruction'') as an interim measure for CY 2011, and expanded it to apply to small rural hospitals having 100 or fewer beds (75 FR 72007). We continued to consider the issue further in our annual OPPS notice-and-comment rulemaking, and implemented an independent review process in 2012 to obtain advice from the HOP Panel on this matter (76 FR 74360 through 74371). Under this process used since CY 2012, the HOP Panel considers and advises CMS regarding stakeholder requests for changes in the required level of supervision of individual hospital outpatient therapeutic services. In addition, we extended the enforcement instruction through CY 2012 and CY 2013. The enforcement instruction has not been in effect since December 31, 2013. Congress has taken legislative action (Pub. L. 113–198 and Pub. L. 114–112) to extend nonenforcement of the direct supervision requirement for hospital outpatient therapeutic services in CAHs and small rural hospitals having 100 or fewer beds since December 31, 2013. The latest legislative action (Pub. L. 114–255) extended nonenforcement until December 31, 2016. The current enforcement instruction is available on the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/Moratorium-on-Hospital-Supervision-Enforcement.pdf*.

As discussed in the CY 2018 OPPS/ASC proposed rule, stakeholders have consistently requested that CMS continue the nonenforcement of the direct supervision requirement for hospital outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds. Stakeholders stated that some small rural hospitals and CAHs have insufficient staff available to furnish direct supervision. The primary reason stakeholders cited for this request is the difficulty that CAHs and small rural hospitals have in recruiting physicians and nonphysician practitioners to practice in rural areas. These stakeholders noted that it is particularly difficult to furnish direct supervision for critical specialty services, such as radiation oncology services, that cannot be directly supervised by a hospital emergency department physician or nonphysician practitioner because of the volume of emergency patients or lack of specialty expertise. In addition, we are not aware of any quality of care complaints from beneficiaries or providers relating to the enforcement instruction related to direct physician supervision.

Therefore, in the CY 2018 OPPS/ASC proposed rule, we proposed to reinstate the enforcement instruction for outpatient therapeutic services furnished in CAHs and small rural hospitals having 100 or fewer beds for CYs 2018 and 2019 to give these CAHs and small rural hospitals more time to comply with the supervision requirements for outpatient therapeutic services and to give all parties additional time to submit specific services to be evaluated by the HOP Panel for a recommended change in the supervision level. We stated that these hospitals will continue to be subject to conditions of participation for hospitals and other Medicare rules regarding supervision. We welcomed public comments on this proposal.

Comment: A few commenters opposed the proposal to reinstate the enforcement instruction for CAHs and small rural hospitals because of concerns about patient safety or having qualified physicians perform certain medical services. One commenter believed that supervision requirements should be applied uniformly to hospitals in all care settings to ensure patient safety. Another commenter focused on radiation oncology services and believed that those services should be delivered by personnel trained in radiation oncology. The commenter understood concerns about physician availability in rural areas, but encouraged CMS to create more incentives for radiation oncologists to practice in rural areas instead of not enforcing requirements for direct supervision.

Response: We agree that patient safety is a critically important consideration for each service, and that only qualified physicians and nonphysician practitioners who are practicing within their State scope of practice should perform and oversee therapeutic services, as applicable. We note that our proposal did not change State licensure and scope of practice requirements. We would expect all hospitals to ensure that appropriate clinical personnel direct and oversee each beneficiary's care such that patient safety is not compromised. As stated in our proposal, we are not aware of any quality of care complaints from beneficiaries or providers relating to the level of physician supervision for hospital outpatient therapeutic services. In addition, CAHs and small rural hospitals will continue to be subject to the Medicare conditions of participation for hospitals and other Medicare rules regarding supervision.

Comment: Several commenters supported the proposal for CYs 2018 and 2019. Some commenters suggested that CMS adopt the nonenforcement policy for CY 2017 and permanently beyond CY 2019. Commenters also suggested changing the level of supervision for some or most hospital outpatient therapeutic services, such as therapy services, to general supervision as the default supervision level. These commenters also suggested that the change in supervision level should apply to additional categories of hospitals or to all hospitals and not just for CAHs and small rural hospitals. The commenters believed changing the level of supervision for all hospitals will help rural providers with the shortages of

health care professionals and reduce the regulatory burden on providers while providing a level of supervision consistent with the conditions of participation for CAHs.

Response: We appreciate the support for this proposal. Permanent changes to the supervision level for outpatient therapeutic services for all hospitals are beyond the scope of this proposal. We note that we have an established process for stakeholders to submit specific services to be evaluated by the HOP Panel for a recommended change in the supervision levels. Likewise, permanently reinstating the enforcement instruction after CY 2019 is beyond the scope of this proposal. As we stated in the CY 2018 OPPS/ASC proposed rule, we proposed to reinstate the enforcement instruction for 2 years to give small rural hospitals and CAHs additional time to comply with the supervision requirements for outpatient therapeutic services and to give all parties additional time to submit specific services to be evaluated by the HOP Panel for a recommended change in the supervision level.

With respect to applying the nonenforcement policy to CY 2017, we proposed to reinstate the enforcement instruction prospectively, for services administered beginning on the effective date of this final rule with comment period, which is scheduled for January 1, 2018; and we are finalizing that proposal. We anticipate issuing guidance outside of this rule to address enforcement policy for the direct supervision requirement for outpatient therapeutic services for CY 2017.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to reinstate the nonenforcement policy for direct supervision enforcement of outpatient therapeutic services furnished in CAHs and small rural hospitals having 100 or fewer beds, and to reinstate our enforcement instruction for CYs 2018 and 2019.

E. Payment Changes for Film X-Ray Services and Payment Changes for X-Rays Taken Using Computed Radiography Technology

Section 502 of Division O, title V of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), which was enacted on December 18, 2015, contains provisions to incentivize the transition from traditional X-ray imaging to digital radiography. In particular, section 502(b) of Public Law 114–113 amended section 1833(t)(16) of the Act by adding subparagraph (F), which includes provisions that limit payment for film X-ray imaging services and computed radiography imaging services.

Section 1833(t)(16)(F)(i) of the Act specifies that, effective for services furnished during 2017 or a subsequent year, the payment under the OPPS for imaging services that are X-rays taken using film (including the X-ray component of a packaged service) that would otherwise be made under the OPPS (without application of subparagraph (F)(i) and before application of any other adjustment under section 1833(t) of the Act) shall be reduced by 20 percent. Section 1833(t)(16)(F)(iii) of the Act provides that the reductions made under section 1833(t)(16)(F) of the Act shall not be considered an adjustment under section 1833(t)(2)(E) of the Act, and shall not be implemented in a budget neutral manner.

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33649 through 33650), consistent with section 1833(t)(16)(F)(iv) of the Act, which requires the implementation of the reductions in payment set forth in subparagraph (F) through appropriate mechanisms, which may include modifiers, we implemented section 1833(t)(16)(F)(i) of the Act by establishing the modifier ''FX'' (X-ray taken using film), effective January 1, 2017. The payment for X-rays taken using film and furnished during 2017 or a subsequent year is reduced by 20 percent when modifier ''FX'' (X-ray taken using film) is reported with the appropriate HCPCS codes. The applicable HCPCS codes describing imaging services can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site). When payment for an X-ray service taken using film is packaged into the payment for another item or service under the OPPS, no separate payment for the X-ray service is made and, therefore, there is no payment amount that can be attributed to the X-ray service. Accordingly, the amount of the payment reduction for a packaged film X-ray service is $0 (20 percent of $0). Further discussion of these policies and modifier ''FX'' can be found in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79729 through 79730).

Section 1833(t)(16)(F)(ii) of the Act provides for a phased-in reduction of payments for imaging services that are taken using computed radiography technology (as defined in section 1848(b)(9)(C) of the Act). Payments for such services (including the X-ray component of a packaged service) furnished during CY 2018, 2019, 2020, 2021, or 2022, that would otherwise be determined under section 1833(t) of the Act (without application of subparagraph (F)(ii) and before application of any other adjustment), will be reduced by 7 percent, and if such services are furnished during CY 2023 or a subsequent year, by 10 percent. For purposes of this reduction, computed radiography technology is defined in section 1848(b)(9)(C) of the Act as cassette-based imaging which utilizes an imaging plate to create the image involved. (82 FR 33650).

To further implement this provision, we stated in the proposed rule that we were establishing a new modifier (82 FR 33650), specifically, ''FY'' (X-ray taken using computed radiography technology/cassette-based imaging), as permitted by section 1833(t)(16)(F)(iv) of the Act, that would be reported on claims to identify those HCPCS codes that describe X-rays taken using computed radiography technology. (We note that modifier ''FY'' was listed as placeholder ''XX'' in the CY 2018 OPPS/ASC proposed rule and that we indicated (82 FR 33650) that the 2-digit modifier and long descriptor would be described in this final rule with comment period.) We proposed that the payment reduction would be taken when this payment modifier is reported with the applicable HCPCS code(s) to describe imaging services that are taken using computed radiography technology (82 FR 33650). In the proposed rule, we stated that the applicable HCPCS codes describing imaging services could be found in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site). When payment for an X-ray service taken using computed radiography imaging is packaged into the payment for another item or service under the OPPS, no separate payment for the X-ray service is made and, therefore, there is no payment amount that can be attributed to the X-ray. Accordingly, the amount of the payment reduction for a packaged X-ray service would be $0 (7 percent of $0, and 10 percent of $0). We invited public comments on these proposals.

Comment: One commenter believed that reporting the modifier ''FY'' would be burdensome to hospitals and create another opportunity for miscoding.

Response: Modifier ''FY'' will be reported by hospitals only to identify those services that involve X-rays taken using computed radiography technology. We do not believe that the use of this modifier would be unduly burdensome to hospitals. The reporting of this modifier is similar to the reporting of other existing modifiers that hospitals currently include when

reporting HCPCS codes and modifiers for procedures, services, and items on Medicare claims under the OPPS. To the extent the hospital is already reporting a code for an X-ray taken using computed radiography, appending the modifier to the same claim should not be unduly burdensome. Further, Medicare is required by law to make this payment adjustment and the commenter did not offer an alternative (less burdensome) method by which Medicare could ensure payment accuracy for these services.

Comment: One commenter urged CMS to publish the list of specific CPT and HCPCS codes that would apply to this new modifier (''FY'') as well as to the film X-ray modifier (''FX'') that was implemented last year. The commenter indicated that not having published lists is burdensome to providers and also exposes them to additional risk of audit. This same commenter offered to provide technical assistance from its X-ray manufacturer members on the creation of such a list.

Response: We thank the commenter for the offer of assistance. However, we expect hospitals to appropriately report the ''FY'' modifier to identify those services that involve X-rays taken using computed radiography technology, and to appropriately report the ''FX'' modifier to identify those X-ray services taken using film. The applicable HCPCS codes describing imaging services can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

Comment: One commenter requested detailed guidance on the implementation of the computed radiography to digital X-ray payment differential. Specifically, the commenter stated that CMS instructions are unclear as to which specific CPT and HCPCS codes require the amended modifier. Prior to implementation, the commenter suggested that CMS publish all applicable codes requiring the modifier, with specific billing guidance.

Response: As indicated above, the new ''FY'' modifier will be used to report those services that involve X-rays taken using computed radiography technology. HOPDs should append modifier ''FY'' to those HCPCS codes that involve the use of X-ray systems taken using computed radiography technology. We believe that hospitals should know when they are billing a HCPCS code that involves the use of an X-ray taken using computed radiography and, therefore, we are not providing a list of codes.

In addition, in accordance with section 1833(t)(16)(F)(ii) of the Act, payments for X-rays taken using computed radiography technology will be reduced by 7 percent during CY 2018, 2019, 2020, 2021, or 2022, and thereafter by 10 percent when furnished during CY 2023 or a subsequent year. Specifically, the payment reduction will apply when the ''FY'' modifier is reported with the applicable HCPCS code(s) to describe imaging services that are taken using computed radiography technology. In addition, when payment for an X-ray service taken using computed radiography imaging is packaged into the payment for another item or service under the OPPS, no separate payment for the X-ray service is made and, therefore, there is no payment amount that can be attributed to the X-ray. Accordingly, the amount of the payment reduction for a packaged X-ray service will be $0 (7 percent of $0, and 10 percent of $0). We note that the applicable HCPCS codes describing imaging services could be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

Comment: Some commenters supported the transition to digital radiography. However, several commenters expressed concern with the statute requiring hospitals to upgrade to digital radiography systems and indicated that the requirement is financially burdensome and difficult to justify. One commenter stated that a typical computed radiography reader can cost between $60,000 and $80,000, while a new digital radiography system can cost up to $200,000. Another commenter indicated that it estimated its cost to replace or retrofit its nearly 120 computed radiography systems to digital radiography systems to be approximately $11 million.

One commenter suggested that, to truly incentivize the transition to digital radiography technology, CMS should offer bonus payments similar to the recently proposed 2015 Certified Health Record Technology (CEHRT) bonus under the Quality Payment Program (QPP) Year 2. This same commenter recommended that, in lieu of bonus payments, CMS work with Congress to implement a delay of these cuts for the useful life of a typical computed radiography machine (5 years) to allow practices time to replace older equipment with digital radiography technology.

Other commenters further indicated there is no clinical benefit to using digital radiography systems, and that, for certain clinical situations, computed radiography systems are preferable. Still other commenters stated that the reduction in payments not only penalizes hospitals, particularly in rural and underserved communities that do not have the financial resources to update their equipment systems, but would also force small clinics and hospitals to no longer provide imaging services that require computed radiography technology.

Response: We are required by section 1833(t)(16)(F) of the Act to reduce payments under the OPPS for X-rays taken using film and X-rays taken using computed radiography technology. We note that the statute did not address either bonus payments to incentivize the transition to digital radiography technology or a delay in the implementation of section 1833(t)(16)(F) of the Act.

After consideration of the public comments we received, we are finalizing our proposal to establish a new modifier ''FY'' (X-ray taken using computed radiography technology/cassette-based imaging) as permitted by section 1833(t)(16)(F)(iv) of the Act, that will be reported on claims to identify those HCPCS codes that describe X-rays taken using computed radiography technology. The payment reduction will be taken when this modifier is reported with the applicable HCPCS code(s) to describe imaging services that are taken using computed radiography technology. The applicable HCPCS codes describing imaging services can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

In addition, although we adopted the payment reduction for the film X-ray imaging services, as required by section 1833(t)(16)(F)(i) of the Act in the CY 2017 OPPS/ASC final rule with comment period, we did not adopt corresponding regulation text. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33650 and 33723 through 33724), we proposed to add new regulation text at 42 CFR 419.71 to codify our existing policies and our proposed policies for computed radiography technology services. We proposed to add the definition of ''computed radiography technology,'' as it is defined in section 1848(b)(9)(C) of the Act, in paragraph (a) of proposed new § 419.71. We stated that the proposed regulation text under paragraph (b) of proposed new § 419.71 would specify the 20-percent reduction for film X-ray imaging services. We proposed that the phased-in payment reduction for computed radiography technology imaging services would be codified at paragraph (c) of proposed new § 419.71. Finally, we proposed that paragraph (d) of proposed new § 419.71

would provide that the payment reductions taken under the section are not considered adjustments under section 1833(t)(2)(E) of the Act and are not implemented in a budget neutral manner. We invited public comments on this proposed regulation text.

We did not receive any public comments on our proposed regulation text. Therefore, we are finalizing our proposal to codify our previously adopted and newly finalized policies regarding section 1833(t)(16)(F) of the Act, without modifications.

F. Revisions to the Laboratory Date of Service Policy

1. Background on the Medicare Part B Laboratory Date of Service Policy

As we discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33650), the date of service (DOS) is a required data field on all Medicare claims for laboratory services. However, a laboratory service may take place over a period of time—the date the physician orders the laboratory test, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date the laboratory performs the test, and the date results are produced may occur on different dates. In the final rule on coverage and administrative policies for clinical diagnostic laboratory services published in the **Federal Register** on November 23, 2001 (66 FR 58791 through 58792), we adopted a policy under which the DOS for clinical diagnostic laboratory services generally is the date the specimen is collected.

A special rule was developed to apply to ''archived'' specimens. For laboratory tests that use an archived specimen, we established that the DOS is the date the specimen was obtained from storage (66 FR 58792).

In 2002, we issued Program Memorandum AB–02–134 which permitted contractors discretion in making determinations regarding the length of time a specimen must be stored to be considered ''archived.'' In response to comments requesting that we issue a national standard to clarify when a stored specimen can be considered ''archived,'' in the Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services final notice, published in the **Federal Register** on February 25, 2005 (70 FR 9357), we defined an ''archived'' specimen as a specimen that is stored for more than 30 calendar days before testing. We established that the DOS for archived specimens is the date the specimen was obtained from storage. Specimens stored for 30 days or less continued to have a DOS of the date the specimen was collected.

2. Current Medicare DOS Policy (''14-Day Rule'')

In the final rule with comment period entitled, in relevant part, ''Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B'' published in the **Federal Register** on December 1, 2006 (MPFS final rule) (71 FR 69705 through 69706), we added a new § 414.510 in Title 42 of the CFR regarding the clinical laboratory DOS requirements and revised our DOS policy for stored specimens. We explained in the MPFS final rule that the DOS of a test may affect payment for the test, especially in situations in which a specimen that is collected while the patient is being treated in a hospital setting (for example, during a surgical procedure), is later used for testing after the patient has been discharged from the hospital. We noted that payment for the test is usually bundled with payment for the hospital service, even where the results of the test did not guide treatment during the hospital stay. To address concerns raised for tests related to cancer recurrence and therapeutic interventions, we finalized modifications to the DOS policy in § 414.510(b)(2)(i) for a test performed on a specimen stored less than or equal to 30 calendar days from the date it was collected (a non-archived specimen), so that the DOS is the date the test was *performed* (instead of the date of collection) if the following conditions are met:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

As we stated in the MPFS final rule, we established these five criteria, which we refer to as the ''14-day rule,'' to distinguish laboratory tests performed as part of post-hospital care from the care a beneficiary receives in the hospital. When the 14-day rule applies, laboratory tests are not bundled into the hospital stay, but are instead paid separately under Medicare Part B (as explained in more detail below).

We also revised the DOS requirements for a chemotherapy sensitivity test performed on live tissue. As discussed in the MPFS final rule (71 FR 69706), we agreed with commenters that these tests, which are primarily used to determine post-hospital chemotherapy care for patients who also require hospital treatment for tumor removal or resection, appear to be unrelated to the hospital treatment in cases where it would be medically inappropriate to collect a test specimen other than at the time of surgery, especially when the specific drugs to be tested are ordered at least 14 days following hospital discharge. As a result, we revised the DOS policy for chemotherapy sensitivity tests, based on our understanding that the results of these tests, even if they were available immediately, would not typically affect the treatment regimen at the hospital. Specifically, we modified the DOS for chemotherapy sensitivity tests performed on live tissue in § 414.510(b)(3) so that the DOS is the date the test was performed if the following conditions are met:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

We explained in the MPFS final rule that, for chemotherapy sensitivity tests that meet this DOS policy, Medicare would allow separate payment under Medicare Part B, that is, separate from the payment for hospital services.

3. Billing and Payment for Laboratory Services Under the OPPS

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33651), the DOS requirements at 42 CFR 414.510 are used to determine whether a hospital bills Medicare for a clinical diagnostic laboratory test (CDLT) or whether the laboratory performing the test bills Medicare directly. This is because separate regulations at 42 CFR

410.42(a) and 411.15(m) generally provide that Medicare will not pay for a service furnished to a hospital patient during an encounter by an entity other than the hospital unless the hospital has an arrangement (as defined in 42 CFR 409.3) with that entity to furnish that particular service to its patients, with certain exceptions and exclusions. These regulations, which we will call the ''under arrangements'' provisions in this discussion, require that if the DOS falls during an inpatient or outpatient stay, payment for the laboratory test is usually bundled with the hospital service.

Under our current rules, if a test meets all DOS requirements in § 414.510(b)(2)(i) or § 414.510(b)(3), the DOS is the date the test was performed, and the laboratory would bill Medicare directly for the test and would be paid under the Clinical Laboratory Fee Schedule (CLFS) directly by Medicare. However, if the test does *not* meet the DOS requirements in § 414.510(b)(2)(i) or § 414.510(b)(3), the DOS is the date the specimen was collected from the patient. In that case, the *hospital* would bill Medicare for the test and then would pay the laboratory that performed the test, if the laboratory provided the test under arrangement.

In recent rulemakings, we have reviewed appropriate payment under the OPPS for certain diagnostic tests that are not commonly performed by hospitals. In CY 2014, we finalized a policy to package certain CDLTs under the OPPS (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17) and 419.22(l)). In CYs 2016 and 2017, we made some modifications to this policy (80 FR 70348 through 70350; 81 FR 79592 through 79594). Under our current policy, certain CDLTs that are listed on the CLFS are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. Specifically, we conditionally package most CDLTs and only pay separately for a laboratory test when it is: (1) The only service provided to a beneficiary on a claim; (2) considered a preventive service; (3) a molecular pathology test; or (4) an advanced diagnostic laboratory test (ADLT) that meets the criteria of section 1834A(d)(5)(A) of the Act (78 FR 74939 through 74942; 80 FR 70348 through 70350; and 81 FR 79592 through 79594). In the CY 2016 OPPS/ASC final rule with comment period, we excluded all molecular pathology laboratory tests from packaging because we believed these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.

For similar reasons, in the CY 2017 OPPS/ASC final rule with comment period, we extended the exclusion to also apply to all ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act.[32] We stated that we will assign status indicator ''A'' (Separate payment under the CLFS) to ADLTs once a laboratory test is designated an ADLT under the CLFS. Laboratory tests that are separately payable and are listed on the CLFS are paid at the CLFS payment rates outside the OPPS.

4. ADLTs Under the New Private Payor Rate-Based CLFS

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), requires significant changes to how Medicare pays for CDLTs under the CLFS. Section 216(a) of PAMA also establishes a new subcategory of CDLTs known as ADLTs with separate reporting and payment requirements under section 1834A of the Act. In the CLFS final rule published in the **Federal Register** on June 23, 2016, entitled ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule'' (CLFS final rule) (81 FR 41036), we implemented the requirements of section 1834A of the Act.

As defined in § 414.502, an ADLT is a CLDT covered under Medicare Part B that is offered and furnished only by a single laboratory. In addition, an ADLT cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. Also, an ADLT must meet either Criterion (A), which implements section 1834A(d)(5)(A) of the Act, or Criterion (B), which implements section 1834A(d)(5)(B) of the Act, as follows:

- *Criterion (A):* The test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins; when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies); provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and may include other assays.

Or:

- *Criterion (B):* The test is cleared or approved by the Food and Drug Administration.

Generally, under the revised CLFS, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, updates to ADLT payment rates occur annually instead of every 3 years. The payment methodology for ADLTs is detailed in the CLFS final rule (81 FR 41076 through 41083).

5. Discussion of Potential Revisions to the Laboratory DOS Policy in the CY 2018 OPPS/ASC Proposed Rule

In the CY 2018 OPPS/ASC proposed rule (82 FR 33650 through 33653), we described the history of our laboratory DOS policy and discussed potentially modifying the DOS policy for certain ADLTs and molecular pathology tests. We explained that, recently, we have heard from certain laboratory stakeholders about operational issues the current laboratory DOS policy creates for hospitals and laboratories with regard to molecular pathology tests and laboratory tests they expect will be designated by CMS as ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. These stakeholders have expressed that although these particular tests are not packaged under the OPPS, under current DOS policy, if the tests are ordered within 14 days of a patient's discharge from the hospital, Medicare still treats the tests as though they were ordered and furnished by the hospital itself. Under those circumstances, laboratories cannot directly seek Medicare payment for the molecular pathology test or ADLT. The hospital must bill Medicare for the test, and the laboratory must seek payment from the hospital. Specifically, we noted that stakeholders representing laboratories have expressed the following concerns:

- The current DOS policy permits hospitals to bill for tests they did not perform and that may have no relationship to or bearing on treatment received by the patient while in the hospital.
- The DOS policy may create inconsistent billing for specialty laboratories. For example, if the hospital is located in a different jurisdiction than the MAC used by the laboratory, a different MAC may be billed.

[32] Under section 1834A(d)(5)(A) of the Act, an ADLT is a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and . . . ''the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.'' CMS has established a regulatory definition for this type of ADLT in 42 CFR 414.502.

• Hospitals may be discouraged from utilizing ADLTs because billing for such tests that are not performed by hospitals could create administrative and financial complexities.

• The DOS policy is a potential barrier to CMS' goal of promoting personalized medicine because the policy may disproportionately impact smaller laboratories performing innovative diagnostic tests.

• Billing complexities may affect beneficiary access to needed laboratory tests and therapies. For example, orders might be delayed until at least 14 days after discharge or even canceled to avoid the DOS policy. This may restrict patient access to tests and reduce efficacy of treatment plans due to hospitals delaying or foregoing patient testing to avoid financial risk.

• The DOS policy may limit access for Medicare beneficiaries under original Medicare fee-for-service (that is, Medicare Part A and Part B) due to the fact that Medicare Advantage Plans under Medicare Part C and private payors allow laboratories to bill directly for tests they perform.

As we stated in the proposed rule (82 FR 33652), we recognize that the current laboratory DOS rule may impose administrative difficulties for hospitals and laboratories that furnish laboratory tests that are excluded from OPPS packaging and therefore paid separately at CLFS payment rates. Hospitals may be reluctant to bill Medicare for laboratory tests they do not perform, which as noted by stakeholders, could lead to delays in patient access to care.

In light of the concerns raised by stakeholders, we stated in the proposed rule that we were considering potential modifications to the DOS policy that would allow laboratories to bill Medicare directly for certain laboratory tests excluded from the OPPS packaging policy. We noted that one approach under consideration would create a new exception to the DOS policy for molecular pathology tests and ADLTs that meet the criteria of section 1834A(5)(A) of the Act and have been granted ADLT status by CMS. As we stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592 through 79594), we believe these tests are relatively new and may have a different pattern of clinical use than more conventional laboratory tests, which may make them generally less tied to a primary service in the hospital outpatient setting than more common and routine laboratory tests that are packaged. In the proposed rule, we sought public comment on whether these tests, by their nature, are appropriately separable from the hospital stay that preceded the test and therefore should have a DOS that is the date of performance rather than the date of collection.

As an example, we stated that we would consider modifying 42 CFR 414.510(b) by adding a new paragraph (5) to establish that in the case of a molecular pathology test or an ADLT that meets the criteria of section 1834A(d)(5)(A) of the Act, the DOS must be the date the test was performed only if:

• The physician orders the test following the date of a hospital outpatient's discharge from the hospital outpatient department;

• The specimen was collected from a hospital outpatient during an encounter (as both are defined 42 CFR 410.2);

• It would be medically inappropriate to have collected the sample from the hospital outpatient other than during the hospital outpatient encounter;

• The results of the test do not guide treatment provided during the hospital outpatient encounter; and

• The test was reasonable and medically necessary for the treatment of an illness.

We requested specific comments on this potential modification to the current laboratory DOS policy, which would allow laboratories to bill Medicare directly for molecular pathology tests and ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act and have been granted ADLT status by CMS, when the specimen is collected during a hospital outpatient procedure and the test is ordered after the patient is discharged from the hospital outpatient department. We also noted that we would consider finalizing this modification (82 FR 33653).

Comment: Many commenters supported revising the laboratory DOS policy so that laboratories may bill Medicare and receive payment directly for ADLTs and molecular pathology tests performed on specimens collected from hospital outpatients, which are excluded from the OPPS packaging policy. The commenters indicated that revising the current laboratory DOS policy so that the performing laboratory can bill Medicare directly for molecular pathology tests and ADLTs is consistent with CMS' policy of excluding ''precision diagnostics'' performed on specimens collected in the hospital outpatient setting from the OPPS packaging policy. In general, commenters urged CMS to finalize a policy that focuses on whether the test was performed outside the hospital after the outpatient encounter, rather than on the date the specimen was collected or the date the test was initially ordered. These commenters stated that this approach would be consistent with how tests are ordered and billed for under Medicare Advantage plans and commercial insurers, which allow laboratories to bill directly for these tests.

Commenters also reiterated previous concerns regarding administrative and billing complexities resulting from the current DOS policy that may affect timely beneficiary access to necessary molecular pathology tests. These commenters noted that hospitals may be reluctant to order a test that the hospital itself does not perform until at least 14 days following the date the patient is discharged from the hospital outpatient department so that the laboratory performing the test may bill Medicare directly for the test. One commenter explained that, for molecular pathology tests performed by an independent laboratory that is not affiliated with the hospital, the administrative complexity of the current laboratory DOS policy frequently leads hospitals to delay ordering of these tests.

In addition, several commenters recommended specific modifications to the potential revisions to laboratory DOS policy discussed in the CY 2018 OPPS/ASC proposed rule. These suggested modifications are summarized below.

• *Expand the laboratory tests subject to the DOS exception.* Commenters suggested that CMS expand the laboratory tests subject to the potential DOS exception to include *all* ADLTs (that is, both Criterion (A) and Criterion (B) ADLTs) and *all* Multi-Analyte Assays with Algorithmic Analysis (MAAA), Genomic Sequencing Procedures (GSP), and Proprietary Laboratory Analysis (PLA) test codes, even if they are not currently excluded from the OPPS packaging policy. The commenters argued that expanding the potential revision to the DOS policy to include the aforementioned laboratory tests would encompass all laboratory testing that has a different pattern of clinical use from routine testing and therefore is unconnected to the primary hospital outpatient service.

• *Remove the test order date requirement.* Several commenters recommended that CMS not finalize a requirement that the physician must order the test following the date of a hospital outpatient's discharge from the hospital outpatient department because testing on a ''liquid-based'' specimen is typically ordered before the specimen is collected. These commenters noted that requiring the physician to *order* the test at least 1 day following the date of a patient's discharge from the hospital

outpatient department would exclude a blood-based molecular pathology test from an exception to the laboratory DOS policy.

• *Require that it be ''medically appropriate'' to have collected the sample during the hospital outpatient encounter.* Several commenters noted that it would be medically appropriate for an independent laboratory that is not associated with the hospital to collect a liquid-based specimen. These commenters suggested that the potential revision to the laboratory DOS policy that specified it would be medically *inappropriate* to have collected the sample from the hospital outpatient other than during the hospital outpatient encounter, applies to tests performed on tissue-based samples, but could inadvertently create incentives for hospitals to require hospital outpatients to go elsewhere for liquid-based specimen collection. These commenters also stated that requiring a patient to travel to a different location for the specimen collection could present access issues for patients with limited mobility. Therefore, these commenters suggested a modification to the potential revised DOS policy to focus on what *is* medically appropriate rather than what is not medically appropriate. To that end, these commenters requested that CMS replace the term ''medically inappropriate'' with a requirement that it ''was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter.''

A few additional commenters suggested regulatory language to modify the existing laboratory DOS policy in accordance with the specific recommendations discussed previously. Specifically, these commenters suggested adding a new exception to the DOS policy so that, in the case of a molecular pathology test or an ADLT that meets the criteria of section 1834A(d)(5) of the Act, or a test that is a MAAA, the date of service must be the date the test was performed only if: (1) The specimen was collected from a hospital outpatient during an encounter (as both are defined 42 CFR 410.2); (2) it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (3) the results of the test do not guide treatment provided during the hospital outpatient encounter; and (4) the test was reasonable and medically necessary for the diagnosis or treatment of an illness or injury.

Response: We appreciate the support from commenters for our potential revisions to the laboratory DOS policy. We agree that some of the potential revisions to the laboratory DOS policy that we described in the CY 2018 OPPS/ASC proposed rule may not allow ADLT or molecular pathology testing performed on liquid-based samples to qualify for a DOS exception. In particular, we recognize that a requirement that it would be ''medically inappropriate'' to have collected the specimen from the hospital outpatient other than during the hospital outpatient encounter is primarily applicable to tissue-based specimens. It would not be applicable to liquid-based samples because it could be medically *appropriate* to collect a liquid-based specimen in settings outside of a hospital outpatient encounter, such as an independent laboratory not associated with the hospital. As such, we believe use of the term ''medically inappropriate'' would inappropriately exclude laboratory testing performed on liquid-based specimens from qualifying for the proposed exception to the laboratory DOS policy. Therefore, we believe the revision suggested by the commenters, that is, to specify that it ''was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter,'' would address concerns that the DOS exception should encompass testing performed on liquid-based samples as well as testing performed on tissue-based samples.

In addition, we agree with the commenters that requiring the physician to order the test following the date of a hospital outpatient's discharge from the hospital outpatient department (as we described in the proposed rule) could also inappropriately exclude tests performed on liquid-based specimens from the DOS exception, because a blood test is typically ordered before the sample is collected. We proposed including the order date requirement for the same reason we included such a requirement in the 14-day rule: Because we believe it is more difficult to determine that a test ordered before discharge is appropriately separable from the hospital stay that preceded the test (71 FR 69706). However, as discussed more fully below, we believe the ADLTs and molecular pathology tests excluded from the OPPS packaging policy are, by their nature, tests that are used to determine posthospital care, and therefore can be legitimately distinguished from the care the patient receives in the hospital even if they are ordered prior to the patient's discharge. Therefore, we do not believe it is necessary to include an order date requirement as part of this exception. However, to help ensure that only tests that are not related to the care provided in the hospital fall under this provision, we will specify that the tests must be *performed* following the hospital outpatient's discharge. That is, in order for the DOS to be the date the test was performed, instead of the date the sample was collected, the test must be performed following a hospital outpatient's discharge from the hospital outpatient department. We understand this is standard practice for these types of tests and, therefore, we would not expect this provision to change current laboratory practices or have any adverse effect on patient care.

We note that some of the commenters' suggested modifications to our potential DOS revisions are inconsistent with the current OPPS packaging policy and would result in allowing the laboratory to bill Medicare directly for a test that is not paid at the CLFS rate but paid under the hospital OPPS bundled rate. In the proposed rule (82 FR 33652), we specifically discussed creating an exception to the current DOS policy for ADLTs approved by CMS under section 1834A(d)(5)(A) of the Act and molecular pathology tests because we have already recognized that these tests may have a different pattern of clinical use than more conventional laboratory tests, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine tests that are packaged. In addition, these tests are already paid separately outside of the OPPS at CLFS payment rates. We note that laboratory tests granted ADLT status under section 1834A(d)(5)(B) of the Act [33] currently are not excluded from the OPPS packaging policy. Likewise, GSP testing, PLA tests, and protein-based MAAAs that are not considered molecular pathology tests are also conditionally packaged under the OPPS at this time. In the proposed rule, we did not specifically discuss expanding the laboratory tests that may qualify for a DOS exception beyond the ADLTs and molecular pathology tests that are currently excluded from OPPS packaging, and therefore we are not including ADLTs under Criterion (B), GSP tests, PLA tests, or protein-based MAAAs in the revised DOS policy at this time. We intend to study this issue

[33] Under section 1834A(d)(5)(B) of the Act, an ADLT is a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and . . . ''[t]he test is cleared or approved by the Food and Drug Administration.'' CMS has established a regulatory definition for this type of ADLT in 42 CFR 414.502.

and, if warranted, consider proposing changes to the laboratory tests subject to a DOS exception in future rulemaking.

As noted previously in this section, we believe the current laboratory DOS policy creates administrative complexities for hospitals and laboratories with regard to molecular pathology tests and laboratory tests expected to be designated by CMS as ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. Under the current laboratory DOS policy, if the tests are ordered less than 14 days following a hospital outpatient's discharge from the hospital outpatient department, laboratories generally cannot bill Medicare directly for the molecular pathology test or ADLT. In those circumstances, the hospital must bill Medicare for the test, and the laboratory must seek payment from the hospital. We have heard from commenters that because ADLTs are performed by only a single laboratory and molecular pathology tests are often performed by only a few laboratories, and hospitals may not have the technical ability to perform these complex tests, the hospital may be reluctant to bill Medicare for a test it would not typically (or never) perform. As a result, the hospital might delay ordering the test until at least 14 days after the patient is discharged from the hospital outpatient department or even cancel the order to avoid the DOS policy, which may restrict a patient's timely access to these tests. In addition, we have heard from commenters that the current laboratory DOS policy may disproportionately limit access for Medicare beneficiaries under original Medicare fee-for-service (that is, Medicare Part A and Part B) because Medicare Advantage plans under Medicare Part C and other private payors allow laboratories to bill directly for tests they perform.

We also recognize that greater consistency between the laboratory DOS rules and the current OPPS packaging policy would be beneficial and would address some of the administrative and billing issues created by the current DOS policy. As noted previously, we exclude all molecular pathology tests and ADLTs under section 1834A(d)(5)(A) of the Act from the OPPS packaging policy because we believe these tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged. Under the current DOS policy, we have established exceptions that permit the DOS to be the date of performance for certain tests that we believe are not related to the hospital treatment and are used to determine posthospital care. We believe a similar exception is justified for the molecular pathology tests and ADLTs excluded from the OPPS packaging policy, which we understand are used to guide and manage the patient's care after the patient is discharged from the hospital outpatient department. We believe that, like the other tests currently subject to DOS exceptions, these tests can legitimately be distinguished from the care the patient receives in the hospital, and thus we would not be unbundling services that are appropriately associated with hospital treatment. Moreover, as noted previously, these tests are already paid separately outside of the OPPS at CLFS payment rates. Therefore, we agree with the commenters that the laboratory performing the test should be permitted to bill Medicare directly for these tests, instead of relying on the hospital to bill Medicare on behalf of the laboratory under arrangements.

For these reasons and in light of the commenters' suggestions, we are revising the current laboratory DOS policy at 42 CFR 414.510(b) for tests granted ADLT status by CMS under section 1834A(d)(5)(A) of the Act and molecular pathology tests that are excluded from the OPPS packaging policy under 42 CFR 419.2(b), so that the performing laboratory may bill and be paid by Medicare directly for these tests under the circumstances described below. The revision will provide an exception to the general laboratory DOS rule—that is, the DOS is the date the specimen was collected—so that the DOS for these tests is the date the laboratory test was performed. This exception to the current laboratory DOS policy will only apply to tests granted ADLT status by CMS under paragraph (1) of the definition of ''advanced diagnostic laboratory test'' in 42 CFR 414.502, which CMS promulgated to implement section 1834A(d)(5)(A) of the Act, and molecular pathology tests excluded from the OPPS packaging policy as defined in 42 CFR 419.2(b). By adding an exception to the current laboratory DOS policy at 42 CFR 414.510(b) for molecular pathology tests and ADLTs that are excluded from the OPPS packaging policy under 42 CFR 419.2(b), the performing laboratory will be required to bill Medicare directly for tests that meet this exception. The hospital will no longer bill Medicare for these tests, and the laboratory will no longer have to seek payment from the hospital for these tests, if all of the conditions are met.

We note that this new exception to the laboratory DOS policy will *not* apply to tests granted ADLT status by CMS under section 1834A(d)(5)(A) of the Act and molecular pathology tests when performed on a specimen collected from a hospital inpatient. As discussed more fully below, we believe adding a laboratory DOS exception for hospital inpatients would have policy and ratesetting implications under the IPPS diagnosis related group (DRG) payment, and we did not solicit comments on potential revisions to our current laboratory DOS policy specific to the hospital inpatient setting.

In order to allow a laboratory to bill Medicare directly for an ADLT or molecular pathology test excluded from the OPPS packaging policy, we are modifying 42 CFR 414.510(b) by adding a new paragraph (5) to establish that, in the case of a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of advanced diagnostic laboratory test in 42 CFR 414.502, the DOS of the test must be the date the test was performed only if—

- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

We intend to continue to study the laboratory DOS policy and determine whether any additional changes are warranted. In particular, we will consider whether there should be any changes to the current 14-day rule, including whether to address any inconsistencies with our new exception, and any changes to the ''under arrangements'' provisions, including with respect to the hospital inpatient setting. We expect to propose any future changes to the laboratory DOS policy through notice-and-comment rulemaking.

Comment: A few commenters requested that any changes to the laboratory DOS policy apply to ADLTs and molecular pathology tests performed on specimens collected from both hospital inpatients and hospital outpatients. These commenters stated

that it would be an administrative burden on hospitals that collect specimens, and laboratories that furnish and bill for ADLTs and molecular pathology tests, to track tests ordered for hospital outpatients in a way that is inconsistent with those performed on specimens obtained from hospital inpatients.

One commenter stated that consistency between the DOS for hospital inpatients and hospital outpatients is important for evaluating data on patient outcomes. For example, the commenter noted that laboratory tests ordered for hospital inpatients do not have the tests' HCPCS code(s) on the inpatient claim. As a result, CMS cannot track patients who have received these tests using claims data, or evaluate how advanced testing contributes to cancer care and other advanced treatments, or evaluate the total cost of care. To that end, a few commenters suggested that CMS use coding modifiers to identify ADLTs and molecular pathology tests that do not guide treatment during an inpatient hospital stay so that separate payment can be made at the HCPCS code level for these laboratory tests.

In contrast to the commenters suggesting a laboratory DOS revision for both hospital outpatients and hospital inpatients, one commenter requested that CMS limit revisions to the laboratory DOS policy to outpatient laboratory tests that are excluded from the OPPS packaging policy and separately payable at CLFS rates because it would merely change which entity bills for the laboratory test. The commenter noted that because all laboratory testing ordered on specimens obtained from hospital *inpatients* less than 14 days after discharge are currently bundled into the hospital IPPS rates, a change in the laboratory DOS policy for hospital inpatients would entail many other policy changes.

Response: As discussed previously, we believe an exception to the DOS policy that is limited to the hospital outpatient setting is warranted for Criterion (A) ADLTs and molecular pathology tests excluded from the OPPS packaging policy because these tests are already paid at CLFS rates and not paid under the OPPS, among other reasons. We did not discuss or propose an analogous DOS exception for tests performed on specimens collected from hospital inpatients in the CY 2018 OPPS/ASC proposed rule, and we agree with the commenter who stated that such an exception would have broader policy implications for the IPPS that need to be carefully considered. We acknowledge that there could be an administrative burden for hospitals and laboratories to track the DOS for ADLTs and molecular pathology tests ordered for hospital outpatients in a way that is different from those ordered for hospital inpatients. However, because laboratories will no longer need to seek payment from the hospital outpatient department for these tests if all requirements in new § 414.510(b)(5) are met, we believe that some of the additional burden mentioned by the commenters is likely to be offset by the revised DOS policy. With regard to the comments on evaluating data on patient outcomes, we note that, in the CY 2018 OPPS/ASC proposed rule, we focused only on potential revisions to the laboratory DOS policy for Criterion (A) ADLTs and molecular pathology tests excluded from the OPPS packaging policy that are performed on a specimen collected from a hospital outpatient during a hospital outpatient encounter to enable the laboratory to bill Medicare directly for those tests. We did not discuss revising the laboratory DOS policy to improve CMS' ability to evaluate patient outcomes. As noted previously, we intend to continue studying this issue and, if warranted, consider changes to the laboratory DOS policy for laboratory tests performed on specimens collected during an inpatient hospital stay in future rulemaking.

Comment: A few commenters suggested that any changes to the DOS rule also apply to ''referred nonpatient specimens.'' The commenters explained that hospitals receive tissue and/or blood samples for testing from physician's offices or other locations in circumstances in which no hospital encounter occurs. The commenters recommended that CMS allow this type of testing to be billed separately and not be required to be billed with other outpatient hospital services.

Response: In the situation described by the commenters, the laboratory would be performing the test as a hospital outreach laboratory. A hospital outreach laboratory is a hospital-based laboratory that furnishes laboratory tests to patients who are not admitted hospital inpatients or registered outpatients of the hospital. As discussed previously, the new exception to the laboratory DOS policy will apply to tests granted ADLT status under Criterion (A) by CMS and molecular pathology tests excluded from the OPPS packaging policy that are performed on a specimen collected from a hospital outpatient during a hospital outpatient encounter. Because hospital outreach laboratories perform laboratory tests on specimens collected from beneficiaries who are not patients of the hospital, a revision to the laboratory DOS policy is not necessary to allow a hospital outreach laboratory to bill Medicare separately for the test.

Comment: One commenter requested clarification as to whether an exception to the laboratory DOS policy would allow a hospital to continue billing for ADLTs or molecular pathology tests excluded from the OPPS packaging policy or whether the policy change would require a laboratory to bill Medicare directly for these tests. Another commenter recommended that any change to laboratory DOS policy or the ''under arrangements'' provisions should allow either the hospital or the laboratory that performed the test to bill the Medicare program directly. The commenter indicated that, in some circumstances, other laboratory tests in addition to ADLTs and or molecular pathology tests are ordered following the patient's discharge from the hospital outpatient department and that it may be less of a burden on the laboratory to allow the hospital to bill for all laboratory tests ordered rather than require some tests to be billed by the hospital and other tests to be billed by the laboratory.

Response: If a test meets all requirements for the new exception to the DOS policy in § 414.510(b)(5), the DOS of the test must be the date the test was performed, which means the laboratory performing the test must bill Medicare for the test. The hospital would no longer be permitted to bill for these tests unless the hospital laboratory actually performed the test. That is, if the hospital laboratory performed the ADLT or molecular pathology test, the hospital laboratory would bill Medicare for the test. We believe the potential administrative burden on the laboratory to bill for some of the tests performed on a specimen collected from a hospital outpatient during a hospital outpatient encounter will be offset, to some degree, because the laboratory would no longer need to seek payment from the hospital outpatient department for those tests, if all requirements in § 414.510(b)(5) are met.

Comment: A few commenters requested that CMS clarify that the date of performance is the date of a laboratory's final report. They suggested this clarification would avoid any ambiguity regarding the date of performance of the test. One commenter urged CMS to define the DOS as the date of final report for all laboratory tests.

Response: We considered the commenters' suggestion to use the date of final report as the DOS for ADLTs and molecular pathology tests excluded from the OPPS packaging policy that are

performed on a specimen collected from a hospital outpatient during a hospital outpatient encounter. However, we have concerns with this approach because we believe there is no clear and consistent definition of ''final report'' that applies to all laboratories and all types of specimens collected; that is, liquid-based, cellular, or tissue samples. Regarding the comment requesting a revision to the DOS policy for all laboratory tests, we note that we focused on potential revisions regarding Criterion (A) ADLTs and molecular pathology tests excluded from the OPPS packaging policy in the CY 2018 OPPS/ASC proposed rule, and did not discuss potential revisions to the DOS policy for all laboratory tests.

Comment: A few commenters requested that CMS modify the 14-day rule requirement for all laboratory tests because it is operationally complicated and may result in delays in testing until after the 14-day window has passed.

Response: As discussed previously in this section, the discussion in the CY 2018 OPPS/ASC proposed rule was primarily focused on potential modifications to the DOS policy for Criterion (A) ADLTs and molecular pathology tests excluded from the OPPS packaging policy. We did not address potential modifications to the DOS policy that would apply to all laboratory tests, so we will not make such changes in this rule. However, as noted previously, we intend to continue studying this issue and, if warranted, will consider proposing further changes to the DOS policy in future rulemaking.

(a) Limiting the DOS Rule Exception to ADLTs

In the CY 2018 OPPS/ASC proposed rule (82 FR 33653), we also indicated that we were considering potentially revising the DOS rule to create an exception only for ADLTs that meet the criteria in section 1834A(d)(5)(A) of the Act. This exception would not cover molecular pathology tests. We stated that we were considering this approach because ADLTs approved by CMS under Criterion (A), like all ADLTs, are offered and furnished only by a single laboratory (as defined in 42 CFR 414.502). The hospital, or another laboratory, that is not the single laboratory (as defined in 42 CFR 414.502), cannot furnish the ADLT. Therefore, we noted in the proposed rule that there may be additional beneficiary access concerns for these ADLTs that may not apply to molecular pathology tests, and that could be addressed by allowing the laboratories to bill Medicare directly for these tests. For example, a hospital may not have an arrangement with the single laboratory that furnishes a particular ADLT, which could lead the hospital to delay the order for the ADLT until 14 days after the patient's discharge to avoid financial risk and thus potentially delay medically necessary care for the beneficiary.

We stated in the proposed rule that we believe the circumstances may be different for molecular pathology tests, which are not required to be furnished by a single laboratory. In particular, we understood there may be ''kits'' for certain molecular pathology tests that a hospital can purchase, allowing the hospital to perform the test. Therefore, we stated that molecular pathology tests may not present the same concerns of delayed access to medically necessary care as ADLTs, which *must* be performed by a single laboratory.

Thus, in the proposed rule, we requested specific comments on potentially creating an exception to the DOS policy that is limited to ADLTs that meet the criteria in section 1834A(d)(5)(A) of the Act and have been granted ADLT status by CMS. We also requested public comments on how the current laboratory DOS policy may affect billing for other separately payable laboratory test codes that are not packaged under the OPPS, such as a laboratory test that is the only service provided to a beneficiary on a claim or molecular pathology tests.

Comment: Many commenters supported revising the current laboratory DOS policy for both Criterion (A) ADLTs and molecular pathology tests. They did not support an exception to the current laboratory DOS policy that would be limited only to ADLTs that meet the criteria in section 1834A(d)(5)(A) of the Act and have been granted ADLT status by CMS (and therefore exclude molecular pathology tests from the DOS exception). Several commenters noted that creating an exception for only ADLTs would not be consistent with current OPPS packaging policy, which excludes both Criterion (A) ADLTs and molecular pathology tests.

In addition, a few commenters indicated that beneficiary access issues similar to those for ADLTs, which are furnished by a single laboratory, may also exist for molecular pathology tests because molecular pathology testing is highly specialized and may be performed by only a few laboratories. The commenters also noted that a coverage policy for a given molecular pathology test may have only been issued by a MAC in the jurisdiction in which the laboratory is located. This could be problematic if the hospital that is billing for the test is located in a different MAC jurisdiction from the laboratory, and the MAC processing claims for the jurisdiction in which the hospital is located has not made a coverage determination for the test.

A few other commenters explained that molecular pathology tests are important tools that guide patient treatment plans and that many hospitals currently lack the in-house technical expertise and Clinical Laboratory Improvement Amendments (CLIA) licensure to perform these tests and, therefore, send them out to a performing laboratory. The commenters noted that molecular pathology ''kits'' (as referenced by CMS in the CY 2018 OPPS/ASC proposed rule) are different from those used for other CDLTs. For example, the commenters explained that molecular pathology test kits require the hospital to have the highest licensure level under CLIA, as well as obtain specialized training for correct use and interpretation of the results, and that most hospitals are unlikely to have either the expertise or the technology to use these kits. To ensure appropriate access to molecular pathology tests by rural and community hospitals, as well as academic and specialty hospitals, the commenters requested that the revisions to the current laboratory DOS policy apply to both ADLTs and molecular pathology tests.

Response: We agree with commenters that limiting the new laboratory DOS exception to include only ADLTs (and not molecular pathology tests) would be inconsistent with the OPPS packaging policy, which currently excludes tests granted ADLT status by CMS under section 1834A(d)(5)(A) of the Act and molecular pathology tests. As noted by the commenters, relatively few laboratories may perform certain molecular pathology testing. We also acknowledge that hospitals may not have the technical expertise or certification requirements necessary to perform molecular pathology testing and therefore must rely on independent laboratories to perform the test. Therefore, we believe similar beneficiary access concerns that apply to ADLTs may also apply to molecular pathology tests. As indicated previously, after consideration of the public comments received on this issue, in this final rule with comment period, we are revising the current laboratory DOS policy to create a new exception for tests granted ADLT status by CMS under Criterion (A) and molecular pathology tests excluded from the OPPS packaging policy.

(b) Other Alternative Approaches

Finally, in the CY 2018 OPPS/ASC proposed rule (82 FR 33653), we invited public comments on alternative approaches to addressing stakeholders' concerns regarding the DOS policy, such as potentially modifying the ''under arrangements'' provisions in 42 CFR 410.42 and 411.15(m). Specifically, we requested comments on whether an exception should be added to § 410.42(b) and/or § 411.15(m)(3) for molecular pathology tests and ADLTs that are excluded from the OPPS packaging policy under 42 CFR 419.2(b) and how such an exception should be framed.

Comment: Several commenters preferred modifications to the ''under arrangements'' provisions to a laboratory DOS revision. They stated that modifying the ''under arrangements'' provisions could be a more direct approach for permitting a performing laboratory to bill Medicare directly for ADLTs and molecular pathology tests. Therefore, the commenters requested that CMS add another exception to the ''under arrangements'' provisions so that a revision to the laboratory DOS policy would not be necessary. They suggested that changes to the ''under arrangements'' provisions could be made in lieu of modifying the laboratory DOS rules and asserted that this approach would only revise the ''billing regulation'' for tests performed on hospital outpatient specimens to align with CMS' existing exclusions from the OPPS packaging policy.

In addition, a few commenters noted that certain practitioner services, such as physician services and nurse practitioner services, are not performed by the hospital outpatient department and paid under a separate fee schedule, and therefore, are currently excluded from the ''under arrangements'' provisions. They contended that adding an exception to the ''under arrangements'' provisions for nonpackaged laboratory tests which are paid at the CLFS rates would be consistent with the exceptions for other services (for example, physician services) paid separately from the hospital service.

A few commenters also provided specific recommendations on how CMS should revise the ''under arrangements'' regulations at §§ 410.42(b) and 411.15(m). Similar to their recommendations for revising the laboratory DOS policy, the commenters suggested adding an exception to the ''under arrangements'' provisions for molecular pathology tests, *all* ADLTs, and *all* MAAAs, irrespective of whether these tests are currently excluded from the OPPS packaging policy.

Response: We appreciate the feedback that commenters provided in response to our request for comments on potential modifications to the ''under arrangements'' provisions. As discussed previously, in this final rule with comment period, we are finalizing a revision to the current laboratory DOS policy so that laboratories performing Criterion (A) ADLTs and molecular pathology tests excluded from the OPPS packaging policy can bill Medicare directly for those tests, instead of seeking payment from the hospital outpatient department. We believe including this revision as part of § 414.510 is more consistent with how we have historically addressed laboratory DOS issues and, at this stage, is the appropriate way to address stakeholders' administrative and billing concerns regarding these tests. As noted previously, we intend to continue to study this issue and specifically consider whether further revisions to the ''under arrangements'' provisions are warranted. If we believe revisions to the ''under arrangements'' provisions may be warranted, we expect we would propose those changes through notice-and-comment rulemaking.

In summary, after considering the public comments we received, we are adding an additional exception to our current laboratory DOS regulations at § 414.510(b)(5) so that the DOS for molecular pathology tests and tests designated by CMS as Criterion (A) ADLTs is the date the test was performed only if: (1) The test was performed following a hospital outpatient's discharge from the hospital outpatient department; (2) the specimen was collected from a hospital outpatient during an encounter (as both are defined in § 410.2); (3) it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (4) the results of the test do not guide treatment provided during the hospital outpatient encounter; and (5) the test was reasonable and medically necessary for the treatment of an illness. This new exception to the laboratory DOS policy will enable laboratories performing Criterion (A) ADLTs and molecular pathology tests excluded from the OPPS packaging policy to bill Medicare directly for those tests, instead of requiring them to seek payment from the hospital outpatient department.

XI. CY 2018 OPPS Payment Status and Comment Indicators

A. CY 2018 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33653), for CY 2018, we did not propose to make any changes to the definitions of status indicators that were listed in Addendum D1 to the CY 2017 OPPS/ASC final rule with comment period available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.*

We requested public comments on the proposed definitions of the OPPS status indicators for CY 2018. We did not receive any public comments. We believe that the existing CY 2017 definitions of the OPPS status indicators continue to be appropriate for CY 2018. Therefore, we are finalizing our proposed CY 2018 definitions of the OPPS status indicators without modifications.

The complete list of the payment status indicators and their definitions that apply for CY 2018 is displayed in Addendum D1 to this final rule with comment period, which is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

The CY 2018 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this final rule with comment period, which are available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

B. CY 2018 Comment Indicator Definitions

In the CY 2018 OPPS/ASC proposed rule (82 FR 33654), we proposed to use four comment indicators for the CY 2018 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2017 and we proposed to continue their use in CY 2018. The proposed CY 2018 OPPS comment indicators are as follows:

• ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.

• ''NC''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will *not* be accepted on the final APC assignment for the new code.

• ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

• ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

We requested public comments on our proposed use of comment indicators for CY 2018. We did not receive any public comments. We believe that the CY 2017 definitions of the OPPS comment indicators continue to be appropriate for CY 2018. Therefore, we are continuing to use those definitions without modification for CY 2018.

The definitions of the final OPPS comment indicators for CY 2018 are listed in Addendum D2 to this final rule with comment period, which is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

XII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012, 2013, 2014, 2015, 2016, and 2017 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; and 81 FR 79732 through 79753, respectively).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under 42 CFR 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate to be furnished to Medicare beneficiaries in ASCs. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS (72 FR 42478).

In the August 2, 2007 final rule (72 FR 42495), we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66932 through 66934), we expanded the scope of ASC covered ancillary services to include certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS when they are provided integral to an ASC covered surgical procedure. Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests (CRs) to update services covered under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the AMA and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process, which we finalized in the CY 2012 OPPS/ASC final rule with comment period, is used to update HCPCS and CPT codes (76 FR 42291; 76 FR 74380 through 74381).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS

inpatient list), new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

3. Definition of ASC Covered Surgical Procedures

Since the implementation of the ASC prospective payment system, we have defined a ''surgical'' procedure under the payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the American Medical Association (AMA) defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42478). We also have included as ''surgical,'' procedures that are described by Level II HCPCS codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, would not expect to require an overnight stay when performed in an ASC, and are separately paid under the OPPS (72 FR 42478).

As we noted in the CY 2008 final rule that implemented the revised ASC payment system, using this definition of surgery would exclude from ASC payment certain invasive, ''surgery-like'' procedures, such as cardiac catheterization or certain radiation treatment services that are assigned codes outside the CPT surgical range (72 FR 42477). We stated in that final rule that we believed continuing to rely on the CPT definition of surgery is administratively straightforward, is logically related to the categorization of services by physician experts who both establish the codes and perform the procedures, and is consistent with a policy to allow ASC payment for all outpatient surgical procedures (72 FR 42477).

Recently, some stakeholders have suggested that certain procedures that are outside the CPT surgical range but that are similar to surgical procedures currently covered in an ASC setting should be ASC covered surgical procedures. For example, these stakeholders stated that certain cardiac catheterization services, cardiac device programming services, and electrophysiology services should be added to the covered surgical procedures list. While we continue to believe that using the CPT code range to define surgery represents a logical, appropriate, and straightforward approach to defining a surgical procedure, we also believe it may be appropriate for us to use the CPT surgical range as a guide rather than a requirement as to whether a procedure is surgical, which would give us more flexibility to include ''surgery-like'' procedures on the ASC Covered Procedures List (CPL). We are cognizant of the dynamic nature of ambulatory surgery and the continued shift of services from the inpatient setting to the outpatient setting over the past decade. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33655), we solicited public comments regarding services that are described by Category I CPT codes outside of the surgical range, or Level II HCPCS codes or Category III CPT codes that do not directly crosswalk and are not clinically similar to procedures in the CPT surgical range, but that nonetheless may be appropriate to include as covered surgical procedures that are payable when furnished in the ASC setting. In particular, we stated our interest in the public's views regarding additional criteria we might use to consider when a procedure that is surgery-like could be included on the ASC CPL. We requested that commenters on this issue take into consideration whether each individual procedure can be safely and appropriately performed in an ASC, as required by the regulations at 42 CFR 416.166 (including that standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure), and whether the procedure requires the resources, staff, and equipment typical of an ASC. We also indicated that we were interested in the public's views on whether and how, if we were to include such services as ASC covered surgical procedures, we would need to revise our definition of ASC covered surgical procedures.

Comment: Some commenters suggested that revising the definition of ASC covered surgical procedures would inappropriately move procedures from a hospital setting to an ASC setting and place Medicare patients in greater risk. Some commenters also suggested that revising the definition could further stress hospitals in isolated rural care settings because many ASCs are located in rural areas.

Other commenters suggested that CMS develop and solicit comments on a clear definition and criteria for surgical site selection. Commenters also suggested patient selection and risk stratification protocols that would harmonize the different criteria of hospital outpatient departments and ASCs. In addition, they recommended that further clinical evaluation of the consequences to the Medicare population be performed before revising the definition of ASC covered surgical procedures.

Many commenters supported revising the definition of ASC covered surgical procedures. Commenters supporting the revision of the definition of ASC covered surgical procedures suggested that the CPT surgical code range (10000–69999) has not properly accounted for technical advances in treatment and does not include invasive procedures that do not pose a significant safety risk, do not require an overnight stay for Medicare patients, and would otherwise be appropriate procedures to be added to the ASC list of covered surgical procedures. For example, some commenters believed that several catheter-based procedures would be appropriately performed in the ASC setting. Further, commenters stated that CMS has relied on alternative definitions of a surgical procedure in other operations of the Medicare program that are broader than the current definition of an ASC covered surgical procedure.

Response: We appreciate the feedback we received from commenters. We acknowledge the importance of having clear criteria for covered surgical procedures that account for advances in surgical treatment in an ASC setting that also do not expose Medicare patients to significant safety risks. In the CY 2018 OPPS/ASC proposed rule (82 FR 33654 through 33655), we did not propose any revisions to our current definition of ASC covered surgical procedures. For CY 2018, we will continue to define ''surgical'' procedures under the payment system as those procedures described by Category I CPT codes within the range the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999), or Level II HCPCS codes or Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an

ASC, and are separately paid under the OPPS. However, we will take these comments into consideration in future rulemaking.

B. Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised Category I and Category III CPT Codes and Level II HCPCS Codes

Category I CPT, Category III CPT, and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify items, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2018 OPPS/ASC final rule with comment period.

We have separated our discussion below based on when the codes are released and whether we propose to solicit public comments in the CY 2018 OPPS/ASC proposed rule (and respond to those comments in the CY 2018 OPPS/ASC final rule with comment period) or whether we are soliciting public comments in this CY 2018 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2019 OPPS/ASC final rule with comment period).

We note that we sought public comments in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79735 through 79736) on the new and revised Level II HCPCS codes effective October 1, 2016, or January 1, 2017. These new and revised codes, with an effective date of October 1, 2016, or January 1, 2017, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2017 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2017 OPPS/ASC final rule with comment period. We are responding to public comments and finalize the treatment of these codes under the ASC payment system in this CY 2018 OPPS/ASC final rule with comment period.

In Table 79 below, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS.

TABLE 79—COMMENT AND FINALIZATION TIMEFRAMES FOR NEW OR REVISED HCPCS CODES

ASC quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2017 ..	Level II HCPCS Codes	April 1, 2017 ..	CY 2018 OPPS/ASC proposed rule.	CY 2018 OPPS/ASC final rule with comment period.
July 1, 2017 ...	Level II HCPCS Codes	July 1, 2017 ...	CY 2018 OPPS/ASC proposed rule.	CY 2018 OPPS/ASC final rule with comment perio.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2017 ...	CY 2018 OPPS/ASC proposed rule.	CY 2018 OPPS/ASC final rule with comment period.
October 1, 2017.	Level II HCPCS Codes	October 1, 2017.	CY 2018 OPPS/ASC final rule with comment period.	CY 2019 OPPS/ASC final rule with comment period.
January 1, 2018.	Level II HCPCS Codes	January 1, 2018.	CY 2018 OPPS/ASC final rule with comment period.	CY 2019 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes	January 1, 2018.	CY 2018 OPPS/ASC proposed rule.	CY 2018 OPPS/ASC final rule with comment period.

Note: In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. We refer readers to section III.A.3. of this CY 2018 OPPS/ASC final rule with comment period for further discussion of this issue.

2. Treatment of New and Revised Level II HCPCS Codes Implemented in April 2017 for Which We Solicited Public Comments in the CY 2018 OPPS/ASC Proposed Rule

In the April 2017 ASC quarterly update (Transmittal 3726, CR 9998, dated March 03, 2017), we added six new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 31 of the proposed rule listed the new Level II HCPCS codes that were implemented April 1, 2017, along with their payment indicators for CY 2018.

We invited public comments on these proposed payment indicators and the proposed payment rates for the new Level II HCPCS codes that were recognized as ASC covered ancillary services in April 2017 through the quarterly update CRs, as listed in Table 31 of the proposed rule. We proposed to finalize their payment indicators and their payment rates in the CY 2018 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding the proposed ASC payment indicators and payment rates. Therefore, we are adopting as final the CY 2018 proposed payment indicators for these codes, as indicated in Table 80. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2018. Their replacement codes are listed in Table 80. The final payment rates for these codes can be found in Addendum BB to this final rule with comment period (which is available via the Internet on

the CMS Web site). In addition, the payment indicator meanings can be found in Addendum DD1 to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 80—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2017

CY 2017 HCPCS Code	CY 2018 HCPCS Code	CY 2018 Long descriptor	CY 2018 Payment indicator
C9484	J1428	Injection, eteplirsen, 10 mg	K2
C9485	J9285	Injection, olaratumab, 10 mg	K2
C9486	J1627	Injection, granisetron extended release, 0.1 mg	K2
C9487*	J3358	Ustekinumab, for intravenous injection, 1 mg	K2
C9488	C9488	Injection, conivaptan hydrochloride, 1 mg	K2
J7328	J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	K2

*HCPCS code C9487, which was effective April 1, 2017, was deleted June 30, 2017 and replaced with HCPCS code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017 through December 31, 2017.

3. Treatment of New and Revised Level II HCPCS Codes Implemented in July 2017 for Which We Solicited Public Comments in the CY 2018 OPPS/ASC Proposed Rule

In the July 2017 ASC quarterly update (Transmittal 3792, CR 10138, dated June 9, 2017), we added seven new Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 32 of the proposed rule listed the new Level II HCPCS codes that are effective July 1, 2017. The proposed payment rates, where applicable, for these July codes were included in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site).

Through the July 2017 quarterly update CR, we also implemented ASC payment for one new Category III CPT code as an ASC covered surgical procedure, effective July 1, 2017. This code was listed in Table 33 of the proposed rule, along with its proposed payment indicator. The proposed payment rate for this new Category III CPT code was included in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

We invited public comments on these proposed payment indicators and the proposed payment rates for the new Category III CPT code and Level II HCPCS codes that were or are expected to be newly recognized as ASC covered surgical procedures or covered ancillary services in July 2017 through the quarterly update CRs, as listed in Tables 32 and 33 of the proposed rule. We proposed to finalize their payment indicators and their payment rates in the CY 2018 OPPS/ASC final rule with comment period.

Comment: One commenter supported the assignment of HCPCS code Q9986 (Injection, hydroxyprogesterone caproate (Makena), 10 mg) to payment indicator ''K2''. However, the commenter requested that CMS review the calculated payment rate for the new HCPCS code Q9986, as it appeared to the commenter to be inaccurate. The commenter pointed out the following: The July 2017 OPPS and ASC Update indicates that this new HCPCS code is ''per 10 mg'' with a payment rate of $2.72 (as indicated in the July 2017 Addendum B/BB and in Addendum B and Addendum BB to the CY 2018 OPPS/ASC proposed rule). Prior to July 1, 2017, Makena® (NDC #64011–0247–02 and NDC #64011–0243–01) was reported under HCPCS code J1725, which had a dose and measure of ''per 1 mg'' and a payment rate of $2.74 (April 2017 Addendum B/BB). Makena® also has a WAC price of $30.57 per 10 mg. The commenter believed that when the new HCPCS code was added with a description of 10 mg instead of the prior 1 mg, the payment rate was not appropriately adjusted to reflect the dosage change.

Response: We agree with the commenter. The July 2017 and October 2017 OPPS and ASC addenda incorrectly reflected a price for HCPCS code Q9986 based on a 1 mg dose rather than the revised 10 mg dose descriptor. We intend to correct the price for HCPCS code Q9986 retroactive to July 1, 2017, in the respective January 2018 updates to the OPPS and ASC payment systems. Applicable program instructions will be posted to the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017-Transmittals.html*.

After consideration of the public comment we received, we are finalizing the proposed payment indicators for the new Category III CPT code and Level II HCPCS codes that were newly recognized as ASC covered surgical procedures or covered ancillary services in July 2017 through the quarterly update CRs, as indicated in Table 81 below. We note that several of the HCPCS C- and Q-codes have been replaced with HCPCS J-codes, effective January 1, 2018. Their replacement codes are listed in Table 81 below. The CY 2018 final payment rates, where applicable, for these July codes can be found in Addendum BB to this final rule with comment period rule (which is available via the Internet on the CMS Web site). Table 82 below lists Category III CPT code 0474T, along with its final payment indicator. The CY 2018 final payment rate for this new Category III CPT code can be found in Addendum AA to the final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 81—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2017

CY 2017 HCPCS Code	CY 2018 CPCS Code	CY 2018 Long descriptor	CY 2018 Payment indicator
C9489	J2326	Injection, nusinersen, 0.1 mg	K2
C9490	J0565	Injection, bezlotoxumab, 10 mg	K2
C9745	C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube	J8

TABLE 81—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2017—Continued

CY 2017 HCPCS Code	CY 2018 CPCS Code	CY 2018 Long descriptor	CY 2018 Payment indicator
C9746	C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed.	J8
C9747	C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance.	J8
Q9986	J1726	Injection, hydroxyprogesterone caproate (Makena), 10 mg	K2
Q9989*	J3358	Ustekinumab, for intravenous injection, 1 mg	K2

*HCPCS code C9487, which was effective April 1, 2017, was replaced with HCPCS code Q9989 (Ustekinumab, for intravenous injection, 1 mg) effective July 1, 2017.

TABLE 82—NEW CATEGORY III CPT CODE FOR COVERED SURGICAL PROCEDURE EFFECTIVE ON JULY 1, 2017

CY 2017 CPT Code	CY 2018 CPT Code	CY 2018 Long descriptor	CY 2018 Payment indicator
0474T	0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space.	J8

4. Process for New and Revised Level II HCPCS Codes That Are Effective October 1, 2017 and January 1, 2018 for Which We Are Soliciting Public Comments in This CY 2018 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new and revised Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the OPPS and the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS Web site, and also through the January OPPS quarterly update CRs. In the past, we also released new and revised Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33657), for CY 2018, consistent with our established policy, we proposed that the Level II HCPCS codes that will be effective October 1, 2017, and January 1, 2018, would be flagged with comment indicator ''NI'' in Addendum B to the CY 2018 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2018. We did not receive any public comments on our proposal. As we stated we would do in the proposed rule, we are inviting public comments in this CY 2018 OPPS/ASC final rule with comment period on the interim payment indicators and payment rates for these codes that will be finalized in the CY 2019 OPPS/ASC final rule with comment period.

5. Process for Recognizing New and Revised Category I and Category III CPT Codes That Are Effective January 1, 2018 for Which We Are Soliciting Public Comments in This CY 2018 OPPS/ASC Final Rule With Comment Period

For new and revised CPT codes effective January 1, 2018, that were received in time to be included in the CY 2018 OPPS/ASC proposed rule, we proposed APC and status indicator assignments (82 FR 33657). We stated in the proposed rule that we would accept comments and finalize the APC and status indicator assignments in the CY 2018 OPPS/ASC final rule with comment period. For those new/revised CPT codes that were received too late for inclusion in the CY 2018 OPPS/ASC proposed rule, we stated that we may either make interim final assignments in the final rule with comment period or possibly use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle.

We stated in the proposed rule that, for the CY 2018 ASC update, the new and revised CY 2018 Category I and III CPT codes will be effective on January 1, 2018, and were included in ASC Addendum AA and Addendum BB to the proposed rule (which are available via the Internet on the CMS Web site). The new and revised CY 2018 Category I and III CPT codes were assigned to comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year, as compared to the current calendar year, and that comments will be accepted on the proposed payment indicator. Further, in the proposed rule, we reminded readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not fully describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors for the new and revised CY 2018 CPT codes in Addendum O to the proposed rule (which is available via the Internet on the CMS Web site) so that the public can have time to adequately comment on our proposed payment indicator assignments. We stated in the proposed rule that the 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled ''CY 2018 OPPS/ASC Proposed Rule 5-Digit Placeholder Code,'' to the proposed rule. We stated that the final CPT code numbers would be included in the CY 2018 OPPS/ASC final rule with comment period. We noted that not every code listed in Addendum O is subject to comment. For the new/revised Category I and III CPT codes, we requested comments on only those codes that are assigned to comment indicator ''NP''.

In summary, we solicited public comments on the proposed CY 2018 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2018. The CPT codes were listed in Addendum AA and Addendum BB to the proposed rule with short descriptors only. We

listed them again in Addendum O to the proposed rule with long descriptors. We also proposed to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2018 OPPS/ASC final rule with comment period. The proposed payment indicators for these codes were included in Addendum AA and Addendum BB to the proposed rule (which are available via the Internet on the CMS Web site).

Comment: Some commenters addressed the proposed establishment of HCPCS G-codes under the MPFS to report the insertion and removal of buprenorphine hydrochloride, formulated as a 4-rod, 80 mg, long-acting subdermal drug implant for the treatment of opioid addiction (82 FR 34011 through 34012). Specifically, the commenters requested that the MPFS proposal also apply to the OPPS and ASC payment systems. In addition, the commenters recommended that CMS assign the HCPCS G-codes to payment indicator ''P3'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility Practice Expense Relative Value Units (PE RVUs); payment based on MPFS nonfacility PE RVUs).

Response: As discussed in section III.D. (OPPS APC-Specific Policies) of this final rule with comment period, we are establishing these HCPCS G-codes in the OPPS, effective January 1, 2018, with status indicator ''Q1'' (Packaged APC payment if billed on the same claim as a HCPCS code assigned status indicator ''S'', ''T'', or ''V''). However, because these services are conditionally packaged under the OPPS, they are unconditionally packaged under the ASC payment system (payment indicator ''N1''). Therefore, we are not accepting the commenters' request to assign payment indicator ''P3'' to these HCPCS G-codes.

Comment: One commenter disagreed with the proposed payment rate for four new CPT codes (31XX2, 31XX3, 31XX4, and 31XX5) that describe endoscopic sinus surgery services. The commenter noted that the multiple procedure reduction applies to these procedures when performed in an ASC which results in payment at 100 percent for the highest ranking procedure and 50 percent for each subsequent procedure when performed in the same encounter. Because the commenter believed that these payment rates are inadequate, the commenter requested that CMS consider an ASC payment rate that more closely aligns with ASCs' costs.

Response: The national unadjusted ASC payment rates are calculated using our standard ASC ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year. We have no cost data or information to assess whether ASC payments rates calculated using the standard ratesetting methodology align with ASC costs. Therefore, we are not accepting the commenter's recommendation and we are finalizing payment for proposed CPT codes 31XX2, 31XX3, 31XX4, and 31XX5, as replaced by CPT codes 31253, 31257, 31259, and 31298, respectively, according to our standard ASC ratesetting methodology for CY 2018. We note the OPPS cost data informs ASC payment rates, and as data become available from hospitals paid under the OPPS, we will reassess the APC assignments for these codes.

After consideration of the public comments we received, we are finalizing, without modification, the proposed CY 2018 ASC payment indicator assignments for new and revised CPT codes, effective January 1, 2018. The final CY 2018 payment indicators for the new and revised Category I and III CPT codes (with their final CPT code numbers) that will be effective January 1, 2018 are listed in Addendum AA and Addendum BB to this final rule with comment period with short descriptors only. We list them again in Addendum O to the final rule with comment period with long descriptors.

C. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC list of covered surgical procedures beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the list of covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

(2) Changes for CY 2018 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2018 OPPS/ASC proposed rule and this final rule with comment period, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2016 volume and utilization data and the clinical characteristics for all covered surgical procedures that are assigned payment indicator ''G2'' (Nonoffice-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2016, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2'', ''P3'', or ''R2'' in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79736 through 79738).

As discussed in the CY 2018 OPPS/ASC proposed rule, our review of the CY 2016 volume and utilization data resulted in our identification of two covered surgical procedures, CPT code 37241 (Vascular embolize/occlude venous) and CPT code 67227

(Destruction extensive retinopathy), that we believe meet the criteria for designation as office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and we believe that the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT codes that we proposed to permanently designate as office-based for CY 2018 were listed in Table 34 of the proposed rule.

TABLE 83—ASC COVERED SURGICAL PROCEDURES NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2018

CY 2018 CPT Code	CY 2018 Long descriptor	CY 2017 ASC Payment indicator	CY 2018 ASC Payment indicator *
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varioceles).	G2	P3
67227	Destruction of extensive or progressive retinopathy (eg, diabetic retinopathy), cryotherapy, diathermy.	G2	P3

* Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 MPFS final rule with comment period.

We also reviewed CY 2016 volume and utilization data and other information for 10 procedures designated as temporary office-based in Tables 48 and 49 in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79736 through 79738). Of these 10 procedures, there were very few claims in our data and no claims data for 8 procedures: CPT code 0402T (Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)); CPT code 10030 (Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity, abdominal wall, neck), percutaneous); CPT code 36473 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated); CPT code 36901 (Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report); CPT code 64461 (Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed); CPT code 64463 (Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed)); CPT code 65785 (Implantation of intrastromal corneal ring segments); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (for example, retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we proposed to maintain the temporary office-based designations for these eight codes for CY 2018. We listed all of these codes for which we proposed to maintain the temporary office-based designations for CY 2018 in Table 35 of the proposed rule. The procedures for which the proposed office-based designations for CY 2018 are temporary also were indicated by asterisks in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

The volume and utilization data for one procedure that has a temporary office-based designation for CY 2017, HCPCS code G0429 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies), is sufficient to indicate that this procedure is performed predominantly in physicians' offices and, therefore, should be assigned an office-based payment indicator in CY 2018. Consequently, we proposed to assign payment indicator ''P2/P3'' to this covered surgical procedure code in CY 2018.

HCPCS code 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound) was finalized for temporary office-based status in the CY 2017 OPPS/ASC final rule with comment period. However, this code will be deleted by the AMA, effective December 31, 2017.

We invited public comment on our proposals.

Comment: One commenter objected to the proposal to designate CPT codes 10030, 36473, and 36901 as temporarily office-based procedures for CY 2018. The commenter did not provide a clinical rationale but stated that, in the absence of data to examine site of service, it is premature to designate these CPT codes as temporarily office-based.

Response: In consultation with our medical advisors, we reviewed the clinical characteristics, utilization, and volume of related codes and determined that the procedures described by CPT codes 10030, 36473, and 36901 would be predominantly performed in physicians' offices. However, because we do not have utilization data for these CPT codes, we made the office-based designation temporary rather than permanent for CY 2018. We will reevaluate office-based status for CPT codes 10030, 36473, and 36901 in the CY 2019 rulemaking.

After consideration of the public comment we received, for CY 2018 we are finalizing our proposal, without modification, to designate the procedures listed in Table 84 below as temporary office-based.

TABLE 84—CY 2018 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED IN THE CY 2018 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2018 CPT code	CY 2018 long descriptor	CY 2017 ASC payment indicator *	CY 2018 ASC payment indicator **
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2 *	NA
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed).	R2 *	R2 **
10030	Image-guided fluid collection drainage by catheter (e.g., abscess, hematoma, seroma, lymphocele, cyst), soft tissue (e.g., extremity abdominal wall, neck), percutaneous.	P2 *	P2 **
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated.	P2 *	P2 **
36901	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow, including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report.	P2 *	P2 **
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	P3 *	P3 **
64463	Continuous infusion by catheter (includes imaging guidance, when performed)	P3 *	P3 **
65785	Implantation of intrastromal corneal ring segments	R2 *	P2 **
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy.	R2 *	R2 **
G0429	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	P3 *	P3 **

* If designation is temporary.
** Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 MPFS final rule with comment period.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33660), for CY 2018, we proposed to designate one new CY 2018 CPT code for ASC covered surgical procedures as temporary office-based, as displayed in Table 36 of the proposed rule. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedure described by this new CPT code would be predominantly performed in physicians' offices. However, because we had no utilization data for the procedure specifically described by this new CPT code, we proposed to make the office-based designation temporary rather than permanent, and we stated that we will reevaluate the procedure when data become available. The procedure for which the proposed office-based designation for CY 2018 is temporary was indicated by asterisks in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

We did not receive any public comments on our proposal. Therefore, for CY 2018, we are finalizing our proposal, without modification, to designate CPT code 38222 as temporary office-based for CY 2018 as displayed in Table 85 of this final rule with comment period. The procedure for which the office-based designation for CY 2018 is temporary is indicated by asterisks in Addendum AA to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 85—CY 2018 PAYMENT INDICATORS FOR NEW CY 2018 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED

CY 2017 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2018 CPT code	CY 2018 long descriptor	CY 2018 ASC payment indicator **
382X3	38222	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	P3 *

* If designation is temporary.
** Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 MPFS final rule with comment period.

b. ASC Covered Surgical Procedures To Be Designated as Device-Intensive

(1) Background

As discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79739 through 79740), we implemented a payment methodology for calculating the ASC payment rates for covered surgical procedures that are designated as device-intensive. Under § 416.171(b)(2) of the regulations, we define an ASC device-intensive procedure as a procedure with a HCPCS code-level device offset of greater than 40 percent when calculated according to the standard OPPS APC ratesetting methodology.

According to this ASC payment methodology, we apply the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We calculate the service portion of the ASC payment for device-intensive procedures by applying the uniform ASC conversion factor to the service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the revised ASC payment system.

We also finalized that device-intensive procedures will be subject to all of the payment policies applicable to procedures designated as an ASC device-intensive procedure under our established methodology, including our policies on device credits and discontinued procedures.

In addition, in the CY 2017 OPPS/ASC final rule with comment period, we adopted a policy for new HCPCS codes describing procedures involving the implantation of medical devices that do not yet have associated claims data, to designate these procedures as device-intensive with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset for the procedures (81 FR 79739 through 79740). This default device offset amount of 41 percent would not be calculated from claims data; instead, it would be applied as a default until claims data are available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that involve the implantation of medical devices would be to ensure ASC access for new procedures until claims data become available. However, in certain rare instances, for example, in the case of a very expensive implantable device, we may temporarily assign a higher offset percentage if warranted by additional information, such as pricing data from a device manufacturer. Once claims data are available for a new procedure involving the implantation of a medical device, the device-intensive designation will be applied to the code if the HCPCS code device offset is greater than 40 percent, according to our policy of determining device-intensive status, by calculating the HCPCS code-level device offset.

(2) Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2018

In the CY 2018 OPPS/ASC proposed rule, for CY 2018, we proposed to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, reflecting the proposed individual HCPCS code device-offset percentages based on CY 2016 OPPS claims and cost report data available for the proposed rule (82 FR 33660).

The ASC covered surgical procedures that we proposed to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2018, are assigned payment indicator ''J8'' and were included in Addendum AA to the proposed rule (which is available on the CMS Web site). The CPT code, the CPT code short descriptor, the proposed CY 2018 ASC payment indicator, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy would apply also were included in Addendum AA to the proposed rule.

We invited public comments on the proposed list of ASC device-intensive procedures.

Comment: A few commenters requested that CMS lower the ASC device offset threshold to 30 percent to qualify a larger number of ASC procedures as device-intensive.

Response: We did not propose to change to lower the ASC device offset threshold and, therefore, are not accepting this request. We note that we addressed a similar comment in the CY 2017 OPPS/ASC final rule with comment period, and we refer readers to our response (81 FR 79739).

Comment: One commenter requested that CMS designate CPT code 55X87 (which is replaced by CPT code 55874 in this final rule with comment period and effective January 1, 2018) as a device-intensive procedure in the ASC. The commenter stated that the procedure described by CPT code 55874 requires the implantation of an expensive device which represents an approximate range of 80 to 87 percent of the procedure cost.

Response: When claims data are available for a new procedure requiring the implantation of a medical device, device-intensive status will be applied to the code if the HCPCS code level device offset is greater than 40 percent, according to our finalized policy of determining device-intensive status by calculating the HCPCS code-level device offset (81 FR 79658). With respect to CPT code 55874, although the CPT code is new, the procedure itself was previously described by two predecessor codes, HCPCS code C9743 and CPT code 0438T, for which we have claims data. Therefore, based on our analysis of the OPPS claims data used to determine the packaged device costs attributed to the predecessor HCPCS codes, CPT code 55874 is not eligible for device-intensive status because the device offset for its predecessor codes are below the 40 percent threshold. For more information on how codes are designated as device-intensive status, we refer readers to section IV.B. (Device-Intensive Procedures) of this final rule with comment period.

Comment: Commenters requested that CMS designate CPT code 0275T, a procedure described as percutaneous image guided lumbar decompression (PILD) for lumbar spinal stenosis, as a device-intensive procedure until claims data become available. Commenters stated that, beginning in CY 2017, PILD is the only procedure reported with CPT code 0275T. In addition, to ensure CMS collects robust data on the cost of the device, one commenter requested that CMS establish a specific device code.

Response: As discussed in section IV.B.2 of this final rule with comment period, claims data for CPT code 0275T shows that the percentage of packaged device cost is below the 40 percent threshold; therefore, it is not eligible for designation as a device-intensive procedure. CPT code 0275T was implemented as a payable code in the OPPS and ASC settings on July 1, 2011 (July 2011 OPPS Update, Transmittal 2234, Change Request 7443). We are unclear why a separate device code is needed if PILD is the only procedure reported with CPT code 0275T.

Comment: One commenter requested that CMS designate CPT code 67027 (Implant eye drug system) as a device-intensive procedure in the ASC.

Response: CPT code 67027 does not have a device offset that is greater than 40 percent. Accordingly, it is not device-intensive under current policy.

After consideration of the public comments we received, we are designating the ASC covered surgical procedures displayed in Addendum AA as device-intensive and subject to the device-intensive procedure payment methodology for CY 2018. The CPT code, the CPT code short descriptor, the final CY 2018 ASC payment indicator, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy will apply are included in the ASC policy file labeled ''CY 2018 ASC Procedures to which the No Cost/Full Credit and Partial Credit Device Adjustment Policy Applies,''' which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Policy-Files.html.*

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted in ASCs at no cost/full credit or partial credit, as set forth in § 416.179 of our regulations, is consistent with the OPPS policy that was in effect until CY 2014. Specifically, the OPPS policy that was in effect through CY 2013 provided a reduction in OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device (77 FR 68356 through 68358). The established ASC policy reduces payment to ASCs when a specified device is furnished without cost or with full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices (73 FR 68742 through 68744).

As discussed in section IV.B. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPPS, our policy was to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnished a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital received partial credit in the amount of 50 percent or more (but less than 100 percent) of the cost for the specified device. For CY 2014, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a replaced device, capped at the device offset amount.

Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in that final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual amount received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33661), we proposed to update the list of ASC covered device-intensive procedures that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2018. Specifically, when a device-intensive procedure is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line in the claim with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

For partial credit, we proposed to reduce the payment for implantation procedures that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC would append the HCPCS ''FC'' modifier to the HCPCS code for a device-intensive surgical procedure that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs would have the option of either: (1) Submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost/full credit or partial credit, we apply our FB/FC policy to all device-intensive procedures.

We invited public comments on our proposals to adjust ASC payments for no cost/full credit and partial credit devices.

We did not receive any public comment on these proposals. Therefore, we are finalizing these proposals without modification. Specifically, we will apply the HCPCS ''FB''/''FC'' modifier policy to all device-intensive procedures in CY 2018. For CY 2018, we will reduce the payment for the procedures listed in the ASC device adjustment file by the full device offset amount if a device is furnished without cost or with full credit. ASCs must append the HCPCS modifier ''FB'' to the HCPCS code for a surgical procedure listed in the ASC device adjustment file previously mentioned when the device

is furnished without cost or with full credit. In addition, for CY 2018, we will reduce the payment for the procedures listed in the ASC device adjustment file by one-half of the device offset amount if a device is provided with partial credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the device cost. The ASC must append the HCPCS ''FC'' modifier to the HCPCS code for a surgical procedure listed in the ASC device adjustment file when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device.

d. Additions to the List of ASC Covered Surgical Procedures

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33661), we conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, we proposed to update the list of ASC covered surgical procedures by adding three procedures to the list for CY 2018. These procedures included procedures described by CPT codes 22856, 22858, and 58572. We determined that these three procedures are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. Therefore, we proposed to include these three procedures on the list of ASC covered surgical procedures for CY 2018.

The procedures that we proposed to add to the ASC list of covered surgical procedures, including the HCPCS code long descriptors and the proposed CY 2018 payment indicators, were displayed in Table 37 of the proposed rule. We invited public comments on our proposals.

Comment: Some commenters supported adding the three procedures described by CPT codes 22856, 22858, and 58572 to the ASC list of covered surgical procedures. These commenters believed that all three procedures met the criteria to be added to the ASC list of covered surgical procedures.

Response: We appreciate the commenters' support. As indicated later in this section, we are finalizing our proposal to add these procedures to the ASC list of covered surgical procedures.

Comment: One commenter suggested that including the procedures described by CPT codes 22856, 22858, and 58572 on the ASC list of covered surgical procedures would allow physicians to inappropriately direct patients to receive these procedures in an ASC setting with which they have a financial relationship rather than an inpatient hospital setting, and thereby jeopardize patient access to these procedures in an inpatient setting.

Response: We do not believe that including the procedures described by CPT codes 22856, 22858, and 58572 on the ASC list of covered surgical procedures would lead to inappropriate shifting of patients to the ASC setting or jeopardize access to these procedures in an inpatient hospital setting. We believe the decision regarding the most appropriate care setting for a given surgical procedure is made by the physician based on the beneficiary's individual clinical needs and preferences. In addition, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 and 74378), section 1832(a)(2)(F)(i) of the Act provides that benefits under Medicare Part B include payment for facility services furnished in connection with surgical procedures specified by the Secretary that are performed in an ASC. Under 42 CFR 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, we define covered surgical procedures as those procedures which are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. We believe it is appropriate and necessary to include procedures that meet these criteria on the list of ASC covered surgical procedures for Medicare patients who may be suitable candidates to undergo these procedures in an ASC setting.

After consideration of the public comments we received, we are finalizing our proposal to add the three procedures described by CPT codes 22856, 22858, and 58572 to the ASC list of covered surgical procedures. The procedures that we are adding to the ASC list of covered surgical procedures, including the code long descriptors and the final CY 2018 payment indicators, are displayed in Table 86 below.

TABLE 86—ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2018

CY 2018 CPT code	CY 2018 long descriptor	CY 2018 ASC payment indicator
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical.	J8
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (list separately in addition to code for primary procedure).	N1
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250g	G2

e. Discussion of Comment Solicitation on Adding Additional Procedures to the ASC Covered Procedures List

As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68724), we adopted a policy to include, in our annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS IPO list for possible inclusion on the ASC list of covered surgical procedures.

In the CY 2017 OPPS/ASC proposed rule (81 FR 45679 through 45681), we solicited comments regarding whether the TKA procedure described by CPT code 27447 should be removed from the OPPS IPO list. During the comment period, some stakeholders requested that CMS also add the TKA procedure to the list of surgical procedures covered in an ASC setting. In the CY 2017 OPPS/ASC proposed rule, we solicited public

comments on removing the TKA procedure from the OPPS IPO list for CY 2017. However, in the CY 2018 OPPS/ASC proposed rule (82 FR 33643 through 33644), we proposed to remove the TKA procedure from the OPPS IPO list for CY 2018, as discussed in section IX. of both the proposed rule and this final rule with comment period. In light of the public comments we received on the CY 2017 OPPS/ASC proposed rule (81 FR 79697 through 79699) and our proposal to remove the TKA procedure from the OPPS IPO list for CY 2018, in the CY 2018 OPPS/ASC proposed rule, we solicited public comments on whether the TKA procedure should also be added to the ASC list of covered surgical procedures. We also invited public comments on our proposed continued exclusion of CPT code 55866 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed) from the list of ASC covered surgical procedures.

In considering whether or not the TKA procedure should be added to the ASC list of covered surgical procedures, we requested that commenters take into consideration the regulations at 42 CFR 416.2 and 416.166. We indicated that commenters should assess, for example, whether this procedure would be expected to pose a significant risk to beneficiary safety when performed in an ASC, whether standard medical practice dictates that the beneficiary would typically be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''), and whether this procedure would fall under our general exclusions for covered surgical procedures at 42 CFR 416.166(c) (for example, would it generally result in extensive blood loss, require major or prolonged invasion of body cavities, directly involve major blood vessels, among others).

As discussed in the CY 2018 OPPS/ASC proposed rule, we evaluated each of the procedures described by CPT codes 27447 and 55866 that we proposed to remove from the OPPS IPO list for CY 2018 according to the criteria for inclusion on the list of ASC covered surgical procedures, and considered whether they should be added to the list of ASC covered surgical procedures for CY 2018. We stated that, because our understanding is that these procedures typically require more than 24 hours of active medical care following the procedure, we believed they should continue to be excluded from the list of ASC covered surgical procedures.

In addition, in the CY 2018 OPPS/ASC proposed rule, we solicited comments on whether CPT codes 27125 (Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)) and 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft) meet the criteria to be removed from the OPPS IPO list, as discussed in section IX. of the proposed rule. As noted in that section, we also solicited comments on whether these two procedures meet the criteria to be added to the ASC covered surgical procedures list.

Comment: In addition to the comments CMS received as to whether CPT codes 27447, 27125, 27130, and 55866 should be removed from the OPPS IPO list, several commenters suggested that these procedures should be added to the ASC covered surgical procedures list. The commenters argued that many ASCs are equipped to perform these procedures and orthopedic surgeons in ASCs are increasingly performing these procedures safely and effectively on non-Medicare patients and appropriate Medicare patients. They also noted that CPT code 27446 (Arthroplasty, knee, condyle and plateau; medial or lateral compartment) is a similar procedure that is currently included on the list of ASC covered surgical procedures. In addition, the commenters also stated that adding TKA and partial and total hip arthroplasty procedures to the ASC covered surgical procedures list allows for greater choices in care settings for Medicare patients and would provide a more patient-centered approach to joint arthroplasty procedures. Further, commenters stated that, in some cases, it may be safer to have joint arthroplasty procedures performed in an outpatient setting to prevent certain hospital-acquired infections.

Some commenters suggested a stepwise approach to transitioning TKA to the ASC setting and recommended allowing performance of 1 to 2 years in the hospital outpatient department setting before adding TKA to the ASC covered surgical procedures list. Other commenters recommended that ASCs obtain enhanced certification from a national accrediting organization that certifies an ASC meets higher quality standards to safely perform joint arthroplasty procedures.

Some commenters opposed adding procedures described by CPT codes 27447, 27125, 27130, and 55866 to the ASC covered surgical procedures list. These commenters believed that the vast majority of ASCs are not equipped to safely perform these procedures on patients and that the vast majority of Medicare patients are not suitable candidates to receive ''overnight'' joint arthroplasty procedures in an ASC setting.

Response: We appreciate the feedback we received as to whether TKA, partial and total hip replacement procedures meet the criteria to be added to the ASC covered surgical procedures list. For CY 2018, we are not removing CPT codes 27125 and 27130 from the OPPS IPO list. While we are finalizing our proposal to remove CPT codes 27447 and 55866 from the OPPS IPO list for CY 2018, we are not adding these procedures to the ASC covered surgical procedures list for CY 2018. We solicited comments on whether to add these procedures to the ASC list of covered surgical procedures, and we will take the suggestions and recommendations into consideration for future rulemaking.

Comment: Many commenters requested that CMS add certain CPT codes that are outside of the 10000–69999 CPT code surgical range. These codes are shown in Table 87 below and included gastrointestinal diagnostic procedures, chemotherapy, cardiac catheterization procedures, and cardiac diagnostic procedures, as well as other cardiology procedures.

TABLE 87—PROCEDURES REQUESTED BY COMMENTERS FOR ADDITION TO THE CY 2018 LIST OF ASDC COVERED SURGICAL PROCEDURES

CY 2018 CPT/HCPCS code	CY 2018 short descriptor
23470	Reconstruct shoulder joint.
23472	Reconstruct shoulder joint.
27702	Reconstruct ankle joint.
27703	Reconstruction ankle joint.
91010	Esophagus motility study.
91013	Esophgl motil w/stim/perfus.
91020	Gastric motility studies.
91022	Duodenal motility study.
91030	Acid perfusion of esophagus.
91034	Gastroesophageal reflux test.
91035	G-esoph reflx tst w/electrod.
91037	Esoph imped function test.
91038	Esoph imped funct test > 1hr.
91040	Esoph balloon distension tst.
91110	Gi tract capsule endoscopy.
91111	Esophageal capsule endoscopy.
91112	Gi wireless capsule measure.
91117	Colon motility 6 hr study.
91120	Rectal sensation test.
91122	Anal pressure record.
92920	Prq cardiac angioplast 1 art.
92921	Prq cardiac angio addl art.
92924	Prq card angio/athrect 1 art.
92925	Prq card angio/athrect addl.
92928	Prq card stent w/angio 1 vsl.
92929	Prq card stent w/angio addl.
92937	Prq revasc byp graft 1 vsl.
92938	Prq revasc byp graft addl.

TABLE 87—PROCEDURES REQUESTED BY COMMENTERS FOR ADDITION TO THE CY 2018 LIST OF ASDC COVERED SURGICAL PROCEDURES—Continued

CY 2018 CPT/HCPCS code	CY 2018 short descriptor
92960	Cardioversion electric ext.
92973	Prq coronary mech thrombect.
92978	Endoluminl ivus oct c 1st.
92979	Endoluminl ivus oct c ea.
93312	Echo transesophageal.
93313	Echo transesophageal.
93315	Echo transesophageal.
93316	Echo transesophageal.
93451	Right heart cath.
93452	Left hrt cath w/ventrclgrphy.
93453	R&l hrt cath w/ventriclgrphy.
93454	Coronary artery angio s&i.
93455	Coronary art/grft angio s&i.
93456	R hrt coronary artery angio.
93457	R hrt art/grft angio.
93458	L hrt artery/ventricle angio.
93459	L hrt art/grft angio.
93460	R&l hrt art/ventricle angio.
93461	R&l hrt art/ventricle angio.
93462	L hrt cath trnsptl puncture.
93463	Drug admin & hemodynmic meas.
93505	Biopsy of heart lining.
93530	Rt heart cath congenital.
93531	R & l heart cath congenital.
93532	R & l heart cath congenital.
93533	R & l heart cath congenital.
93563	Inject congenital card cath.
93564	Inject hrt congntl art/grft.
93565	Inject l ventr/atrial angio.
93566	Inject r ventr/atrial angio.
93567	Inject suprvlv aortography.
93568	Inject pulm art hrt cath.
93600	Bundle of his recording.
93602	Intra-atrial recording.
93603	Right ventricular recording.
93612	Intraventricular pacing.
93613	Electrophys map 3d add-on.
93620	Electrophysiology evaluation.
93621	Electrophysiology evaluation.
93622	Electrophysiology evaluation.
93623	Stimulation pacing heart.
93624	Electrophysiologic study.
93650	Ablate heart dysrhythm focus.
93653	Ep & ablate supravent arrhyt.
93654	Ep & ablate ventric tachy.
93655	Ablate arrhythmia add on.
93656	Tx atrial fib pulm vein isol.
93657	Tx l/r atrial fib addl.
96413	Chemo iv infusion 1 hr.
96415	Chemo iv infusion addl hr.
0237T	Trluml perip athrc brchiocph.
0398T	Mrgfus strtctc les abltj.
C9600	Perc drug-el cor stent sing.
C9601	Perc drug-el cor stent bran.
C9602	Perc d-e cor stent ather s.
C9603	Perc d-e cor stent ather br.
C9604	Perc d-e cor revasc t cabg s.
C9605	Perc d-e cor revasc t cabg b.

Response: We reviewed all of the codes that commenters requested for addition to the ASC list of covered surgical procedures. Of the codes requested for addition to the ASC list, we did not consider procedures that are reported by CPT codes that are on the OPPS IPO list. Codes that are on the OPPS IPO list for CY 2018 are not eligible for addition to the ASC list of covered surgical procedures.

As we discussed in section XII.A.3. of this final rule with comment period, we solicited public comments regarding our definition of a surgical procedures and whether services described by Category I CPT codes outside of the surgical range (10000–69999), or Level II HCPCS codes or Category III CPT codes that do not directly crosswalk and are not clinically similar to procedures in the CPT surgical range, may nonetheless be appropriate to include as covered surgical procedures that are payable when furnished in the ASC setting. We did not propose any revisions to our definition of covered surgical procedures, and, for CY 2018, we continue to use the current definition of surgical procedure.

We appreciate the commenters' recommendations for procedures that may be suitable candidates to include on the list of ASC covered surgical procedures. We acknowledge that some of the procedures may be ''surgery-like.'' However, we remain concerned that these procedures may impose a significant safety risk to the Medicare population in an ASC setting. For CY 2018, we continue to rely on defining surgical procedures as those that are described by Category I CPT codes within the surgical range, or Level II HCPCS codes or Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range. Therefore, we do not believe that the remaining codes should be added to the list of ASC covered surgical procedures for CY 2018 because they do not meet our criteria for inclusion on the list. However, we will take these comments into consideration in future rulemakings.

D. ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2''. Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator ''A2'' because it is used to identify procedures that are exempted from the application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79732 through 79753), we updated the CY 2016 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2'', ''G2'', and ''J8'' using CY 2015 data, consistent with the CY 2017 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2017 OPPS device offset percentages calculated under the standard APC ratesetting methodology, as discussed earlier in this section.

Payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') are the lower of the MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2018 MPFS proposed and final rules) or the amount calculated using the ASC standard rate setting methodology for the procedure. In the CY 2017 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2017 rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2017 payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures.

For CY 2014, we finalized a policy to conditionally package payment for device removal codes under the OPPS. Under the OPPS, a conditionally packaged code (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There would be no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To address this concern, for the device removal procedures that are conditionally packaged in the OPPS (status indicator ''Q2''), we assigned the current ASC payment indicators associated with these procedures and continued to provide separate payment since CY 2014.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2018

In the CY 2018 OPPS/ASC proposed rule (82 FR 33663), we proposed to update ASC payment rates for CY 2018 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XII.C.1.b. of the proposed rule. Because the proposed OPPS relative payment weights are based on geometric mean costs, the ASC system would use geometric means to determine proposed relative payment weights under the ASC standard methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''.

We proposed to calculate payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') and device-intensive procedures (payment indicator ''J8'') according to our established policies and, for device-intensive procedures, using our modified definition of device-intensive procedures, as discussed in section XII.C.1.b. of the proposed rule. Therefore, we proposed to update the payment amount for the service portion of the device-intensive procedures using the ASC standard rate setting methodology and the payment amount for the device portion based on the proposed CY 2018 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures would be at the lesser of the proposed CY 2018 MPFS nonfacility PE RVU-based amount or the proposed CY 2018 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2017, for CY 2018, we proposed to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2'') would be assigned the current ASC payment indicators associated with these procedures and would continue to be paid separately under the ASC payment system.

We invited public comments on these proposals.

Comment: A few commenters objected to the proposed payment indicator of ''G2'' (Non-office-based surgical procedure) for CPT code 0465T (Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)) and requested that CMS designate it an office-based procedure. The commenters noted CMS' recognition of CPT code 0465T as an office-based procedure in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79735).

Response: We agree with the commenters that CPT code 0465T is an office-based procedure. Therefore, we are modifying our proposal to assign CPT code 0465T to payment indicator ''R2'' for CY 2018.

Comment: One commenter requested that CMS use the CY 2016 ASC payment rates for six procedures to set the CY 2018 ASC payment rate for the same procedures. The specific procedures include:

- CPT 62321 (Cervicothoracic epidural);
- CPT 62323 (Lumbosacral epidural);
- CPT 64490 (Cervicothoracic facet joint injection);
- CPT 64493 (Lumbosacral facet joint injection);
- CPT G0620 (Sacroiliac joint injection); and
- CPT 62264 (Percutaneous adhesiolysis).

Response: We are required by law to review and update the data on which we establish payment rates on an annual basis. The ASC payment is dependent upon the APC assignment for the procedure. Based on our analysis of the latest hospital outpatient and ASC claims data used for this final rule with comment period, we are updating ASC payment rates for CY 2018 using the established rate calculation methodologies under § 416.171 and using our finalized modified definition of device-intensive procedures, as discussed in section XII.C.1.b. of this final rule with comment period. We do not generally make additional payment adjustments to specific procedures.

After consideration of the public comments we received, we are finalizing our proposed policies, without modification, to calculate the CY 2018 payment rates for ASC covered surgical procedures according to our established methodologies using the modified definition of device-intensive procedures. For those covered office-based surgical procedures where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the MPFS nonfacility PE RVU-based amount, the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the MPFS PE RVUs and conversion factor effective January 1, 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 MPFS final rule with comment period.

2. Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N'', ''Q1'', and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged code describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are

conditionally packaged under the OPPS are always packaged (payment indictor ''N1'') under the ASC payment system (except for device removal codes, as discussed in section IV. of the CY 2018 OPPS/ASC proposed rule). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates. We generally pay for separately payable radiology services at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount (''Z3''), regardless of which is lower.

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (42 CFR 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; 42 CFR 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include a reference to diagnostic services and those for which the payment is based on the MPFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include a reference to diagnostic services.

b. Payment for Covered Ancillary Services for CY 2018

In the CY 2018 OPPS/ASC proposed rule (82 FR 33663), for CY 2018 and subsequent years, we proposed to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2018 OPPS and ASC payment rates and subsequent year payment rates. We also proposed to continue to set the CY 2018 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2018 and subsequent year payment rates.

Covered ancillary services and their proposed payment indicators for CY 2018 were listed in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site). For those covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard rate setting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in the proposed rule were based on a comparison using the proposed MPFS rates effective January 1, 2018. For a discussion of the MPFS rates, we referred readers to the CY 2018 MPFS proposed rule that is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

We did not receive public comments on our proposals regarding payment for covered ancillary services. Therefore, we are finalizing these policies as proposed for CY 2018.

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

- Applicants submit their NTIOL requests for review to CMS by the annual deadline. For a request to be considered complete, we require submission of the information that is

found in the guidance document entitled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class'' posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html.*

- We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at 42 CFR 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.
- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments;

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2018

We did not receive any requests for review to establish a new NTIOL class for CY 2018 by March 1, 2017, the due date published in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79748).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we did not propose to revise the payment adjustment amount for CY 2018. The final ASC payment adjustment amount for NTIOLs for CY 2018 is $50.

4. Announcement of CY 2019 Deadline for Submitting Requests for CMS Review of Applications for a New Class of NTIOLs

In accordance with § 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective beginning in CY 2019, requests for review of applications for a new class of new technology IOLs must be received at CMS by 5:00 p.m. EST, on March 1, 2018. Send requests to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include the information requested on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html.*

F. ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC list of covered services prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators used in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NP'' also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In the CY 2017 OPPS/ASC final rule with comment period, we responded to public comments and finalized the ASC treatment of all codes that were labeled with comment indicator ''NP'' in Addenda AA and BB to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The ''CH'' comment indicator is used in Addenda AA and BB to the proposed rule (which are available via the Internet on the CMS Web site) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year; an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79748 through 79749), for CY 2017 and subsequent years, we finalized our policy to continue using the current comment indicators of ''NP'' and ''CH''.

2. ASC Payment and Comment Indicators

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33665), for CY 2018, there are proposed new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Therefore, proposed Category I and III CPT codes that are new and revised for CY 2017 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2018 compared to the CY 2017 descriptors that were included in ASC Addenda AA and BB to the proposed rule are labeled with proposed new comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes were open for comment as part of the proposed rule. Comment indicator ''NP'' in the proposed rule meant a new code for the next calendar

year or an existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year; and denotes that comments will be accepted on the proposed ASC payment indicator for the new code.

We stated in the proposed rule that we will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2018 OPPS/ASC final rule with comment period. We referred readers to Addenda DD1 and DD2 to the proposed rule (which are available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2018 update.

We did not receive any public comments on the ASC payment and comment indicators. Therefore, we are finalizing their use as proposed without modification. Addenda DD1 and DD2 to this final rule with comment period (which are available via the Internet on the CMS Web site) contain the complete list of ASC payment and comment indicators for the CY 2018 update.

G. Calculation of the ASC Conversion Factor and the ASC Payment Rates

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; 42 CFR 416.171(e)).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2. of this final rule with comment period), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf*). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13–01 for the IPPS hospital wage index beginning in FY 2015. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66937), we finalized a 1-year transition policy that we applied in CY 2015 for all ASCs that experienced any decrease in their actual wage index exclusively due to the implementation of the new OMB delineations. This transition does not apply in CY 2018.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB

occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. The complete list of statistical areas incorporating these changes is provided in the attachment to OMB Bulletin No. 15–01. According to OMB, ''[t]his bulletin establishes revised delineations for the Nation's Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provides delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas.'' A copy of this bulletin may be obtained on the Web site at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf*.

OMB Bulletin No. 15–01 made changes that are relevant to the IPPS and ASC wage index. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79750) for a discussion of these changes and our implementation of these revisions.

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33667), for CY 2018, the proposed CY 2018 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin No. 15–01).

We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). For example, for CY 2014, we applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA) and CBSA 08 (Rural Delaware).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). (In other situations, where there are no IPPS hospitals located in a relevant labor market area, we continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.)

Comment: A few commenters made the same recommendation that was made in the CY 2010 (74 FR 60625), CY 2011 (75 FR 72059), CY 2012 (76 FR 74446), CY 2013 (77 FR 68463), CY 2014 (78 FR 75086), CY 2015 (79 FR 66937), CY 2016 (80 FR 70499), and CY 2017 (81 FR 79750) OPPS/ASC rulemakings—that is, that CMS adopt for the ASC payment system the same wage index values used for hospital payment under the OPPS.

Response: We have responded to this comment in the prior OPPS/ASC rules mentioned above, and believe our prior rationale for using unadjusted wage indexes is still sound. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by almost all Medicare payment systems, appropriately account for geographic variance in labor costs for ASCs. We refer readers to our response to this comment in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72059).

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2018 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). Consistent with our established policy, in the CY 2018 OPPS/ASC proposed rule (82 FR 33667), we proposed to scale the CY 2018 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2016, we proposed to compare the total payment using the CY 2017 ASC relative payment weights with the total payment using the CY 2018 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2017 and CY 2018. We proposed to use the ratio of CY 2017 to CY 2018 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2018. The proposed CY 2018 ASC weight scalar was 0.8995 and scaling would apply to the ASC relative payment weights of the covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of the proposed rule, we had available 98 percent of CY 2016 ASC claims data.

To create an analytic file to support calculation of the weight scalar and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2016 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2016 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for the proposed rule, is posted on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html*.

Comment: Several commenters requested that CMS not scale the ASC relative payment weights when

calculating the final CY 2018 ASC payment rates. Some commenters requested that if CMS must apply a weight scalar, as an alternative, CMS make a one-time adjustment to restore the historical relativity between the OPPS and ASC setting at 65 percent.

Response: We note that applying the weight scalar in calculation of ASC payment rates ensures that the ASC payment system remains budget neutral. For a more detailed discussion on why we apply a budget neutrality adjustment to the ASC ratesetting methodology, we refer readers to the August 2, 2007 final rule (72 FR 42531 through 42533). We refer the commenters to that discussion for our detailed response in promulgating the scaling policy that was initially applied in CY 2009 to maintain budget neutrality of the ASC payment system. The ASC weight scaling methodology is consistent with the OPPS methodology for scaling the relative payment weights and the increased payment differentials between the ASC and OPPS payments for the same services are not, for the most part, attributable to scaling ASC relative payment weights. With respect to the relativity between the OPPS and the ASC payment system, we recognize that the relativity has declined from 65 percent in 2008 to 56 percent in 2017. We believe this change in relativity is based on a number of factors, including the addition of new surgical procedures in both payment settings, packaged payment policies, device-intensive policies, and the advent of the C–APC policy, which was implemented under the OPPS effective January 1, 2015, but could not be implemented in the ASC system, given systems limitations in ASC claims processing because ASC claims are submitted on the professional claim and are not processed by the same system as hospital claims. Further, the absence of cost data from ASCs makes it difficult to determine what an appropriate relativity between the two payment systems would be. That is, without cost data from ASCs, we are unable to determine precisely how ASC costs compare to those of hospitals paid under the OPPS. We note that the commenters did not provide any empirical evidence to support increasing ASC payment rates relative to OPPS payment rates.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2018, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2016 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2018 ASC wage indexes. Specifically, holding CY 2016 ASC utilization, service-mix, and the proposed CY 2018 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2017 ASC wage indexes (which would fully reflect the new OMB delineations) and the total adjusted payment using the proposed CY 2018 ASC wage indexes. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2017 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2018 ASC wage indexes and applied the resulting ratio of 1.0004 (the proposed CY 2018 ASC wage index budget neutrality adjustment) to the CY 2017 ASC conversion factor to calculate the proposed CY 2018 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI–U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. Therefore, the statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI–U (referred to as the CPI–U update factor).

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v), which requires that any annual update under the ASC payment system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, effective with the calendar year beginning January 1, 2011. 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 (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). Clause (iv) of section 1833(i)(2)(D) of the Act authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) of section 1833(i)(2)(D) of the Act states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASC Quality Reporting (ASCQR) Program. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), we finalized a methodology to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for the CY 2014 payment determination and subsequent years. The application of the 2.0 percentage point reduction to the annual update factor, which currently is the CPI–U, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We amended §§ 416.160(a)(1) and 416.171 to reflect these policies.

In accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the ''percentage increase'' in the CPI–U, which we interpret cannot be a negative percentage. Thus, in the instance where the percentage change in the CPI–U for a year is negative, we would hold the CPI–U update factor for the ASC payment system to zero. For the CY 2014 payment determination and

subsequent years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality information under the rules established by the Secretary in accordance with section 1833(i)(7) of the Act. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the annual update factor, after application of any quality reporting reduction, by the MFP adjustment, and states that application of the MFP adjustment to the annual update factor after application of any quality reporting reduction may result in the update being less than zero for a year. If the application of the MFP adjustment to the annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting update to the ASC payment rates would be negative and payments would decrease relative to the prior year. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064) for examples of how the MFP adjustment is applied to the ASC payment system.

For the proposed rule, based on IHS Global Inc.'s (IGI's) 2017 first quarter forecast with historical data through the fourth quarter of 2016, for the 12-month period ending with the midpoint of CY 2018, the CPI–U update was projected to be 2.3 percent. Also, based on IGI's 2017 first quarter forecast, the MFP adjustment for the period ending with the midpoint of CY 2018 was projected to be 0.4 percent. We finalized the methodology for calculating the MFP adjustment in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501).

In the CY 2018 OPPS/ASC proposed rule (82 FR 33668), for CY 2018, we proposed to reduce the CPI–U update of 2.3 percent by the MFP adjustment of 0.4 percentage point, resulting in an MFP-adjusted CPI–U update factor of 1.9 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a 1.9 percent MFP-adjusted CPI–U update factor to the CY 2017 ASC conversion factor for ASCs meeting the quality reporting requirements. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the CPI–U for ASCs that fail to meet the ASCQR Program requirements. We proposed to reduce the CPI–U update of 2.3 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then apply the 0.4 percentage point MFP adjustment. Therefore, we proposed to apply a −0.1 percent MFP-adjusted CPI–U update factor to the CY 2017 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also proposed that if more recent data are subsequently available (for example, a more recent estimate of the CY 2018 CPI–U update and MFP adjustment), we would use such data, if appropriate, to determine the CY 2018 ASC update for the final rule with comment period.

For CY 2018, we proposed to adjust the CY 2017 ASC conversion factor ($45.003) by the proposed wage index budget neutrality factor of 1.0004 in addition to the MFP-adjusted CPI–U update factor of 1.9 percent discussed above, which resulted in a proposed CY 2018 ASC conversion factor of $45.876 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2017 ASC conversion factor ($45.003) by the proposed wage index budget neutrality factor of 1.0004 in addition to the quality reporting/MFP-adjusted CPI–U update factor of −0.1 percent discussed above, which resulted in a proposed CY 2018 ASC conversion factor of $44.976.

We invited public comments on these proposals.

Comment: Numerous commenters urged CMS to update ASC payment rates using the same update factor as hospital outpatient departments, which is the IPPS hospital market basket. Commenters argued that because the ASC relative weights are derived from the OPPS weights, the same annual update factor that is used for the OPPS should also be used for ASCs. Commenters stated that the use of different update indices has contributed to the divergence in payments between the HOPD and ASC setting. Several commenters cited findings from a 2013 Ambulatory Surgery Center Association (ASCA) study (with cost savings analysis produced by the University of California-Berkeley) that found ASCs saved the Medicare program and its beneficiaries $7.5 billion during the 4-year period from 2008 to 2011 over what would have been paid if care had been provided in other settings. The study also projected that ASCs have the potential to save the Medicare system an additional $57.6 billion over the next decade ''if policymakers take steps to encourage the use of these innovative healthcare facilities within the Medicare system.'' [34]

One commenter, a trade association representing several ASCs noted that surgical care in too many markets continues to be provided predominantly in hospitals, which the commenter attributed to Medicare's failure to pay competitive rates to ASCs. The commenter asserted that this lack of migration comes at a high price to the Medicare program, the taxpayers who fund it, and the beneficiaries who needlessly incur higher out-of-pocket expenses. This commenter also noted that the hospital market basket is comprised of data that reflects the cost of items and services necessary to furnish an outpatient surgical procedure, such as compensation, utilities, labor-related services and non-labor related services. In addition, in response to the comment solicitation on ASC payment reform (including the collection of cost data), described later in this section, this commenter stated its willingness to work with the Secretary to collaborate on ideas and asserted its belief that that the same types of costs that apply to the hospital outpatient department are also present in the ASC, but that it did not know if they are weighted the same. This commenter welcomed the opportunity to discuss how ASCs might potentially use a simple, cost-effective survey, perhaps voluntary in nature, that calculates expense categories as a percentage of total expenses to help determine the appropriate weights and price proxies for the ASC setting. The commenter noted that ''a complicating factor, however, remains the heterogeneity of the ASC model—the range of size and specialty care varies greatly from one ASC to the next.''

Commenters also made the following arguments in support of replacing the CPI–U with the hospital market basket:

- The CPI–U does not accurately represent the costs borne by ASC facilities to furnish surgical services. Approximately 8.5 percent of the CPI–U inputs are directly related to health care, yet the CPI–U is based on consumer experience purchasing health care rather than a provider's experience necessary to furnish a health care service.

[34] ASCA. Medicare Cost Savings Tied to Ambulatory Surgery Centers with Cost Analysis done by Nicholas C. Petris University of California-Berkeley Center on Health Care Markets and Consumer Welfare. September 2013. Available at: *http://www.ascassociation.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=7b33b916-f3f1-42e5-a646-35cc2f38fe4d&forceDialog=0.*

• ASCs are one of few remaining Medicare payment systems tied to the CPI–U. Most other systems use indices derived from the basket of goods those providers purchase (for example, ESRD PPS uses ESRD bundled market basket; FQHC PPS uses Medicare Economic Index; IPPS and OPPS uses the hospital market basket).

• The hospital market basket is a more accurate reflection of ASC costs because it is comprised of data that reflects the cost of items and services necessary to furnish an outpatient surgical procedure, such as compensation, utilities, labor-related services and nonlabor-related services.

MedPAC objected to the proposed 1.9 percent update based on CPI–U and recommended that CMS not update payments to ASCs in 2018, consistent with its recommendation to Congress in the March 2017 Report to the Congress. MedPAC contended that, because indicators of payment adequacy for ASCs—capacity and supply of providers, volume of services, access to capital, payment to providers per fee-for-service beneficiary—are positive, and in light of the importance of maintaining financial pressure on providers to constrain costs, the proposed 1.9 percent update is unnecessarily high. While MedPAC acknowledged that the CPI–U likely does not reflect ASC's cost structure because the CPI–U is heavily weighted for factors that have a relatively small effect on ASCs such as housing and transportation, it commented that it understood that the method for arriving at the proposed 1.9 percent CPI–U update is mandated by law. MedPAC strongly urged CMS to collect cost data from ASCs to better assess payment adequacy to ASCs.

Response: As we have stated in response to similar comments in the past (for example, 77 FR 68465; 78 FR 75088 through 75089; 79 FR 66939; 80 FR 70501; and 81 FR 79752), we continue to believe that, while commenters believed that the items included in the CPI–U index may not adequately measure inflation for the goods and services provided by ASCs, the hospital market basket may also not be well aligned with the cost structures of ASCs. While there are some similarities between the cost structure of hospitals and ASCs, hospitals provide a wider range of services, such as room and board and emergency services, and the costs associated with providing these services do not appear to be part of the ASC cost structure. Therefore, at this time, we do not believe that it is appropriate to use the hospital market basket for the ASC annual update.

Nonetheless, we recognize that ASCs may incur some of the same costs that hospitals incur and share the commenters' concern that the disparity in payments between the OPPS and ASC payment systems may affect migration from the HOPD setting to the less costly ASC setting. To the extent that it is clinically appropriate for a beneficiary to receive services in a lower cost setting, we believe it would be appropriate to continue to develop payment incentives and remove payment disincentives to facilitate this choice. We will continue to monitor access to services, such as by reviewing utilization in different settings and soliciting stakeholder input, to ascertain the degree to which choices are available. While there are several factors that contribute to the divergence in payment between the two systems, certain of which are identified in the comment solicitation on ASC payment reform, we believe that an alternative update factor could be a mitigating step to address the differential between OPPS and ASC payment. In other words, to the extent that the CPI–U has been lower than the hospital market basket, we believe this difference or gap has contributed to the difference between payments for services when they are provided by an ASC or a HOPD. Additionally, we believe that, in response to our proposal and comment solicitation, commenters have raised an important issue that merits consideration given the Administration's priorities, particularly those seeking to promote and improve affordability and accessibility of care. For example, under Executive Order 13813 (issued October 12, 2017), entitled ''Presidential Executive Order Promoting Healthcare Choice and Competition Across the United States,'' ''it shall be the policy of the executive branch, to the extent consistent with law, to facilitate . . . the development and operation of a healthcare system that provides high-quality care at affordable prices for the American people'' and the Administration shall ''continue to focus on promoting competition in healthcare markets and limiting excessive consolidation throughout the healthcare system.'' [35]

While MedPAC recommends a zero percent update, we do not believe that such update would serve to promote competition in health care markets and it could hinder ASCs' ability to provide services to Medicare beneficiaries at a lower cost than HOPDs. We know that the differential in payments between hospitals paid under the OPPS and the ASC has increased from approximately 65 percent in 2008 to approximately 56 percent in 2017. Accordingly, we plan to study this issue further to ensure ASCs can continue to offer lower cost surgical services to Medicare beneficiaries.

With respect to MedPAC's comment about collecting cost data and comments from ASCs expressing a willingness to work with CMS to share data in a way that balances administrative risk with the benefit of collecting such data, we will take these comments under advisement for future consideration, as discussed in greater detail in the comment solicitation section below. For the reasons stated above, we are finalizing our proposal to use the CPI–U update factor to update ASC rates for CY 2018. However, given the many comments supporting alternative update methodologies, such as the hospital market basket, and given our interest in site neutrality and the efficiency of care in the ASC setting, we intend to explore this issue further.

After consideration of the public comments we received, we are finalizing our proposal to apply our established methodology for determining the final CY 2018 ASC conversion factor. Using more complete CY 2016 data for this final rule with comment period than were available for the proposed rule, we calculated a wage index budget neutrality adjustment of 1.0007. Based on IGI's 2017 third quarter forecast, the CPI–U for the 12-month period ending with the midpoint of CY 2018 is now projected to be 1.7 percent, while the MFP adjustment (as discussed in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396), and revised in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301) and in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501)) is 0.5 percent, resulting in an MFP-adjusted CPI–U update factor of 1.2 percent for ASCs that meet the quality reporting requirements. The final ASC conversion factor of $45.575, for ASCs that meet the quality reporting requirements, is the product of the CY 2017 conversion factor of $45.003 multiplied by the wage index budget neutrality adjustment of 1.0007 and the MFP-adjusted CPI–U payment update of 1.2 percent. For ASCs that do not meet the quality reporting requirements, we are reducing the CPI–U update of 1.7 percent by 2.0 percentage points and then we are applying the 0.5 percentage point MFP adjustment, resulting in a −0.8 percent MFP adjusted CPI–U update factor for CY 2018. The final

[35] Available at: *https://www.gpo.gov/fdsys/pkg/FR-2017-10-17/pdf/2017-22677.pdf.*

ASC conversion factor of $44.663 for ASCs that do not meet the quality reporting requirements is the product of the CY 2017 conversion factor of $45.003 multiplied by the wage index budget neutrality adjustment of 1.0007 and the MFP-adjusted CPI–U payment update of −0.8 percent.

3. Discussion of Comment Solicitation on ASC Payment Reform

a. Historical Perspective

In 1982, Medicare implemented the ASC benefit to provide payment to ASCs to perform certain covered surgical procedures.[36] ASCs were recognized by Medicare as a less costly alternative to hospital inpatient care given differences in patient acuity and specialization of services, which promotes efficient and cost-effective delivery of care. Medicare's initial payment rates to ASCs were based on ASC historical cost and charge data from 1979 and 1980 collected from approximately 40 ASCs and used to establish four facility payment rate groups (55 FR 4527).

The ASC facility payment rate was set as a standard overhead amount based on CMS' (known then as the Health Care Financing Administration (HCFA)) estimate of a fair fee, taking into account the costs incurred by ASCs generally in providing facility services in connection with the performance of a specific procedure. The Report of the Conference Committee accompanying section 934 of the Omnibus Budget Reconciliation Act of 1980 (Pub. L. 96–499), which enacted the ASC benefit in December 1980, states, ''This overhead factor is expected to be calculated on a prospective basis . . . utilizing sample survey and similar techniques to establish reasonable estimated overhead allowances for each of the listed procedures which take account of volume (within reasonable limits)'' (H.R. Rep. No 7479, 96th Cong., 2nd Sess. 134 (1980)).

In 1987, we updated the ASC facility payment rates for the first time since 1982. The updated rates were based on the projected increase in the CPI–U from September 1982 to January 1988. CMS (then, HCFA) rebased payments to ASCs in 1990, relying on a survey of 1986 ASC cost, charge, and utilization data. The ASC payments were updated annually based on the 1986 cost data until implementation of the revised ASC payment system in 2008.

Congress directed the GAO to conduct a study comparing the relative costs of procedures furnished in ASCs to those furnished in HOPDs paid under the OPPS, including examining the accuracy of the APC codes, with respect to surgical procedures furnished in ASCs. On November 30, 2006, the GAO published the statutorily mandated report entitled, ''Medicare: Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient Payment System'' (GAO–07–86).[37] As directed by section 626(d) of Public Law 108–173, the report included recommendations on the following issues:

1. Appropriateness of using groups of covered services and relative weights established for the OPPS as the basis of payment for ASCs.

2. If the OPPS relative weights are appropriate for this purpose, whether the ASC payments should be based on a uniform percentage of the payment rates or weights under the OPPS, or should vary, or the weights should be revised based on specific procedures or types of services.

3. Whether a geographic adjustment should be used for ASC payment and, if so, the labor and nonlabor shares of such payment.

We refer readers to the CY 2008 OPPS/ASC final rule with comment period (71 FR 42474) for a detailed summary of the GAO's methodology, results, and recommendations. Notably, based on the findings from the study, the GAO recommended that CMS implement a payment system for procedures performed in ASCs based on the OPPS, taking into account the lower relative costs of procedures performed in ASCs compared to HOPDs in determining ASC payment rates.

We considered the report's methodology, findings, and recommendations implementing the current ASC payment system, effective in 2008 (71 FR 42474). Consistent with statutory requirements and the GAO's recommendations, we finalized policies to implement a revised ASC payment system based on the OPPS resource costs and relativity of service offerings.

The payment system for ASC facility services was designed as a prospective payment system to pay all procedures included in an APC a standard rate. Under a prospective payment system, payment is set to reflect the average cost to furnish a service. That is, some cases may be more costly than the average while others may be less costly. This type of payment system inherently provides incentives for each facility to be more efficient.

MedPAC conducts an annual review of the ASC payment system and submits its findings and recommendations in a report to Congress. As part of this review, MedPAC examines indicators such as beneficiaries' access to care, capacity and supply of providers, and volume of services, in part to assess the adequacy of Medicare payments to ASCs. Based on its analysis of indicators of payment adequacy, in its March 2017 Report to Congress, MedPAC found that the number of Medicare-certified ASCs had increased, beneficiaries' use of ASCs had increased, and access to capital has been adequate. As a result, for CY 2018, MedPAC stated that payments to ASCs are adequate and recommended that no payment update should be given for 2018 (that is, the update factor would be 0 percent). In addition, MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers, which would help inform decisions about the ASC update. Also, while MedPAC is concerned that the CPI–U may not reflect ASCs' cost structure, until cost information is available from ASCs, MedPAC cannot determine whether an alternative update factor would be more appropriate.[38]

b. Solicitation of Comments

In the CY 2018 OPPS/ASC proposed rule (82 FR 33668), we stated that we are broadly interested in feedback, including recommendations and ideas for ASC payment system reform. We recognize that ASCs provide a critically important access point to beneficiaries who may be too ill or have the need for too complicated a procedure to be treated in the physician office setting, but for whom hospital care is either not medically necessary or undesirable. The current ASC payment system was implemented in 2008 and major revisions have not been made since that time. Average ASC payment rates have declined relative to OPPS payments rates over the past 10 years, from 65 percent of average OPPS rates in CY 2008 to 56 percent (as proposed) of average OPPS rates in CY 2018. However, in the absence of ASC-specific cost data, it is difficult, if not impossible, to determine whether ASC facility payment rates are in line with

[36] Omnibus Reconciliation Act of 1980 (ORA), Public Law 96–499, 934(b), 94 Stat. 2599, 2637 (codified, as amended, at 42 U.S.C. 1395l(i)).

[37] Available at: *http://www.gao.gov/assets/260/253992.pdf*.

[38] MedPAC. March 2017 Report to Congress. Chapter 5 ''Ambulatory Surgical Center Services''. Available at: *http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch5.pdf?sfvrsn=0*.

ASC facility resource costs and the impact on beneficiary access to care.

With respect to the update factor that is applied to ASC payments, section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated the payment amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI–U), (U.S. city average), as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. Therefore, the statute does not mandate the adoption of any particular update mechanism, except in the absence of any update, when it requires the payment amounts to be increased by the increase in the CPI–U.

CMS adopted a policy, codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI–U (referred to as the CPI–U update factor). This update factor is adjusted by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1833(i)(2)(D)(v) of the Act. In the CY 2018 OPPS/ASC proposed rule, we solicited comments on the ASC payment system update factor and indicated that we are interested in data from ASCs that would help determine whether the ASC payment system should continue to be updated by the CPI–U, or by an alternative update factor, such as the hospital market basket, the Medicare Economic Index, and a blend of update factors or other mechanism. The hospital market basket update is typically higher than the CPI–U, while the Medicare Economic Index is typically lower. Because the rate update is not applied in a budget neutral manner, applying a higher update factor would be a cost to the Medicare program while applying a lower update factor would result in savings to the Medicare program. As mentioned above, in the absence of an alternative update, the Act requires payments to ASCs to be increased in an amount equal to the percentage increase in the CPI–U.

With respect to the ASC update, in its March 2017 Report to Congress, MedPAC stated that ASCs have a much higher share of expenses for supplies and drugs than do hospitals or physician offices, a much smaller share of employee compensation costs than hospitals, and a smaller share of all other costs (such as rent) than physician offices. In the proposed rule, we sought public comments on information related to ASC costs for items such as supplies, drugs, employee compensation, rent, and other inputs, as compared to those of hospitals or physician offices, including qualitative and quantitative data from ASCs. We stated that information on the cost structure of ASCs will help to identify an appropriate alternative update factor.

In addition, we sought public comments on whether the Secretary should collect cost data from ASCs to use in determining ASC payment rates. To the extent commenters recommend that ASC cost data should be used in the determination of ASC payment rates, we sought comments on what specific method of cost collection commenters recommend (such as cost reports or a survey). We recognize that the submission of costs may be an administrative burden to ASCs, and we stated that we were interested in comments that detail how we could mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. We noted that the ability to calculate ASC-specific costs may obviate the need for tying the ASC payment system to that of the OPPS. In addition, collecting cost data from ASCs could inform whether an alternative input price index would be an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed.

With respect to the ability to adopt payment policies that exist under the OPPS into the ASC payment system, as discussed in prior rulemaking, due to differences in the systems used to process claims for hospitals and ASCs, we were not able to implement certain OPPS payment policies in the ASC payment system, such as comprehensive APCs, conditional packaging, and the ''FD'' value modifier for device credits (79 FR 66923). ASC facilities report services on a professional claim (or CMS–1500) rather than an institutional claim (or UB–04) used by hospitals. The ASC claim form is processed in the Medicare Claims System (MCS), the same system used to process claims submitted by physicians and other clinicians, while hospital claims are processed through the Fiscal Intermediary Shared System (FISS). In part, because of differences in the claim form and the claims processing systems, it is not always possible to adopt OPPS payment policies into the ASC payment system. The resulting divergence in payment policies between the two systems may contribute to unintended disparities in payment rates for the same services. In the CY 2018 proposed rule, we stated that we were interested in stakeholder comments on whether billing on an institutional claim form rather than a professional claim form would address some of the issues affecting ASC payment reform.

As noted earlier in this section, we stated we were broadly interested in feedback from stakeholders and other interested parties on potential reforms to the current ASC payment system, including, but not limited to (1) the rate update factor applied to ASC payments, (2) whether and how ASCs should submit costs, (3) whether ASCs should bill on the institutional claim form rather than the professional claim form, and (4) other ideas to improve payment accuracy for ASCs.

Comment: Many commenters provided detailed comments and their feedback is summarized below.

- *Rate update factor:* The vast majority of commenters were in favor of applying the hospital market basket to update annual ASC payment. Commenters believed that because ASC provide the types of surgical services as hospitals that the hospital market basket is the most appropriate index. As an alternative to the hospital market basket, one commenter noted that there are other indices in the CPI and MEI that would be suitable to both the OPPS and ASC settings; for example, the CPI for medical care.
- *Collection of cost data:* One commenter stated that the same types of costs that apply to HOPDs also apply to ASCs, but they may not be weighted the same. The commenter offered to collaborate with CMS on ways to collect ASC cost information. For example, a simple, cost effective survey, perhaps voluntary, cost collection tool that calculates expense categories as a percentage of total expenses to help determine the appropriate weights and price proxies for the ASC setting. However, the commenter urged CMS to be mindful of imposing an excessive administrative burden. Commenters representing individual ASCs were generally opposed to submitting formal cost reports but expressed a willingness to complete a survey so long as it was not administratively burdensome.

MedPAC recommended that CMS begin collecting new cost data and use that information to examine whether an existing Medicare price index is an appropriate proxy for the cost of ASC facilities or an ASC-specific market basket should be developed. MedPAC suggested that, to minimize burden on ASCs and CMS, CMS could require all ASCs to submit streamlined cost reports or require a random sample of ASCs to respond to annual surveys. For example, MedPAC recommended that CMS

collect cost data for items such as drugs, medical supplies (including costly implantable devices), medical equipment, employee compensation, building expenses (such as rent), and other professional services (such as legal, accounting, and billing services).

• *Billing:* One commenter noted that the major issues affecting the payment differential between the ASC and OPPS would not be fixed by billing on an institutional claim form.

A few ASC facilities expressed support for requiring ASCs to bill on a UB–04 (institutional claim). These commenters stated they currently bill on a UB–04 for commercial payers and would benefit from a consistent claim form across all payers, especially for Medicare crossover claims. One commenter noted that billing on a UB–04 ''is not a foreign concept'' and that it warranted further exploration by CMS. A few commenters acknowledged that because not all ASCs currently bill on an UB–04, a transition period would be necessary to allow for successful implementation, though a suggested timeframe was not provided.

MedPAC also recommended that CMS transition ASCs to billing on an UB–04. MedPAC stated that because the ASC payment system is closely linked to the OPPS, to fully align OPPS payment policies with the ASC payment system, ASCs and hospitals should use the same claim form. However, MedPAC suggested that implementation of a requirement to bill on an UB–04 and to submit cost data should be staggered.

• *Payment relativity:* Several commenters recommended that CMS discontinue applying the ''secondary scaling adjustment'' and instead to apply the OPPS relative weights to ASC services. In addition, commenters also recommended that CMS restore the historical relativity between the OPPS and ASC setting. Some commenters suggested a conservative relativity adjustment of 55 percent while others suggested 65 percent (CY 2008 ratio).

Response: We will take the feedback on all of these potential ASC payment reform issues under advisement and consideration for future policymaking.

4. Display of CY 2018 ASC Payment Rates

Addenda AA and BB to this final rule with comment period (which are available on the CMS Web site) display the final updated ASC payment rates for CY 2018 for covered surgical procedures and covered ancillary services, respectively. For those covered surgical procedures and covered ancillary services where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the MPFS final rates, the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the final MPFS rates that will be effective January 1, 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 MPFS final rule with comment period.

The final payment rates included in these addenda reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the final CY 2018 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''To be Subject to Multiple Procedure Discounting'' indicates that the surgical procedure will be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2018. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the interim payment indicator for the new code. Display of the comment indicator ''NP'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the ASC payment indicator for the new code.

The values displayed in the column titled ''Final CY 2018 Payment Weight'' are the final relative payment weights for each of the listed services for CY 2018. The final relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the final CY 2018 payment rate displayed in the ''Final CY 2018 Payment Rate'' column, each ASC payment weight in the ''Final CY 2018 Payment Weight'' column was multiplied by the final CY 2018 conversion factor of $45.575. The final conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment (as discussed in section XII.G.2.b. of this final rule with comment period).

In Addendum BB, there are no relative payment weights displayed in the ''Final CY 2018 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Final CY 2018 Payment'' column displays the final CY 2018 national unadjusted ASC payment rates for all items and services. The final CY 2018 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in October 2017.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are to be excluded from payment in ASCs for CY 2018.

XIII. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. Consistent with these goals, CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The Hospital OQR Program is generally aligned with the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program).

In addition to the Hospital IQR and Hospital OQR Programs, CMS has

implemented quality reporting programs for other care settings that provide financial incentives for the reporting of quality data to CMS. These additional programs include reporting for care furnished by:

- Physicians and other eligible professionals, under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI)). We note that 2018 is the last year of the PQRS payment adjustment. Beginning in 2019, eligible clinicians may be subject to upward or downward payment adjustments under the Merit-based Incentive Payment System (MIPS) or be able to earn a positive payment incentives through participation in certain advanced alternative payment models (APMs) under the Quality Payment Program (QPP) (81 FR 77008);
- Inpatient rehabilitation facilities, under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals, under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP);
- PPS-exempt cancer hospitals, under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers, under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities, under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program;
- Home health agencies, under the Home Health Quality Reporting Program (HH QRP); and
- Hospices, under the Hospice Quality Reporting Program (HQRP).

In addition, CMS has implemented several value-based purchasing programs that link payment to performance, including the Hospital Value-Based Purchasing (VBP) Program; the Hospital-Acquired Condition (HAC) Reduction Program; and the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP); and the Quality Payment Program (QPP).

In implementing the Hospital OQR Program and other quality reporting programs, we have focused on measures that have high impact and support national priorities for improved quality and efficiency of care for Medicare beneficiaries as reflected in the National Quality Strategy (NQS) and the CMS Quality Strategy for conditions with reported wide cost and treatment variations despite established clinical treatment guidelines. To the extent possible under various authorizing statutes, our ultimate goal is to align the clinical quality measure requirements of the various quality reporting programs. As appropriate, we will consider the adoption of measures with electronic specifications to enable the collection of this information for our quality programs.

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68467 through 68469) for a discussion on the principles underlying consideration for future measures that we intend to use in implementing this and other quality reporting programs. We did not propose any changes to these policies.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program.

3. Regulatory History of the Hospital OQR Program

We refer readers to the CY 2008 through 2017 OPPS/ASC final rules with comment period (72 FR 66860 through 66875; 73 FR 68758 through 68779; 74 FR 60629 through 60656; 75 FR 72064 through 72110; 76 FR 74451 through 74492; 77 FR 68467 through 68492; 78 FR 75090 through 75120; 79 FR 66940 through 66966; 80 FR 70502 through 70526; and 81 FR 79753 through 79797). We have also codified certain requirements under the Hospital OQR Program at 42 CFR 419.46. In the CY 2018 OPPS/ASC proposed rule (82 FR 33671), we proposed editorial changes to 42 CFR 419.46, replacing the terms ''Web'' and ''Web site'' with the terms ''web'' and ''Web site,'' respectively.

We did not receive any comments on our proposal. Therefore, we are finalizing our changes to 42 CFR 419.46 as proposed, by replacing the terms ''Web'' and ''Web site'' with the terms ''web'' and ''Web site,'' respectively.

B. Hospital OQR Program Quality Measures

1. Considerations in the Selection of Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We did not propose any changes to our measure selection policy.

2. Accounting for Social Risk Factors in the Hospital OQR Program

We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [39] and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[40] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[41]

As noted in the FY 2017 IPPS/LTCH PPS final rule, the NQF has undertaken a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period can be assessed to determine whether risk adjustment for selected social risk factors is appropriate

[39] Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[40] Ibid.

[41] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. Since publication of the proposed rule, we have learned that the National Quality Forum (NQF) has concluded their initial trial on risk adjustment for quality measures.[42] Based on the findings from the initial trial, we have been informed that the NQF intends to continue its work to evaluate the impact of social risk factor adjustment on intermediate outcome and outcome measures for an additional three years. We understand that the extension of this work will allow NQF to determine further how to effectively account for social risk factors through risk adjustment and other strategies in quality measurement.

As we continue to consider the analyses and recommendations from these reports and the results of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, in the proposed rule we sought public comment on whether we should account for social risk factors in the Hospital OQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Confidential reporting to providers of measure rates stratified by social risk factors; public reporting of stratified measure rates; and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, we requested public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We requested comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the Hospital OQR Program.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we also welcome comment on operational considerations. CMS is committed to ensuring that its beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

We received extensive comments in response to our request for public comments on whether we should account for social risk factors in the Hospital OQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors.

Comment: Many commenters supported CMS' effort to address social risk factors in the Hospital OQR Program, noting that social risk factors are powerful drivers of outcomes and requested that CMS adopt risk adjustment methodologies soon. Commenters also noted that lack of risk adjustment can contribute to disparities by diverting resources away from communities in need.

One commenter specifically recommended risk adjustment in quality measurement in the psychiatric setting. Another commenter recommended that when identifying social risk factors, CMS consider the relationship with the outcome of interest, a risk factor's presence at the start of care, and whether it can be modified or manipulated through providers' actions. A third commenter noted that approaches to risk adjustment should be measure-specific.

A few commenters recommended that CMS apply risk adjustment by stratifying providers into groups by proportion of patients that are at risk, noting that this approach does not require measure-level research and recommending that risk adjustment results be shared with providers. One commenter supported methodologies including providing confidential reporting of stratified measure rates to providers and risk adjustment of measures. Several commenters expressed concern with public reporting of risk adjusted data, while others recommended that publicly reported data specifically be risk adjusted.

A few commenters noted concern that adjusting for social risk factors will not address the underlying disparities that are associated with poor health outcomes and could instead lead to masking these disparities. One commenter noted that using social risk factors may not be appropriate until it is clear how the information is collected and shared. One commenter recommended that any risk adjustment methodology adopted adhere to CMS' previously adopted standards of setting minimum case volumes and using confidence intervals. Some commenters noted that better data sources for socioeconomic status are needed, including patient-level and community-level data sources.

Response: We appreciate all the comments and interest in this topic. As we have previously stated regarding risk adjustment of publicly reported data for these factors, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities or minimize incentives to improve outcomes for disadvantaged populations. With respect to public reporting, while we agree with commenters and believe it is important to avoid a scenario in which underlying disparities are masked rather than addressed, we also agree with commenters who support the public reporting of risk-adjusted data. We appreciate the need to balance risk adjustment as a strategy to account for social risk factors with the concern that risk adjustment could minimize incentives and reduce efforts to address disparities for patients with social risk factors. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have access to excellent care.

As with previous policies, we intend to follow our previously adopted standards for setting case minimums. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68773 through 68775) where we discuss these standards. In addition, we acknowledge that administrative claims data can be limited; we will investigate the feasibility and appropriateness of

[42] NQF. NQF Initiative to Determine the Impact of Adjusting Healthcare Performance Measures for Social Risk Factors Highlights Successes, Opportunities. Available at: *https://www.qualityforum.org/News_And_Resources/Press_Releases/2017/NQF_Initiative_to_Determine_the_Impact_of_Adjusting_Healthcare_Performance_Measures_for_Social_Risk_Factors_Highlights_Successes,_Opportunities.aspx.*

additional data sources for obtaining patient and community-level data.

We reiterate that we are committed to ensuring that CMS beneficiaries have access to and receive excellent care and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs. We thank the commenters, and we will consider their views as we develop further policy regarding social risk factors in the Hospital OQR Program.

Comment: Many commenters recommended many factors to consider including: Body mass index; race; smoking status; age; sex; back pain; pain in non-operative lower extremity joint; health risk status; mental health factors; chronic narcotic use; socioeconomic status; pre-procedure ambulatory status; literacy; marital status; live-in home support; family support structure; home health resources; patient travel distance; homelessness; community distress; unavoidable readmissions; readmission risks; and poverty; as well as access to health care, transportation, and healthy food.

One commenter recommended that the following variables not be used: American Society of Anesthesiologists score; range of motion; or mode of patient-reported outcome measure collection. Several commenters supported the use of dual eligible status as a factor, while one commenter opposed it and noted concern that that it does not reflect the conditions where the hospital is located and that there are variations between States in dual eligibility status.

Response: We appreciate commenters' recommendations regarding specific social risk factor variables and will consider them as we continue exploring options for accounting for social risk factors in the Hospital OQR Program.

Comment: Several commenters recommended empirical testing to prioritize the national collection of data that are most essential for valid risk adjustment methodologies and that CMS focus on factors that have an empirically proven relationship to outcomes or processes of care metrics. Some commenters recommended that CMS consider recommendations from NQF, ASPE, the National Academy of Medicine, and the Agency for Healthcare Research and Quality (AHRQ). One commenter suggested that CMS engage providers and vendors in demonstration projects allowing collection of sociodemographic data elements in electronic health records. A few commenters recommended that testing and methodologies be made transparent. Some commenters also recommended that CMS monitor any unintended consequences that result from risk adjustment.

Response: We plan to actively perform additional research and monitor for trends to prevent unintended consequences. We intend to conduct further analyses on the impact of different approaches to accounting for social risk factors in quality programs. In addition, we will consider the commenters' suggestion that we conduct empirical testing of risk-adjusted quality metrics, and assess the potential impact of the findings from such testing on the prioritization of national data collection, in relation to risk adjustment methodologies. We look forward to continuing to work with stakeholders such as NQF, ASPE, the National Academy of Medicine, and AHRQ.

We thank commenters for their suggestion that we allow collection of sociodemographic data elements in electronic health records, but note that the Hospital OQR Program does not yet include eCQMs. Any testing and methodologies used would be made transparent through future rulemaking, which includes the public notice and comment process. Moreover, any proposals would be made in future rulemaking after further analysis, research, and continued stakeholder engagement.

Comment: Several commenters recommended that CMS align across quality payment programs when accounting for social risk factors.

Response: We thank the commenters for their feedback. We intend to investigate options for adjusting for social risk factors with continued consideration of alignment across programs.

Comment: Several commenters asked that CMS consider the impact of socioeconomic data collection on the patient as well as on provider burden. A few commenters recommended that CMS consider potential administrative complexities as CMS develops social risk factor adjustment processes.

Response: As we consider the feasibility of collecting patient-level data and the impact of strategies to account for social risk factors through further analysis, we will also continue to evaluate the reporting burden on providers and patients.

We thank all of the commenters for their input and will consider all suggestions as we continue to assess the issue of accounting for social risk factors within individual measures, the Hospital OQR Program as a whole, and across CMS quality programs.

3. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously adopted a policy to retain measures from the previous year's Hospital OQR Program measure set for subsequent years' measure sets in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471). Quality measures adopted in a previous year's rulemaking are retained in the Hospital OQR Program for use in subsequent years unless otherwise specified. We refer readers to that rule for more information. We did not propose any changes to our retention policy for previously adopted measures.

4. Removal of Quality Measures From the Hospital OQR Program Measure Set

a. Considerations in Removing Quality Measures From the Hospital OQR Program

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43863), for the Hospital IQR Program, we finalized a process for immediate retirement, which we later termed ''removal,'' of Hospital IQR Program measures based on evidence that the continued use of the measure as specified raised patient safety concerns. We adopted the same immediate measure retirement policy for the Hospital OQR Program in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635). We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our reasons for changing the term ''retirement'' to ''removal'' in the Hospital OQR Program. We did not propose any changes to our policy to immediately remove measures as a result of patient safety concerns.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized a set of criteria for determining whether to remove measures from the Hospital OQR Program. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our policy on removal of quality measures from the Hospital OQR Program. The benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis (79 FR 66941 through 66942). We note that, under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific criterion. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for our list of factors considered in removing measures from the Hospital OQR Program. We did not

propose any changes to our measure removal policy.

b. Criteria for Removal of ''Topped-Out'' Measures

We refer readers to the CY 2015 OPPS/ASC final rule with comment period where we finalized our proposal to refine the criteria for determining when a measure is ''topped-out'' (79 FR 66942). We did not propose any changes to our ''topped-out'' criteria policy.

c. Removal of Quality Measures From the Hospital OQR Program Measure Set

In the CY 2018 OPPS/ASC proposed rule (82 FR 33673), we proposed to remove a total of six measures. Specifically, beginning with the CY 2020 payment determination, we proposed to remove: (1) OP–21: Median Time to Pain Management for Long Bone Fracture; and (2) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures. In addition, beginning with the CY 2021 payment determination, we proposed to remove: (1) OP–1: Median Time to Fibrinolysis; (2) OP–4: Aspirin at Arrival; (3) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional; and (4) OP–25: Safe Surgery Checklist. By removing these six measures, our intent is to alleviate the maintenance costs and administrative burden to hospitals associated with retaining them. While we proposed to remove two measures beginning with the CY 2020 payment determination and four measures for the CY 2021 payment determination, in this final rule, we are finalizing removal of all six measures for the CY 2020 payment determination. These are discussed in detail below.

(1) Removal of OP–21: Median Time to Pain Management for Long Bone Fracture Beginning With the CY 2020 Payment Determination

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72088), where we adopted the OP–21: Median Time to Pain Management for Long Bone Fracture measure. This process of care measure assesses the median time from emergency department arrival to time of initial oral, nasal, or parenteral pain medication (opioid and non-opioid) administration for emergency department patients with a principal diagnosis of long bone fracture (LBF).

We have previously finalized a policy to note that the benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis (79 FR 66941 through 66942). Accordingly, although it does not exactly meet one of the specific measure removal criteria finalized for the Hospital OQR Program (77 FR 68472 through 68473), it has the potential to lead to negative unintended consequences (removal factor #7). Therefore, we proposed to remove OP–21: Median Time to Pain Management for Long Bone Fracture for the CY 2020 payment determination and subsequent years due to the concerns described in more detail below.

Given the growing body of evidence on the risks of opioid misuse, CMS has developed a strategy to impact the national opioid misuse epidemic by combating nonmedical use of prescription opioids, opioid use disorder, and overdose through the promotion of safe and appropriate opioid utilization, improved access to treatment for opioid use disorders, and evidence-based practices for acute and chronic pain management.[43]

Due to the potential for a misinterpretation of the intent of the measure, we are concerned that OP–21: Median Time to Pain Management for Long Bone Fracture may create undue pressure for hospital staff to prescribe more opioids. We note that the measure only assesses the time to initial, acute administration of pain medication in a specific acute clinical situation, and does not promote long-term pain medication prescriptions. In fact, this measure assesses an element of appropriate pain management, specifically the time to pain medication administration in the case of long bone fracture. In addition, the measure assesses the use of both opioid and nonopioid pain medications. While we acknowledge that pain control is an important issue for patients and clinical care, and the measure does not call for increased opioid prescriptions, many factors outside the control of CMS quality program requirements may contribute to the perception of a link between the measure and opioid prescribing practices. Although we are not aware of any scientific studies that support an association between this measure and opioid prescribing practices, out of an abundance of caution, we proposed to remove the measure in order to remove any potential ambiguity and to avoid misinterpretation of the intent of the measure. We also note that, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79856), we removed the Pain Management dimension of the HCAHPS Survey in the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain beginning with the FY 2018 program year for the Hospital VBP Program for similar reasons. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38342), we finalized refinements to the former pain management questions in the HCAHPS Survey measure for the Hospital IQR Program.

We invited public comment on our proposal to remove the OP–21: Median Time to Pain Management for Long Bone Fracture measure for the CY 2020 payment determination and subsequent years as discussed above.

Comment: Many commenters supported the removal of OP–21 for the CY 2020 payment determination noting concern about the potential incentive to over prescribe opioids. One commenter applauded CMS' efforts to combat the opioid epidemic. A few commenters noted that the measure could be more appropriate or valuable if it were refined, for example to include oral pain medication or to ensure that it does not incentivize prescribing opioids. One commenter recommended that CMS remove the measure for the CY 2019 payment determination.

Response: We disagree that it would be more appropriate to refine this measure. We do not believe that introducing a modified version of the measure would address our main concern regarding potential for misinterpretation of the intent of the measure because whether pain management is initiated, our main concern for misinterpretation, is what this measure is meant to assess. As stated in our proposal, many factors outside the control of CMS quality program requirements may contribute to the perception of a link between the measure and opioid prescribing practices. Although we are not aware of any scientific studies that support an association between this measure and opioid prescribing practices, out of an abundance of caution, we proposed to remove the measure in order to remove any potential ambiguity and to avoid misinterpretation of the intent of the measure. We note that due to operational limitations, we cannot remove the measure for the CY 2019 payment determination. The CY 2020 payment determination (CY 2018 data collection) is the earliest we can remove this measure from the program.

Comment: One commenter did not support the proposal to remove OP–21 and noted that there is a lack of evidence that the measure incentivizes overprescribing of opioids.

[43] CMS Opioid Misuse Strategy 2016. Available at: *https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Prescription-Drug-Information-for-Partners-Items/CMS-Opioid-Misuse-Strategy-2016.html.*

Response: We acknowledge the commenter's concerns. As stated in our proposal, although we are not aware of any scientific studies that support an association between this measure and opioid prescribing practices, out of an abundance of caution, however, we believe it is important to remove the measure in order to remove any potential ambiguity and to avoid any misinterpretation of the intent of the measure. We want to ensure that the Hospital OQR Program measure set does not create any potential undue pressure for hospital staff to overprescribe opioids.

After consideration of the public comments we received, we are finalizing the proposal to remove OP–21: Median Time to Pain Management for Long Bone Fracture for the CY 2020 payment determination and subsequent years, as proposed.

(2) Removal of OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures Beginning With the CY 2020 Payment Determination

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74468), where we adopted OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures beginning with the CY 2014 payment determination. This measure, which is submitted via a web-based tool, collects surgical procedure volume data on eight categories of procedures frequently performed in the outpatient hospital setting.

We believe there is a lack of evidence to support this measure's link to improved clinical quality. The measure requires hospitals to report on the volumes of surgical procedures performed at the facility.[44] This information, number of surgical procedures, does not offer insight into the facilities' overall performance or quality improvement in regard to surgical procedures. Accordingly, this measure meets the following measure removal criterion: performance or improvement on a measure does not result in better patient outcomes (79 FR 66941). We believe the burden of this measure, which is submitted via a web-based tool, outweighs the value, and, therefore, we proposed to remove OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures for the CY 2020 payment determination and subsequent years. We also refer readers to section XIV.B.3.b.(3) of this final rule with comment period, where the ASCQR Program is finalizing the removal of a similar measure.

We invited public comment on our proposal to removal the OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures measure for the CY 2020 payment determination and subsequent years as discussed above.

Comment: Many commenters supported the removal of OP–26 for the CY 2020 payment determination. One commenter recommended that CMS remove the measure for the CY 2019 payment determination.

Response: We thank the commenters for their support and feedback. We note that due to operational limitations, we cannot remove the measure for the CY 2019 payment determination. The CY 2020 payment determination (CY 2018 data collection) is the earliest we can remove this measure from the program.

After consideration of the public comments we received, we are finalizing our proposal to remove OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures for the CY 2020 payment determination and subsequent years, as proposed.

(3) Removal of OP–1: Median Time to Fibrinolysis Beginning With the CY 2020 Payment Determination

We refer readers to the CY 2008 OPPS/ASC final rule with comment period (referred to as ''ED–AMI–2—Median Time to Fibrinolysis'' in 72 FR 66862 through 66865) where we adopted OP–1: Median Time to Fibrinolysis beginning with services furnished in CY 2009. This chart-abstracted measure assesses the median time from ED arrival to administration of fibrinolytic therapy in ED patients with ST-segment elevation on the ECG performed closest to ED arrival and prior to transfer.

We believe that this measure meets the following measure removal criterion—the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic (79 FR 66941). We note that the currently adopted OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (72 FR 66862 through 66865) has been designed with a threshold that is based on a clinical standard, allows us to measure this topic area, and provides meaningful and clinically relevant data on the receipt of fibrinolytic therapy. National guidelines recommend that fibrinolytic therapy be given within 30 minutes of hospital arrival in patients with ST-segment elevation myocardial infarction.[45] Because OP–1: Median Time to Fibrinolysis measures only the median time from door to needle and does not note whether or not that value exceeds the clinical best practice of 30 minutes, we do not believe that reporting of OP–1 improves quality of care or patient outcomes. In addition, we believe that retaining OP–1: Median Time to Fibrinolysis would be redundant with OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival. As a result, we proposed to remove OP–1: Median Time to Fibrinolysis for the CY 2021 payment determination and subsequent years. We note that although OP–1: Median Time to Fibrinolysis is a chart-abstracted measure, we do not expect removing this measure would reduce burden, as the data collected for this measure is required to calculate another program measure in the AMI measure set (OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and will, therefore, continue to be collected even if the proposal to remove OP–1: Median Time to Fibrinolysis is finalized as proposed.

We invited public comment on our proposal to remove OP–1: Median Time to Fibrinolysis for the CY 2021 payment determination and subsequent years as discussed above.

Comment: Several commenters supported the proposal to remove OP–1: Median Time to Fibrinolysis for the CY 2021 payment determination. Some commenters supported the proposal to remove the measure, but recommended that it be removed as soon as possible. Many commenters supported the proposal to remove the measure, but recommended that it be removed beginning with the CY 2020 payment determination, one year earlier than proposed.

Response: We thank the commenters for their support and feedback. While planning for the proposed rule, we did not believe we had the logistical capacity to support successful removal of all six measures at once from our systems. Upon further consideration however, we have determined it is, in fact, operationally feasible to remove OP–1 beginning with the CY 2020 payment determination rather than the

[44] OP–26 Measure Information Form. Available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228775748170.*

[45] Antman EM, Hand M, Armstrong PW, Bates ER, Green LA, Halasyamani LK, et al. 2007 focused update of the ACC/AHA 2004 Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Group to Review New Evidence and Update the ACC/AHA 2004 Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction). Journal of the American College of Cardiology. 2008; 51:210–47.

CY 2021 payment determination as proposed. We believe that removing this measure one year earlier than proposed will reduce hourly and financial burden on hospital. Therefore, we agree that we should remove the measure as soon as possible.

After consideration of the public comments we received, we are finalizing our proposal to remove OP–1: Median Time to Fibrinolysis with modification. Instead of beginning with the CY 2021 payment determination as proposed, we are finalizing the removal of this measure for the CY 2020 payment determination and subsequent years, one year earlier than proposed.

(4) Removal of OP–4: Aspirin at Arrival Beginning With the CY 2020 Payment Determination

We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66862 through 66865) where we adopted OP–4: Aspirin at Arrival beginning with services furnished in CY 2009. This chart-abstracted measure assesses the rate of patients with chest pain or possible heart attack who received aspirin within 24 hours of arrival or before transferring from the emergency department.

We previously finalized two criteria for determining when a measure is ''topped out'' under the Hospital OQR Program: (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (COV) is less than or equal to 0.10 (79 FR 66942). Based on our analysis of Hospital OQR Program measure data, we have determined that performance on this measure is so high and unvarying that meaningful distinctions in improvement cannot be made; specifically, our analyses show that there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance for this measure. These analyses are captured in the table below.

OP–4—ASPIRIN AT ARRIVAL TOPPED OUT ANALYSIS

Encounters	Number of hospitals	75th percentile	90th percentile	Truncated COV
CY 2014	1,706	100.00	100.00	0.030
CY 2015	1,749	100.00	100.00	0.035
CY 2016	1,803	100.00	100.00	0.042

As displayed in the table above, there is no distinguishable difference in hospital performance between the 75th and 90th percentiles under the OP–4: Aspirin at Arrival measure, and the truncated coefficient of variation has been below 0.10 since 2014. Therefore, this measure meets both ''topped out'' measure criteria for the ASCQR Program.

Thus, we believe the burden of reporting this chart-abstracted measure is not justified by the value of retaining it in the program and we proposed to remove OP–4: Aspirin at Arrival from the program for the CY 2021 payment determination and subsequent years.

We invited public comment on our proposal to remove the OP–4: Aspirin at Arrival measure for the CY 2021 payment determination and subsequent years as discussed above.

Comment: Several commenters supported the removal of OP–4: Aspirin at Arrival for the CY 2021 payment determination. Some commenters supported the proposal to remove the measure, but recommended that it be removed as soon as possible. Many commenters supported the proposal to remove the measure, but recommended that it be removed beginning with the CY 2020 payment determination, one year earlier than proposed.

Response: We thank the commenters for their support. While planning for the proposed rule, we did not believe we had the logistical capacity to support successful removal of all six measures at once from our systems. Upon further consideration, we have determined it is, in fact, operationally feasible to remove OP–4 beginning with the CY 2020 payment determination rather than the CY 2021 payment determination as proposed. We believe that removing this measure one year earlier than proposed will reduce hourly and financial burden on hospitals. Therefore, we agree that we should remove the measure as soon as possible.

After consideration of the public comments we received, we are finalizing our proposal to remove OP–4: Aspirin at Arrival measure with modification. Instead of beginning with the CY 2021 payment determination as proposed, we are finalizing the removal of this measure for the CY 2020 payment determination and subsequent years, one year earlier than proposed.

(5) Removal of OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional Beginning With the CY 2020 Payment Determination

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72087 through 72088) where we adopted OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional for the CY 2013 payment determination. This chart-abstracted measure assesses the time from ED arrival to provider contact for Emergency Department patients.

During regular measure maintenance, specific concerns about OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional were raised by a Technical Expert Panel (TEP), comprised of experts representing a variety of stakeholders and was convened by a CMS contractor. These concerns include: (1) Limited evidence linking the measure to improved patient outcomes; (2) validity concerns related to wait times and the accuracy of door-to-door time stamps; and (3) potential for skewed measure performance due to disease severity and institution-specific confounders. After our own analysis, we agree with the TEP's analysis and believe that this measure meets the following measure removal criterion: Performance or improvement on a measure does not result in better patient outcomes. As a result, we believe the burden of continuing to include this chart-abstracted measure in the program outweighs the benefits; and thus, we proposed to remove OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional for the CY 2021 payment determination and subsequent years.

We invited public comment on our proposal to remove OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional for the CY 2021 payment determination and subsequent years as discussed above.

Comment: Several commenters supported the proposal to remove OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional for the CY 2021 payment determination. Some commenters supported the proposal to remove the measure, but recommended that it be removed as soon as possible.

Many commenters supported the proposal to remove the measure, but recommended that it be removed beginning with the CY 2020 payment determination, one year earlier than proposed.

Response: We thank the commenters for their support. While planning for the proposed rule, we did not believe we had the logistical capacity to support successful removal of all six measures at once from our systems. Upon further consideration, we have determined it is, in fact, operationally feasible to remove OP–20 beginning with the CY 2020 payment determination rather than the CY 2021 payment determination as proposed. We believe that removing this measure one year earlier than proposed will reduce hourly and financial burden on hospitals. Therefore, we agree that we should remove the measure as soon as possible.

Comment: A few commenters expressed concern that there are socioeconomic pressures that can vary by community that cause variation in performance on this measure. However, these commenters also noted the value of the measure and recommended that CMS consider a refined version of OP–20 that stratifies by hospital size and other factors related to measure performance.

Response: We acknowledge the suggestion that OP–20 be refined to account for community factors that influence performance. While the TEP found a potential for skewed measure performance due to disease severity and institution-specific confounders, we do not believe modifying the measure to account for social risk factors will address our primary concern that the measure is not adequately tied to better patient outcomes. We thank the commenters for their recommendation, however; we will take these comments into consideration as we continue to review and refine the Hospital OQR Program measure set. In addition, we acknowledge the suggestion that OP–20 be refined to account for community factors that influence performance and note that the TEP found a potential for skewed measure performance due to disease severity and institution-specific confounders. However, modifying the measure to account for social risk factors in this or future rulemaking will not address our primary concern that the measure is not adequately tied to patient outcomes.

After consideration of the public comments we received, we are finalizing our proposal to remove OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional with modification. Instead of beginning with the CY 2021 payment determination as proposed, we are finalizing the removal of this measure for the CY 2020 payment determination and subsequent years, one year earlier than proposed.

(6) Removal of OP–25: Safe Surgery Checklist Use Beginning With the CY 2020 Payment Determination

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74464 through 74466), where we adopted OP–25: Safe Surgery Checklist Use beginning with the CY 2014 payment determination. This structural measure of hospital process assesses whether a hospital employed a safe surgery checklist that covered each of the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data collection period. Based on our review of reported data under the measure, this measure meets our first criterion for measure removal that measure performance is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.

The Hospital OQR Program previously finalized two criteria for determining when a measure is ''topped out'': (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation is less than or equal to 0.10 (79 FR 66942). Our estimations indicate that performance on this measure is trending towards topped out status. This analysis is captured in the table below.

OP–25—SAFE SURGERY CHECKLIST USE PERFORMANCE ANALYSIS

Encounters	Number of hospitals	Rate	75th percentile	90th percentile	Truncated COV
CY 2012	3,227	0.910	100.000	100.000	0.314
CY 2013	3,184	0.949	100.000	100.000	0.232
CY 2014	3,177	0.963	100.000	100.000	0.196
CY 2015	3,166	0.970	100.000	100.000	0.176

Based on the analysis above, the national rate of ''Yes'' response for the OP–25 measure is nearly 1.0, or 100 percent, nationwide, and has remained at this level for the last two years. In addition, the truncated coefficient of variation has decreased such that it is trending towards 0.10 and there is no distinguishable difference in hospital performance between the 75th and 90th percentiles. We have previously stated the benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis (79 FR 66941 through 66942). We believe that removal of this measure from the Hospital OQR Program measure set is appropriate, as there is little room for improvement. We believe that safe surgical checklist is widely used and that hospitals will continue its use. In addition, removal of this measure would alleviate the administrative burden to hospitals associated with reporting on this measure. As such, we believe the reporting burden of this measure outweigh the benefits of keeping the measure in the Hospital OQR Program.

Therefore, we proposed to remove OP–25: Safe Surgery Checklist Use for the CY 2021 payment determination and subsequent years. We refer readers to section XIV.B.3.b.(2) of this final rule with comment period, where the ASCQR Program is finalizing a proposal to remove a similar measure.

We invited public comment on our proposal to remove the OP–25: Safe Surgery Checklist Use measure for the CY 2021 payment determination and subsequent years as discussed above.

Comment: Several commenters supported the proposal to remove OP–25 for the CY 2021 payment determination. Some commenters supported the proposal to remove the measure, but recommended removal as soon as possible. Many commenters supported the proposal to remove the measure, but recommended that it be removed beginning with the CY 2020 payment determination, one year earlier than proposed.

Response: We thank the commenters for their support. While planning for the proposed rule, we did not believe we had the logistical capacity to support

successful removal of all six measures at once from our systems. Upon further consideration, we have determined it is, in fact, operationally feasible to remove OP–25 beginning with the CY 2020 payment determination rather than the CY 2021 payment determination as proposed. We believe that removing this measure one year earlier than proposed will reduce hourly and financial burden on hospitals. Therefore, we agree that we should remove the measure as soon as possible.

Comment: A few commenters opposed the proposal to remove OP–25: Safe Surgery Checklist Use, noting that the measure adds value. One commenter recommended that CMS retain the measure until there is further evidence that the use of a safe surgery checklist is supporting effective perioperative communication.

Response: As stated in our proposal, we believe that there is little room for improvement as shown by the data in our table above. In addition, removal of this measure would alleviate the maintenance costs and administrative burden to hospitals of data collection and reporting. While retaining the measure may add some nominal value, we believe that the burdens outweigh the benefits. In addition, in response to the suggestion that we retain the measure until there is further evidence that the use of a safe surgery checklist is supporting effective perioperative communication, we would like to make clear that high performance on OP–25: Safe Surgery Checklist Use is not intended to indicate whether perioperative communication among team members is effective; this measure is not specified to assess the effectiveness of a team's communication, only whether a safe surgery checklist is used. Therefore, we do not believe continuing to collect—or, conversely, ceasing to collect—data under this measure will assess or affect the effectiveness of perioperative communication within Hospital Outpatient Departments.

After consideration of the public comments we received, we are finalizing our proposal to remove OP–25: Safe Surgery Checklist Use with modification. Instead of beginning with the CY 2021 payment determination as proposed, we are finalizing the removal of this measure for the CY 2020 payment determination and subsequent years, one year earlier than proposed.

5. Delay of OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With the CY 2020 Payment Determination

We refer readers to the CY 2017 OPPS/ASC final rule with comment period where we adopted OP–37a–e (81 FR 79771 through 79784), and finalized data collection and data submission timelines (81 FR 79792 through 79794). These measures assess patients' experience with care following a procedure or surgery in a hospital outpatient department by rating patient experience as a means for empowering patients and improving the quality of their care.

In CY 2018 OPPS/ASC proposed rule (82 FR 33675), we proposed to delay implementation of the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures OP–37a–e beginning with the CY 2020 payment determination (2018 data collection) and subsequent years. Since our adoption of these measures, we have come to believe that we need to collect more operational and implementation data. Specifically, we want to ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; reaffirm the reliability of national implementation of OAS CAHPS Survey data; and appropriately account for the burden associated with administering the survey in the outpatient setting of care. We note that commenters expressed concern over the burden associated with the survey in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79777). We believe that the voluntary national implementation of the survey, which began in January 2016, would provide valuable information moving forward.[46] We plan to conduct analyses of the national implementation data to undertake any necessary modifications to the survey tool and/or CMS systems. We believe it is important to allow time for any modifications before requiring the survey under the Hospital OQR Program. However, we continue to believe that these measures address an area of care that is not adequately addressed in our current measure set and will be useful to assess aspects of care where the patient is the best or only source of information. Further, we continue to believe these measures will enable objective and meaningful comparisons between hospital outpatient departments. Therefore, we proposed to delay implementation of OP–37a–e beginning with the CY 2020 payment determination (2018 data collection) until further action in future rulemaking. We also refer readers to section XIV.B.4. of this final rule with comment period where we are finalizing a similar proposal in the ASCQR Program.

We invited public comment on our proposal to delay the OAS CAHPS Survey measures beginning with the CY 2020 payment determination (2018 data collection) as discussed above.

Comment: Many commenters supported the proposal to delay implementation of the OAS CAHPS Survey, noting agreement that an analysis of the national implementation will provide valuable information. One commenter noted that the high volume of facilities and hospitals participating in the voluntary national implementation indicates that the data collection burden of the survey is low.

Response: We thank the commenters for their support, and note our belief that an analysis of the national implementation of OAS CAHPS Survey will provide valuable information.

Comment: Citing the importance of patient experience data, a few commenters recommended that CMS move toward mandatory data collection in the future as some hospitals have already invested resources to begin data collection. One commenter recommended a dry run for the first quarter of mandatory implementation. A few commenters recommended that the survey be voluntary for all future years of the program. Another commenter recommended that the survey be introduced with advance notice so hospitals can prepare.

Response: We thank the commenters for their recommendations, and will take these comments under consideration as we craft future policy for the OAS CAHPS Survey. First, we acknowledge the work completed thus far by hospitals beginning to prepare for OAS CAHPS Survey data collection and thank them for their commitment to improving patient experience. We note that changes to this measure would be made in notice and comment rulemaking so that stakeholders can prepare. Finally, while we do not anticipate conducting a dry run for this survey at this time, we refer readers to the voluntary national implementation of the OAS CAHPS Survey.[47]

[46] About the National Implementation and Public Reporting. Available at: *https://oascahps.org/General-Information/National-Implementation*.

[47] Ibid.

Comment: Several commenters noted specific concerns about the OAS CAHPS Survey, including that the survey is unnecessarily long, that not all of the questions are relevant, and that requiring a standardized survey prevents hospitals from targeting specific areas for improvement. Some commenters noted that the use of a third-party vendor is too costly. Several commenters recommended that vendors should provide electronic or email options for conducting the OAS CAHPS Survey in order to increase response rates. Others recommended that CMS administer the survey on its Web site. One commenter noted concern that timely results are not provided. A few commenters expressed concern about the use of CPT codes to determine eligibility for the survey and one noted that the CPT codes include procedures that a patient may not perceive as a surgery.

Response: While Web-based surveys are not available survey modes at present, we are actively investigating these modes as possible options for the future. We are exploring whether hospitals and ASCs receive reliable email addresses from patients and whether there is adequate access to the internet across all types of patients. Ultimately, the purpose of the investigation is to ensure that any future survey administration method does not introduce bias in the survey process and reduces length and burden if at all possible. Although we are investigating other modes of survey administration, we do not expect that CMS will directly administer the survey; the survey would still be administered through vendors. Finally, we acknowledge the concern about the use of CPT codes, including those for procedures that patients may not perceive as surgery, and note that we will consider this issue. We note that many CPT codes have been excluded from inclusion in the OAS CAHPS Survey, including services like application of a cast or splint, in order to ensure that only patients receiving applicable procedures are surveyed.[48] We thank the commenters and will take all comments under consideration as we craft future policy for the OAS CAHPS Survey.

Comment: Several commenters recommended that the survey be NQF-endorsed prior to implementation and that the survey should be refined with input from stakeholders.

Response: Section 1833(t)(17)(C)(i) of the Act does not require that each measure we adopt for the Hospital OQR Program be endorsed by a national consensus building entity, or the NQF specifically. While we strive to adopt NQF-endorsed measures when feasible and practicable, we believe the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, stakeholder input via a Technical Expert Panel (TEP), review by the MAP, broad acceptance and use of the measure, and public comments. As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79772), the OAS CAHPS Survey measures were included on the CY 2014 MUC list,[49] and reviewed by the MAP.[50] The MAP encouraged continued development of these survey-based measures; however, we note that these measures had not been fully specified by the time of submission to the MUC List.[51] The MAP stated that these are high impact measures that will improve both quality and efficiency of care and be meaningful to consumers.[52] Further, the MAP stated that given that these measures are also under consideration for the ASCQR Program, they help to promote alignment across care settings.[53] It also stated that these measures would begin to fill a gap MAP has previously identified for this program including patient reported outcomes and patient and family engagement.[54] Several MAP workgroup members noted that CMS should consider how these measures are related to other existing ambulatory surveys to ensure that patients and facilities are not overburdened. In addition, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79775), where we received public comments on this measure during development.

Comment: One commenter requested that survey development and testing data be made public.

Response: We refer commenters to the voluntary national implementation of the OAS CAHPS Survey for more information on results to date (*https://oascahps.org/General-Information/National-Implementation*).

After consideration of the public comments we received, we are finalizing the proposal to delay implementation of the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based Measures (OP–37a–e) beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking, as proposed. We refer readers to section XIV.B.4. of this final rule with comment where we are also finalizing delay of the OAS CAHPS Survey-based measures in the ASCQR Program.

6. Previously Adopted Hospital OQR Program Measure Set for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79784) for the previously finalized measure set for the Hospital OQR Program CY 2020 payment determination and subsequent years. These measures also are listed below.

PREVIOUSLY FINALIZED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
0287	OP–1: Median Time to Fibrinolysis.†
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP–4: Aspirin at Arrival.†
0289	OP–5: Median Time to ECG.†

[48] *OASCAHPS.org.* Additional Procedural Codes for Exclusion from the OAS CAHPS Survey. Available at: *https://oascahps.org/General-Information/Announcements/EntryId/80/Additional-Procedural-Codes-for-Exclusion-from-the-OAS-CAHPS-Survey.*

[49] National Quality Forum. List of Measures under Consideration for December 1, 2014. National Quality Forum, Dec. 2014. Available at: *https://www.qualityforum.org/Setting_Priorities/Partnership/Measures_Under_Consideration_List_2014.aspx.*

[50] National Quality Forum. MAP 2015 Final Recommendations to HHS and CMS. Rep. National Quality Forum, Jan. 2015. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711.*

[51] Ibid.

[52] Ibid.

[53] Ibid.

[54] Ibid.

PREVIOUSLY FINALIZED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF No.	Measure name
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
None	OP–9: Mammography Follow-up Rates.
None	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
None	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery.
None	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
0491	OP–17: Tracking Clinical Results between Visits.†
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
None	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
0499	OP–22: Left Without Being Seen.†
0661	OP–23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival.
None	OP–25: Safe Surgery Checklist Use.
None	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.**
0659	OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.**
1536	OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.***
2539	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
1822	OP–33: External Beam Radiotherapy for Bone Metastases.
None	OP–35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.
2687	OP–36: Hospital Visits after Hospital Outpatient Surgery.
None	OP–37a: OAS CAHPS—About Facilities and Staff.****
None	OP–37b: OAS CAHPS—Communication About Procedure.****
None	OP–37c: OAS CAHPS—Preparation for Discharge and Recovery.****
None	OP–37d: OAS CAHPS—Overall Rating of Facility.****
None	OP–37e: OAS CAHPS—Recommendation of Facility.****

† We note that NQF endorsement for this measure was removed.

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244*.

** We note that measure name was revised to reflect NQF title.

*** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

**** Measure reporting delayed beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of this final rule with comment period.

7. Newly Finalized Hospital OQR Program Measure Set for the CY 2020 Payment Determination and Subsequent Years

In the CY 2018 OPPS/ASC proposed rule (82 FR 33676), we did not propose any new measures for the Hospital OQR Program. However, beginning with the CY 2020 payment determination, in section XIII.B.4.c. of this final rule with comment period, we are finalizing proposals to remove six measures, and in section XIII.B.5. of this final rule with comment period, we are finalizing a proposal to delay OP–37a–e beginning with the CY 2020 payment determination (2018 data collection). The table below outlines the Hospital OQR Program measure set we are finalizing in this final rule with comment period for the CY 2020 payment determination and subsequent years.

NEWLY FINALIZED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure name
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0289	OP–5: Median Time to ECG.†
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
None	OP–9: Mammography Follow-up Rates.
None	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
None	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery.
None	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
0491	OP–17: Tracking Clinical Results between Visits.†
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
0499	OP–22: Left Without Being Seen.†

NEWLY FINALIZED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF No.	Measure name
0661	OP–23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival.
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.*
0659	OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.*
1536	OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**
2539	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
1822	OP–33: External Beam Radiotherapy for Bone Metastases.
None	OP–35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.
2687	OP–36: Hospital Visits after Hospital Outpatient Surgery.
None	OP–37a: OAS CAHPS—About Facilities and Staff.***
None	OP–37b: OAS CAHPS—Communication About Procedure.***
None	OP–37c: OAS CAHPS—Preparation for Discharge and Recovery.***
None	OP–37d: OAS CAHPS—Overall Rating of Facility.***
None	OP–37e: OAS CAHPS—Recommendation of Facility.***

† We note that NQF endorsement for this measure was removed.

○ OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244*.

* We note that measure name was revised to reflect NQF title.

** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

*** Measure reporting delayed beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of this final rule with comment period.

8. Hospital OQR Program Measures and Topics for Future Consideration

In the CY 2018 OPPS/ASC proposed rule (82 FR 33678), we requested public comment on: (1) Future measure topics; and (2) future development of OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival as an electronic clinical quality measure (eCQM). These are discussed in detail below.

a. Future Measure Topics

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the hospital outpatient setting. The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED throughput efficiency, Health Information Technology (health IT) use, care coordination, and patient safety. Measures are of various types, including those of process, structure, outcome, and efficiency. Through future rulemaking, we intend to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in hospital outpatient settings, while aligning quality measures across the Medicare program.

We are moving towards the use of outcome measures and away from the use of clinical process measures across our Medicare quality reporting and value-based purchasing programs. We invited public comments on possible measure topics for future consideration in the Hospital OQR Program. We specifically requested comment on any outcome measures that would be useful to add to the Hospital OQR Program as well as any clinical process measures that should be eliminated from the Hospital OQR Program.

Comment: A few commenters recommended that we adopt the eCQM version of OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.

Response: We thank the commenters for their feedback. We will consider these suggestions as we consider including and developing eCQMs for future rulemaking.

Comment: Several commenters suggested measure topics for future consideration, including measures that address Total Knee Arthroplasty (TKA) and Total Hip Arthroplasty (THA) procedures and measures that address recommended vaccines for adults, including pneumococcal immunization measures. A few commenters noted support for outcome measures, and recommended that CMS engage with stakeholders in identifying priority measurement areas. One commenter specifically recommended patient reported outcomes and patient reported experience measures. A commenter recommended the inclusion of pain experience and management measures. One commenter recommended the following topic areas for quality measures: Patient safety outcomes, readmission rates, risk-adjusted mortality, effective patient transitions, diabetes, obesity, guidelines for overused procedures, end of life care according to preferences, cost per episode, behavioral health and patient experience.

Response: We thank the commenters for their recommendations and suggestions and agree that there are additional high priority topic measurement areas that may be appropriate for the Hospital OQR Program. We will consider the suggested topic areas for future rulemaking and intend to work with stakeholders as we continue to develop the Hospital OQR Program measure set.

b. Possible Future Adoption of the Electronic Version of OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival

We have previously stated that automated electronic extraction and reporting of clinical quality data, including measure results calculated automatically by appropriately certified health IT, could significantly reduce the administrative burden on hospitals under the Hospital OQR Program (81 FR 79785). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79786), some commenters supported CMS' goal to incorporate electronic clinical quality measures (eCQMs) in the Hospital OQR Program.

OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival was finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66865), where

it was designated as ED–AMI–3. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68761), the measure was re-labeled as OP–2 for the CY 2010 payment determination and subsequent years. OP–2 measures the number of AMI patients receiving fibrinolytic therapy during the ED visit with a time from hospital arrival to fibrinolysis of 30 minutes or less.

We are considering developing OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival [55] as an eCQM and proposing the eCQM in future rulemaking. We note that since OP–2 is not yet developed as an eCQM; electronic measure specifications are not available at this time. We are considering OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival in particular because we believe this measure is the most feasible out of all the existing Hospital OQR Program measures for development as an eCQM.

We invited public comment on the possible future development and future adoption of an eCQM version of OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival.

Comment: A few commenters supported the adoption of an eCQM version of OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival. Several commenters noted their support for the adoption of eCQMs, but expressed concern about the future adoption of an eCQM version OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival in the Hospital OQR Program noting that other measures, such as OP–18, are already specified as an eCQM and that other measures may be more relevant to the Hospital OQR Program since fibrinolytic therapy is not always appropriate with the increasing availability of cardiac catheterization labs.

Response: We will consider OP–18 for future rulemaking. In addition, while we acknowledge that OP–2 may not be relevant to all hospitals due to the increased availability of cardiac catheterization labs, we believe this measure would be important for smaller hospitals that continue to rely on fibrinolytic therapy. We thank the commenters for their feedback and will consider these concerns and suggestions before we decide whether to develop an eCQM version of OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival or propose the eCQM in future rulemaking.

Comment: Other commenters opposed the adoption of eCQMs in the Hospital OQR Program and expressed concern that eCQMs add, rather than reduce, administrative burden. Some commenters recommended that CMS delay implementation of eCQMs in the Hospital OQR Program until the vendor and CMS systems issues noted in Hospital IQR Program rulemaking are addressed and until the Hospital IQR Program demonstrates accurate and feasible submission of electronic data.

Response: In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355), commenters raised concerns about EHR system upgrades, the difficulty of transitioning to a new EHR vendor, and updating to new editions of certified health IT. We appreciate commenters sharing their concerns about the challenges associated with eCQM reporting, including the significant expenditure of resources required to make necessary changes to health IT systems, documentation or utilization of EHRs, and workflow process changes and acknowledge commenters' feedback that many hospitals may not be ready to report eCQMs. We will take lessons learned from eCQM submission in the Hospital IQR Program into consideration as we develop policy for the Hospital OQR Program. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57177) regarding the Hospital IQR Program, however, we acknowledge that there are initial costs, but believe that long-term benefits associated with electronic data capture outweigh those costs. In addition, as we stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49696) regarding the Hospital IQR Program, we believe that it is appropriate to consider reporting of eCQMs given that measures available now and those being developed for the future are increasingly based on electronic standards. We thank the commenters for their feedback and acknowledge the concerns raised. We will consider these concerns and suggestions as we further consider developing OP–2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival as an eCQM or proposing the eCQM in future rulemaking.

9. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we modify the Hospital OQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244*.

For a history of our policies regarding maintenance of technical specifications for quality measures, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60631), the CY 2011 OPPS/ASC final rule with comment period (75 FR 72069), and the CY 2013 OPPS/ASC final rule with comment period (77 FR 68469 through 68470). We did not propose any changes to our technical specifications policies.

10. Public Display of Quality Measures

a. Background

We refer readers to the CY 2014 and CY 2017 OPPS/ASC final rules with comment period (78 FR 75092 and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33679), we proposed to update public reporting for the OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients measure.

b. Public Reporting of OP–18c: Median Time From Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients

OP–18 Median Time from ED Arrival to ED Departure for Discharged ED Patients was finalized for reporting for the CY 2013 payment determination and subsequent years in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72086). This measure addresses ED efficiency in the form of the median time from ED arrival to time of departure from the ED for patients discharged from the ED (also known as ED throughput). Reducing the time patients spend in the ED can improve the quality of care. As discussed in the measure specifications and Measure Information Form (MIF),[56] [57] OP–18 measure data is stratified into four separate calculations: (1) OP–18a is defined as the overall rate; (2) OP–18b is defined as the reporting measure; (3) OP–18c is defined as assessing

[55] eCQI Resource Center: *https://ecqi.healthit.gov/eh/ecqms-2016-reporting-period/fibrinolytic-therapy-received-within-30-minutes-hospital-arrival*.

[56] A Measure Information Form provides detail on the rationale for a measure as well as the relevant numerator statements, denominator statements and measure calculations.

[57] Hospital OQR Program ED Throughput Measures Information Form. Available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228775748170*.

Psychiatric/Mental Health Patients; and (4) OP–18d is defined as assessing Transfer Patients.

Section 1833(t)(17)(E) of the Act, requires that the Secretary establish procedures to make data collected under the Hospital OQR Program available to the public and that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public, with respect to the hospital prior to such data being made public. Currently, and as detailed in the OP–18 MIF, the OP–18 measure publicly reports data only for the calculations designated as OP–18b: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Reporting Measure, which excludes psychiatric/mental health patients and transfer patients.[58]

The ICD–10 diagnostic codes for OP–18c include numerous substance abuse codes for inclusion in this subset, along with numerous nonsubstance abuse codes. We believe it is important to publicly report data for OP–18c (Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients) to address a behavioral health gap in the publicly reported Hospital OQR Program measure set. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33679), we proposed to also publicly report OP–18c and begin public reporting as early as July of 2018 using data from patient encounters during the third quarter of 2017. In addition, we would make corresponding updates to our MIF to reflect these proposals,[59] such as: (1) Renaming OP–18b from ''Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Reporting Measure'' to ''OP–18b: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Excluding Psychiatric/Mental Health Patients and Transfer Patients;'' and (2) modifying the form to reflect that OP–18c would also be publicly reported. Administrative changes made to the MIF would not affect hospital reporting requirements or burden. The data required for public reporting are already collected and submitted by participating outpatient hospital departments and our proposal to publicly report OP–18c does not create additional burden. We note that hospitals would be able to preview these data in accordance with our previously established 30-day preview period procedures (81 FR 79791).

In developing this proposal, we also considered proposing to publicly report around July 2019 (not 2018 as proposed) using data from patient encounters occurring during the first quarter of 2018. However, we decided against this timeline, because under this reporting option, we would not be able to publicly report behavioral health data until as early as July of 2019, creating a delay in our efforts to address the behavioral health data gap in the publicly reported measure set.

We invited public comment on our proposal to publicly report OP–18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients beginning with third quarter 2017 data as discussed above.

Comment: Some commenters supported the proposal to publicly display OP–18c Median Time from ED Arrival to ED Departure for Discharged ED Patients—Psychiatric/Mental Health Patient, noting that the data can be valuable to improving patient care.

Response: We thank the commenters for their support; we agree that these data can be useful toward improving patient care for these patients.

Comment: Several commenters opposed the proposal to publicly report OP–18c: Median Time from ED Arrival to ED Departure for Discharged ED Patients—Psychiatric/Mental Health Patients. These commenters expressed concern that publicly reporting the measure will not address the behavioral health gap in the Hospital OQR Program. Several commenters expressed concern that data on time to departure may not help patients make care decisions. One commenter expressed concern that the measure sample size is small, leading to large variation in month-to-month performance. Another commenter recommended that data for substance abuse and non-substance abuse patients be separated in publicly reported OP–18c data, citing a concern that substance abuse patients may spend more time in the ED.

A few commenters cited concerns that delays in discharging psychiatric patients are caused by a lack of community resources rather than poor quality of care. One commenter recommended that publicly displayed data for OP–18c also include data on mental health resources in the community to provide context for the data. Other commenters expressed concern that the data could incentivize limiting the care provided to these patients in the ED in order to discharge them quickly.

Response: We disagree that OP–18c does not address the Hospital OQR Program's gap in measuring behavioral health or that it would not provide useful information. We believe this helps to address a gap in measuring behavioral health by attempting to address the increased wait times experienced by mental health patients in EDs. Research has indicated that mental health patients experience a prolonged ED length of stay as compared to other patients, and that these longer wait times can lead to medication errors and adverse outcomes.[60] Another study demonstrated that patients presenting to the ED with acute myocardial infarction who have a history of depression are given lower priority care.[61] In addition, we believe data from OP–18c will be useful to researchers and hospital staff as they attempt to address these disparities, as well as to patients choosing a care location. We further disagree that measure sample size will lead to inconsistent measure results. This measure has undergone the NQF endorsement process and, as such, has been tested and determined to be reliable.[62] Although, we acknowledge commenters concerns that substance abuse patients may spend more time in the ED, we believe it is important to not separate substance abuse patients in the measure, as research shows that illicit drug use is particularly high among adults with serious mental illnesses and that these co-occurring disorders tend to go undetected and untreated, especially among the elderly population.[63] [64] Given this, we believe it is important to include substance abuse populations for quality improvement.

However, the comments received have shed some light on aspects of this particular subset of data that may need additional consideration prior to posting on the consumer-facing *Hospital*

[58] Ibid.

[59] Ibid.

[60] Pearlmutter, Mark D. et al. Analysis of Emergency Department Length of Stay for Mental Health Patients at Ten Massachusetts Emergency Departments. Annals of Emergency Medicine, Volume 70, Issue 2, 193–202.e16.

[61] Atzema CL, Schull MJ, Tu JV. The effect of a charted history of depression on emergency department triage and outcomes in patients with acute myocardial infarction. CMAJ 2011;183:663–9.

[62] NQF: Median Time from ED Arrival to ED Departure for Discharged ED Patients. Available at: *https://qualityforum.org/qps/0496*.

[63] SAMHSA. Results from the 2014 National Survey on Drug Use and Health: Mental Health Findings.

[64] Robert Drake. ''Dual Diagnosis and Integrated Treatment of Mental Illness and Substance Abuse Disorder.''

Compare Web site. We acknowledge commenters' concerns regarding unintended consequences, including that the time to discharge for mental health patients may be influenced, in part, by the availability of community resources and that the measure could be perceived as creating pressure on providers to inappropriately limit care in order to quickly discharge mental health patients. Literature has shown that the number of inpatient psychiatric beds as decreased from 400,000 in 1970 to 50,000 in 2006.[65]

Therefore, after considering the public comments we received, including these additional factors, we would like to err on the side of caution and take additional time for further consideration prior to posting this particular subset of data on *Hospital Compare,* a consumer-facing Web site. As background, we typically allow 30 days for hospitals to preview their data two months prior to public reporting, after which we deliver final public reporting files for the *Hospital Compare* Web site (77 FR 68483). Simultaneously, in addition to posting on *Hospital Compare,* Hospital OQR Program quality measure data are also typically published on *data.medicare.gov* in downloadable data files.[66] [67] [68] While we will not publicly report OP–18c on *Hospital Compare,* we will instead publish it on *data.medicare.gov*. Affected parties will be notified via CMS listservs, CMS email blasts, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare* (76 FR 74453).

Based on the public comments we received, we intend to make measure data available in a downloadable data file rather than on *Hospital Compare* so that we may continue to evaluate the concerns raised by commenters regarding unintended consequences. We believe this modified approach to our original proposal is more appropriate than publishing on *Hospital Compare,* which is more public facing, because we want to avoid any potential circumstance in which the publication of these data exacerbate the concerns raised by commenters. We continue to believe the measure provides value to hospital quality improvement efforts and to patients. However, out of an abundance of caution, we intend to make data available on *data.medicare.gov* instead of *Hospital Compare* until we have been able to evaluate the concerns raised by commenters.

To be clear, data for what is referred to as OP–18b Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Reporting Measure will still continue to be made available on *Hospital Compare* as it has in the past. In addition, in accordance with our decision to not publish OP–18c data on *Hospital Compare,* we are also not finalizing the proposed measure subset name changes or MIF form changes described in our proposal. We will continue to work toward finding the best means to make this subset of information more easily understandable to the public and consider other measures to help fill the behavioral health gap in the future.

After consideration of the public comments we received, we are finalizing the proposal, with modification, as discussed in our response above, such that we will make OP–18c rates available to the public on *https://data.medicare.gov* in downloadable files. We will take additional time to further assess how best to make this subset of data available on the *Hospital Compare* Web site for consumers. In addition, we are not finalizing our proposals to: (1) Rename OP–18b from ''Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Reporting Measure'' to ''OP 18b: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Excluding Psychiatric/Mental Health Patients and Transfer Patients;'' and (2) modify the MIF to reflect that OP–18c would also be publicly reported on *Hospital Compare.*

C. Administrative Requirements

1. QualityNet Account and Security Administrator

The previously finalized QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109). In that final rule with comment period, we codified these procedural requirements at 42 CFR 419.46(a).

2. Requirements Regarding Participation Status

a. Background

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519) for requirements for participation and withdrawal from the Hospital OQR Program. We also codified these procedural requirements at 42 CFR 419.46(a) and 42 CFR 419.46(b). In the CY 2018 OPPS/ASC proposed rule (82 FR 33679), we proposed changes to the NOP submission deadline, as described below.

b. Proposed Changes to the NOP Submission Deadline

We finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) that participation in the Hospital OQR Program requires that hospitals must: (1) Register on the QualityNet Web site before beginning to report data; (2) identify and register a QualityNet security administrator; and (3) complete and submit an online participation form available at the *QualityNet.org* Web site if this form has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CMS Certification Number (CCN). In addition, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) we finalized the requirement that hospitals must submit the NOP according to the following deadlines:

- If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must complete and submit to CMS a completed Hospital OQR Program Notice of Participation Form by July 31 of the calendar year prior to the affected annual payment update.
- If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date.

These requirements are also codified at 42 CFR 419.46(a).

In the CY 2018 OPPS/ASC proposed rule (82 FR 33680), beginning with the CY 2020 payment determination, we

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[65] Tuttle GA. Report of the Council on Medical Service, American Medical Association: Access to psychiatric beds and impact on emergency medicine [Internet]. Chicago (IL): AMA; 2008.

[66] *Data.medicare.gov* OP Imaging Measures: *https://data.medicare.gov/Hospital-Compare/Outpatient-Imaging-Efficiency-Hospital/wkfw-kthe.*

[67] *Data.medicare.gov* OP Procedure Volume: *https://data.medicare.gov/Hospital-Compare/Outpatient-Procedures-Volume/xbz4-gvaz.*

[68] *Data.medicare.gov* Timely and Effective Care Measures: *https://data.medicare.gov/Hospital-Compare/Timely-and-Effective-Care-Hospital/yv7e-xc69.*

proposed to: (1) Revise the NOP submission deadline described above, and (2) make corresponding revisions at 42 CFR 419.46(a). Specifically, we proposed to change the NOP submission deadlines such that hospitals are required to submit the NOP any time prior to registering on the QualityNet Web site, rather than by the deadlines specified above. For example, under this proposal, and in accordance with the data submission deadlines described in section XIII.D.1. of this final rule with comment period, below and finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), a hospital submitting data for Q1 2019 encounters would be required to submit the NOP only prior to registering on the QualityNet Web site, which must be done prior to the data submission deadline of August 1, 2019 (80 FR 70519 through 70520).

We believe this proposed timeline is appropriate, because registration with the QualityNet Web site is necessary to submit data. We believe that extending the NOP submission deadline will better enable hospitals to meet the Hospital OQR Program participation requirements.

As discussed above, we also proposed to make conforming revisions at 42 CFR 419.46(a).

We invited public comment on our proposals as discussed above.

We did not receive any public comment on our proposal to require submission of the NOP any time prior to registering on the QualityNet Web site. However, due to logistical and operational constraints, participants in the Hospital OQR Program must still first login to QualityNet in order to access the NOP form; therefore, we are unable to implement this proposal. As a result, we are not finalizing our proposals to extend the NOP submission deadline and to make conforming revisions at 42 CFR 419.46(a). We intend to revisit this issue in future rulemaking, because we believe that extending the NOP submission deadline will better enable hospitals to meet the Hospital OQR Program participation requirements.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Payment Determinations

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 through 75111) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), we specified our data submission deadlines. We also codified our submission requirements at 42 CFR 419.46(c).

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), where we finalized our proposal to shift the quarters upon which the Hospital OQR Program payment determinations are based, beginning with the CY 2018 payment determination. The finalized deadlines for the CY 2020 payment determination and subsequent years are illustrated in the tables below.

CY 2020 Payment Determination and Subsequent Years

Patient encounter quarter	Clinical data submission deadline
Q2 2018 (April 1–June 30)	11/1/2018
Q3 2018 (July 1–September 30)	2/1/2019
Q4 2018 (October 1–December 31)	5/1/2019
Q1 2019 (January 1–March 31)	8/1/2019

For the CY 2020 payment determination and subsequent years, we proposed to revise the data submission requirements for hospitals that did not participate in the previous year's Hospital OQR Program. Specifically, we proposed to revise the first quarter for which newly participating hospitals are required to submit data (see details below). We did not propose any changes to the previously finalized data submission deadlines for each quarter.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68482), we finalized the following data submission requirements for hospitals that did not participate in the previous year's Hospital OQR Program:

- If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update;
- If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit data for encounters beginning with the first full quarter following submission of the completed Hospital OQR Program Notice of Participation Form; and
- Hospitals with a Medicare acceptance date before or after January 1 of the year prior to an affected annual payment update must follow data submission deadlines as posted on the QualityNet Web site.

These policies are also codified at 42 CFR 419.46(c)(3). In the CY 2018 OPPS/ASC proposed rule (82 FR 33680), we proposed to: (1) Align the timeline specifying the initial quarter for which hospitals must submit data for all hospitals that did not participate in the previous year's Hospital OQR Program, rather than specifying different timelines for hospitals with Medicare acceptance dates before versus after January 1 of the year prior to an affected annual payment update; and (2) make conforming revisions at 42 CFR 419.46(c)(3). Specifically, we proposed that any hospital that did not participate in the previous year's Hospital OQR Program must submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update. We note that hospitals must still follow data submission deadlines corresponding to the quarter for which they are reporting data as posted on the QualityNet Web site.

We invited public comment on our proposals to align the initial data submission timeline for all hospitals that did not participate in the previous year's Hospital OQR Program and to make conforming revisions at 42 CFR 419.46(c)(3).

We did not receive any public comment on our proposals. Therefore, we are finalizing our proposals to align the initial data submission timeline for all hospitals that did not participate in the previous year's Hospital OQR Program and to make conforming revisions at 42 CFR 419.46(c)(3), as proposed.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of chart-abstracted measures for the CY 2014 payment determination and subsequent years.

We did not propose any changes to our policies regarding the submission of chart abstracted measure data where patient-level data are submitted directly to CMS.

We note that, in section XIII.B.4.c. of this final rule with comment period, we are finalizing the removal of OP–21: Median Time to Pain Management for Long Bone Fracture, OP–1: Median Time to Fibrinolysis, OP–4: Aspirin at Arrival, and OP–20: Door to Diagnostic Evaluation by a Qualified Medical

Professional for the CY 2020 payment determination and subsequent years. Therefore, the following previously finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2020 payment determination and subsequent years:

- OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (NQF #0288);
- OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention (NQF #0290);
- OP–5: Median Time to ECG (NQF #0289);
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496);
- OP–23: Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival (NQF #0661).

3. Claims-Based Measure Data Requirements for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112) for a discussion of the general claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years. We did not propose any changes to our claims-based measures submission policies for the CY 2020 payment determination and subsequent years.

There are a total of nine claims-based measures for the CY 2020 payment determination and subsequent years:

- OP–8: MRI Lumbar Spine for Low Back Pain (NQF #0514);
- OP–9: Mammography Follow-Up Rates;
- OP–10: Abdomen CT—Use of Contrast Material;
- OP–11: Thorax CT—Use of Contrast Material (NQF #0513);
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery (NQF #0669);
- OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT);
- OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539);
- OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and
- OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687).

4. Data Submission Requirements for the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79792 through 79794) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures. However, we refer readers to section XIII.B.5. of this final rule with comment period, where we are finalizing our proposal to delay implementation of the OP–37a–e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 data collection) until further action in future rulemaking.

As noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79815), some commenters suggested shortening sections of the survey, such as the ''About You'' section. We continue to evaluate the utility of individual questions as we collect new data from the survey's voluntary national implementation, and will consider different options for shortening the OAS CAHPS Survey without the loss of important data in the future. Specifically, we continue to consider the removal of two demographic questions—the ''gender'' and ''age'' questions—from the OAS CAHPS Survey in a future update.

Comment: Some commenters supported removal of the gender and age questions from the survey.

Response: We thank the commenters for their support. We will take these comments under consideration as we craft future policies for the OAS CAHPS Survey.

5. Data Submission Requirements for Previously Finalized Measures for Data Submitted via a Web-Based Tool for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521) and the CMS QualityNet Web site (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1205442125082*) for a discussion of the requirements for measure data submitted via the CMS QualityNet Web site for the CY 2017 payment determination and subsequent years. In addition, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the requirements for measure data (specifically, the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431)) submitted via the Centers for Disease Control and Prevention (CDC) NHSN Web site. We did not propose any changes to our policies regarding the submission of measure data submitted via a Web-based tool.

We note that, in section XIII.B.4.c. of this final rule with comment period, we are finalizing the removal of OP–25: Safe Surgery Checklist Use and OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures beginning with the CY 2020 payment determination and for subsequent years. Therefore, the following web-based quality measures previously finalized and retained in the Hospital OQR Program will require data to be submitted via a Web-based tool (CMS' QualityNet Web site or CDC's NHSN Web site) for the CY 2020 payment determination and subsequent years:

- OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data (via CMS' QualityNet Web site);
- OP–17: Tracking Clinical Results between Visits (NQF #0491) (via CMS' QualityNet Web site);
- OP–22: Left Without Being Seen (NQF #0499) (via CMS' QualityNet Web site);
- OP–27: Influenza Vaccination Coverage among Healthcare Personnel (via the CDC NHSN Web site) (NQF #0431);
- OP–29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) (via CMS' QualityNet Web site);
- OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659) (via CMS' QualityNet Web site);
- OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) (via CMS' QualityNet Web site); and
- OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) (via CMS' QualityNet Web site).

6. Population and Sampling Data Requirements for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment

period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our population and sampling requirements.

We did not propose any changes to our population and sampling requirements.

7. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965) for a discussion of finalized policies regarding our validation requirements. We also refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487) for a discussion of finalized policies regarding our medical record validation procedure requirements. We codified these policies at 42 CFR 419.46(e). For the CY 2018 payment determination and subsequent years, validation is based on four quarters of data (validation quarter 1 (January 1–March 31), validation quarter 2 (April 1–June 30), validation quarter 3 (July 1–September 30), and validation quarter 4 (October 1–December 31)) (80 FR 70524).

In the CY 2018 OPPS/ASC proposed rule (82 FR 33682), we: (1) Clarified the hospital selection process previously finalized for validation; (2) proposed to codify the procedures for targeting hospitals at 42 CFR 419.46(e); and (3) proposed to formalize and update our educational review process. These are discussed in more detail below.

a. Clarification

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), we finalized a validation selection process in which we select a random sample of 450 hospitals for validation purposes, and select an additional 50 hospitals based on the following specific criteria:

- Hospital fails the validation requirement that applies to the previous year's payment determination; or
- Hospital has an outlier value for a measure based on the data it submits. We defined an ''outlier value'' for purposes of this targeting as a measure value that appears to deviate markedly from the measure values for other hospitals. Specifically, we would select hospitals for validation if their measure value for a measure is greater than 5 standard deviations from the mean, placing the expected occurrence of such a value outside of this range at 1 in 1,744,278.

We note that the criteria for targeting 50 outlier hospitals, described above, does not specify whether high or low performing hospitals will be targeted. Therefore, we clarified that hospitals with outlier values indicating specifically poor scores on a measure (for example, a long median time to fibrinolysis) will be targeted for validation. In other words, an ''outlier value'' is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score.

Comment: One commenter recommended that CMS target hospitals for validation whether their score is greater than five standard deviations above or below the mean, noting that very good scores may especially indicate a need for validation.

Response: The intent of this policy is to target and prevent extreme negative values rather than to identify high performance. This is also evidenced in the first of our two criteria for targeting hospitals for validation—to target hospitals that fail the validation requirement that applies to the previous year's payment determination. We believe it is appropriate to specifically target hospitals with poor performance, rather than those performing well to encourage improved performance among low performing hospitals. We note that only 50 hospitals will be selected for validation through these targeting criteria and in order to address the issue of very low performance, we believe it is appropriate to use these targeting criteria to identify extreme negative measure values. An additional 450 hospitals will be selected at random, and will include both low and high performing hospitals. However, we thank the commenter for their feedback that extremely high performance could indicate a need for validation, and will take this into consideration as we craft future policies.

b. Codification

We note that the previously finalized procedures for targeting hospitals for validation, described in section XIII.D.7.a. of this final rule with comment period, and finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), are not yet codified at 42 CFR 419.46. We proposed to codify the previously finalized procedures for targeting hospitals and well as the procedures regarding outlier hospitals as discussed and clarified above at 42 CFR 419.46(e)(3).

We invited public comment on our proposal to codify our validation targeting criteria as discussed above.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to codify the previously finalized procedures for targeting hospitals and well as the procedures regarding outlier hospitals as discussed and clarified above at 42 CFR 419.46(e)(3), as proposed.

c. Formalization and Modifications to the Educational Review Process for Chart-Abstracted Measures Validation

(1) Background

We have described our processes for educational review on the QualityNet Web site.[69] We note that historically this process functioned as an outreach and education opportunity we provided to hospitals, but based on our experience, stakeholder feedback, and more robust validation requirements, we believed that it would be beneficial to hospitals to propose formalizing and updating this process.

Under the current informal process, if results of an educational review indicate that CDAC or CMS has incorrectly scored a hospital after validation, those results are not changed, but are taken into consideration if the hospital submits a reconsideration request. Stakeholder feedback, provided via email, has indicated that while the educational review process is helpful to participating hospitals, it is limited in its impact, given that a hospital's validation result is not corrected even after an educational review determines that CMS reached an incorrect conclusion regarding a hospital's validation score for a given quarter. Based on this feedback, we proposed to formalize and update the Hospital OQR Program's chart-abstracted measure validation educational review process. Our goal is to reduce the number of reconsideration requests by identifying and correcting errors before the final yearly validation score is derived. By identifying and correcting any mistakes early on, this process could help decrease the burden during the annual reconsideration process, both for hospitals and CMS.

Therefore, in an effort to streamline this process, we proposed to: (1) Formalize this process; and (2) specify that if the results of an educational review indicate that we incorrectly scored a hospital's medical records

[69] Data Validation—Educational Reviews: Hospitals-Outpatient. Available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic/Page/QnetTier3&cid=1228764927987*.

selected for validation, the corrected quarterly validation score would be used to compute the hospital's final validation score at the end of the calendar year. These proposals are discussed in more detail below.

(2) Educational Review Process for the CY 2020 Payment Determination and Subsequent Years

(a) Formalizing the Educational Review Process

As stated above, our informal processes for educational review have been described on the QualityNet Web site.[70] Under the informal process, hospitals that were selected and received a score for validation may request an educational review in order to better understand the results. Many times, hospitals request an educational review to examine any data element discrepancies, if they believe the score is incorrect, or when they have general questions about their score. Currently, hospitals receive validation results on a quarterly basis [71] and can request informal educational reviews for each quarter. Under this informal process, a hospital has 30 calendar days from the date the validation results are posted on the QualityNet Secure Portal Web site to contact the CMS designated contractor, currently known as the Validation Support Contractor (VSC), to request an educational review.[72] In response to a request, the VSC obtains and reviews medical records directly from the Clinical Data Abstraction Center (CDAC) and provides feedback. CMS, or its contractor, generally provides educational review results and responses via a secure file transfer to the hospital.[73]

We proposed to formalize this educational review process, as described above, for the CY 2020 payment determination and subsequent years—in other words, starting for validations of CY 2018 data affecting the CY 2020 payment determination and subsequent years.

We invited public comment on our proposal to formalize the chart-abstracted measures validation educational review process for the CY 2020 payment determination and subsequent years as described above.

We did not receive any public comments on our proposal. Therefore, we are finalizing the proposal to formalize the chart-abstracted measures validation educational review process for the CY 2020 payment determination and subsequent years, as proposed.

(b) Validation Score Review and Correction

We previously finalized, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105 to 72106), that we calculate validation scores under the Hospital OQR Program using the upper bound of a one-tailed confidence interval (CI) with a 75 percent threshold level with a binomial approach. Using that approach, at the end of each calendar year, CMS computes a CI using the results of all four quarters to determine the final validation score.[74] If the upper bound of this confidence interval is 75 percent or higher, the hospital will pass the Hospital OQR Program validation requirement.[75] We proposed that if the results of a validation educational review determine that the original quarterly validation score was incorrect, the corrected score would be used to compute the final validation score and CI at the end of each calendar year.

To determine whether a quarterly validation score was correct, in the CY 2018 OPPS/ASC proposed rule (82 FR 33683), we proposed to use a similar process as one previously finalized for reconsideration requests. Specifically, we proposed that during an educational review request, evaluating a validation score would consist of and be limited to reviewing data elements that were labeled as mismatched (between the originally calculated measure score and the measure score calculated in validation) in the original validation results. We would also take into consideration written justifications provided by hospitals in the Educational Review request. For more information about the previously finalized reconsideration request procedures, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795).

For the CY 2020 payment determination and subsequent years, we further proposed that if an educational review requested for any of the first 3 quarters of validation yields incorrect CMS validation results for chart-abstracted measures, according to the review process described above, we would use the corrected quarterly score, as recalculated during the educational review process, to compute the final CI at the end of the calendar year.[76] We note that for the last quarter of validation, because of the need to calculate the confidence interval in a timely manner and the insufficient time available to conduct educational reviews prior to the annual payment update, the validation score review and correction would not be available. Instead, the existing reconsideration process would be used to dispute any unsatisfactory validation result. We refer readers to section XIII.D.9. of this final rule with comment period for a discussion about our reconsideration and appeals process.

The corrected scores would be applicable to the corresponding quarter, for the first 3 quarters of validation, for which a request was submitted. Under this proposal, after evaluating the validation score during the educational review process, if results show that there was indeed an error in the originally calculated score, we would take steps to correct it. However, so as not to dissuade participation in the educational review process, corrected scores identified through the educational review would only be used to recalculate the CI if they indicate that the hospital performed more favorably than previously determined. If the hospital performed less favorably, their score would not be updated to reflect the less favorable score.

We note that under this proposal, the quarterly validation reports issued to hospitals would not be updated to reflect the corrected score due to the burden associated with reissuing corrected reports. However, the corrected score would be communicated to the hospital via secure file format as discussed above.

We invited public comment on our proposal, as discussed above for the CY 2020 payment determination and subsequent years, to use corrected quarterly scores, as recalculated during the educational review process

[70] Ibid.

[71] QualityNet: Data Validation—Overview. Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228758729356.*

[72] The educational review request form can be found at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228764927987.*

[73] Hospital OQR Validation Educational Review Process: Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228764927987.*

[74] QualityNet Data Validation Overview. Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228758729356.*

[75] Ibid.

[76] Validation pass-fail status is determined by the confidence interval report. Detail at: *http://www.qualityreportingcenter.com/wp-content/uploads/2017/01/OQR-CY18-Validation-Webinar.508.2.pdf.*

described and finalized in section XIII.D.7.c.(2)(a) of this final rule with comment period above, to compute the final confidence interval for the first 3 quarters of validation.

Comment: Several commenters supported the proposed changes to use the educational review process to correct validation scores, noting that the policy will increase efficiency and help hospitals understand their annual validation score. One commenter recommended that CMS accept educational review requests from facilities that have a passing validation score, given that there could be errors that result in a mistakenly low, though still passing, score.

Response: We thank the commenters for their support and note that under the formalized process we are finalizing, hospitals may request an educational review to examine any data element discrepancies, if they believe the score is incorrect, or when they have general questions about their score (82 FR 33682). Under this process, hospitals receive validation results on a quarterly basis and can request informal educational reviews for each quarter. A hospital has 30 calendar days from the date the validation results are posted on the QualityNet Secure Portal Web site to contact the CMS designated contractor, currently known as the Validation Support Contractor (VSC), to request an educational review. To be clear, educational review requests are not limited to hospitals that fail validation; any hospital that receives validation results (pass or fail) may request a validation educational review.

After consideration of the public comments received, we are finalizing our proposal to use corrected quarterly scores, as recalculated during the educational review process described in section XIII.D.7.c.(2)(a) of this final rule with comment period above, to compute the final confidence interval for the first 3 quarters of validation for the CY 2020 payment determination and subsequent years, as proposed.

8. Extraordinary Circumstances Exception Process for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances extension or exception process under the Hospital OQR Program.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), we finalized an update to our extraordinary circumstances exemption (ECE) policy to extend the ECE request deadline for both chart-abstracted and web-based measures from 45 days following an event causing hardship to 90 days following an event causing hardship, effective with ECEs requested on or after January 1, 2017.

We note that many of our quality reporting and value-based purchasing programs share a common process for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control. The Hospital IQR, Hospital OQR, IPFQR, ASCQR, and PCHQR Programs, as well as the Hospital Acquired Condition Reduction Program and the Hospital Readmissions Reduction Program, share similar processes for ECE requests. We refer readers to policies for the Hospital IQR Program (76 FR 51651 through 51652, 78 FR 50836 through 50837, 79 FR 50277, 81 FR 57181 through 57182, and 42 CFR 412.140(c)(2)), the IPFQR Program (77 FR 53659 through 53660 and 79 FR 45978), the ASCQR Program (77 FR 53642 through 53643 and 78 FR 75140 through 75141), the PCHQR Program (78 FR 50848), the HAC Reduction Program (80 FR 49579 through 49581), and the Hospital Readmissions Reduction Program (80 FR 49542 through 49543) for program specific information about extraordinary circumstances exceptions requests. As noted below, some of these policies were updated in the FY 2018 IPPS/LTCH PPS final rule.

In reviewing the policies for these programs, we recognized that there are five areas in which these programs have variances regarding ECE requests. These are: (1) Allowing the facilities or hospitals to submit a form signed by the facility's or hospital's CEO versus CEO or designated personnel; (2) requiring the form be submitted within 30 days following the date that the extraordinary circumstance occurred versus within 90 days following the date the extraordinary circumstance occurred; (3) inconsistency regarding specification of a timeline for us to provide our formal response notifying the facility or hospital of our decision; (4) inconsistency regarding specification of our authority to grant ECEs due to CMS data system issues; and (5) referring to the program as ''extraordinary extensions/exemptions'' versus as ''extraordinary circumstances exceptions.'' We believe addressing these five areas, as appropriate, can improve administrative efficiencies for affected facilities or hospitals.

We note that, in the FY 2018 IPPS/LTCH PPS final rule, we examined our policies in these areas for the Hospital Readmissions Reduction Program, the HAC Reduction Program, the Hospital IQR Program, the PCHQR Program and the IPFQR Program (82 FR 38240, 38277, 38410, 38425 and 38473 through 38474, respectively) and finalized proposals to address differences in these areas for those programs. In section XIV.D.6. of this final rule with comment period, we are also finalizing revisions to our ECE policies for the ASCQR Program.

With the exception of the specification of a timeline for us to provide our formal response and the terminology used to describe these processes (items 3 and 5 above), the Hospital OQR Program is aligned with the existing and proposed policies for the other quality reporting programs discussed above. As a result, we proposed to rename the process as the extraordinary circumstances exceptions (ECE) policy and make conforming changes to 42 CFR 419.46(d).

a. ECE Policy Nomenclature

We have observed that while all quality programs listed above have developed similar policies to provide exceptions from program requirements to facilities that have experienced extraordinary circumstances, such as natural disasters, these programs refer to these policies using inconsistent terminology. Some programs refer to these policies as ''extraordinary circumstances extensions/exemptions'' while others refer to the set of policies as ''extraordinary circumstances exceptions.'' Several programs (specifically, the Hospital VBP Program, HAC Reduction Program, and the Hospital Readmissions Reduction Program) are not able to grant extensions to required data reporting timelines due to their reliance on data external to their program and, thus, the term, ''extraordinary circumstances extensions/exemptions'' is not applicable to all programs. However, all of the described programs are able to offer exceptions from their reporting requirements.

As stated above, in order to align this policy across CMS quality programs, we proposed to: (1) Change the name of this policy from ''extraordinary circumstances extensions or exemptions'' to ''extraordinary circumstances exceptions'' for the Hospital OQR Program, beginning January 1, 2018; and (2) revise 42 CFR

419.46(d) of our regulations to reflect this change. We note that changing the terminology for this policy does not change the availability for a hospital to request an extension under the Hospital OQR Program.

We invited public comment on these proposals as discussed above.

Comment: One commenter supported the proposed alignment of the ECE process across quality reporting programs.

Response: We appreciate the commenter's support.

After consideration of the public comment we received, we are finalizing the proposal to rename the process as the extraordinary circumstances exceptions (ECE) policy and make conforming changes to 42 CFR 419.46(d), as proposed.

b. Timeline for CMS Response to ECE Requests

We also note that we believe it is important for facilities to receive timely feedback regarding the status of ECE requests. We strive to complete our review of each ECE request as quickly as possible. However, we recognize that the number of requests we receive, and the complexity of the information provided impacts the actual timeframe to make ECE determinations. To improve transparency of our process, we believe it is appropriate to specify that we will strive to complete our review of each request within 90 days of receipt.

9. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795) for a discussion of our reconsideration and appeals procedures. We codified the process by which participating hospitals may submit requests for reconsideration at 42 CFR 419.46(f). We also codified language at § 419.46(f)(3) regarding appeals with the Provider Reimbursement Review Board.

We did not propose any changes to our reconsideration and appeals procedure.

E. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2018 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the final rule, which is available via the Internet on the CMS Web site): ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', or ''U''. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator ''Q4'' because services and procedures coded with status indicator ''Q4'' are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or '''T''. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to

§ 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this final rule with comment period.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2018

In the CY 2018 OPPS/ASC proposed rule (82 FR 33684 through 33685), we proposed to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2018 annual payment update factor. For the CY 2018 OPPS, the proposed reporting ratio was 0.980, calculated by dividing the proposed reduced conversion factor of 74.953 by the proposed full conversion factor of 76.483. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2018 OPPS, we proposed to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', and ''U'' (other than new technology APCs to which we have proposed status indicator assignment of ''S'' and ''T''). We proposed to continue to exclude services paid under New Technology APCs. We proposed to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also proposed to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we proposed to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.

We invited public comments on these proposals but no comments were received. For the CY 2018 OPPS, the final reporting ratio is 0.980, calculated by dividing the final reduced conversion factor of 77.064 by the final full conversion factor of 78.636. We are finalizing the rest of our proposal without modification.

XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIII.A.1. of this final rule with comment period for a general overview of our quality reporting programs.

2. Statutory History of the ASCQR Program

We refer readers to section XIV.K.1. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We seek to promote higher quality and more efficient health care for beneficiaries. This effort is supported by the adoption of widely-agreed-upon quality measures. We have worked with relevant stakeholders to define measures of quality in almost every healthcare setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and outcomes. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of ASC services, we implemented the ASCQR Program. We refer readers to section XV.A.3. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75122), section XIV. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966 through 66987), section XIV. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70526 through 70538) and section XIV. of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79797 through 79826) for an overview of the regulatory history of the ASCQR Program.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for ASCQR Program quality measure selection. We did not propose any changes to this policy.

2. Accounting for Social Risk Factors in the ASCQR Program

We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE)[77] and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a

[77] Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. 21 Dec. 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[78] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine, the body provided various potential methods for accounting for social risk factors, including stratified public reporting.[79]

As noted in the FY 2017 IPPS/LTCH PPS final rule, the NQF has undertaken a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for some performance measures. Since publication of the proposed rule, we have learned that the National Quality Forum (NQF) has concluded their initial trial on risk adjustment for quality measures.[80] Based on the findings from the initial trial, we have been informed that the NQF intends to continue its work to evaluate the impact of social risk factor adjustment on intermediate outcome and outcome measures for an additional three years. We understand that the extension of this work will allow NQF to determine further how to effectively account for social risk factors through risk adjustment and other strategies in quality measurement.

As we continue to consider the analyses and recommendations from these reports and the results of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, in the proposed rule we sought public comment on whether we should account for social risk factors in the ASCQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Confidential reporting to providers of measure rates stratified by social risk factors; public reporting of stratified measure rates; and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, we requested public comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the ASCQR Program. We note that any such changes would be proposed through future notice and comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we also welcome comment on operational considerations. CMS is committed to ensuring that its beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

We received extensive comments in response to our request for public comment on whether we should account for social risk factors in the ASCQR Program, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors.

Comment: Many commenters expressed support for CMS' effort to address social risk factors in the ASCQR Program, noting that social risk factors are powerful drivers of care provision and clinical outcomes.

One commenter recommended that CMS apply risk adjustment by stratifying providers into groups by proportion of at-risk patients, noting that this approach does not require measure-level research. Another commenter recommended that CMS determine whether or not social risk factor disparities exist in the ASC setting prior to committing to adjusting any measures for these factors, and that CMS rely on data elements existing in CMS databases. A few commenters recommended that CMS provide ASCs with both risk-adjusted and unadjusted data in order to allow for transparency.

One commenter noted that better data sources for socioeconomic status are needed, including patient-level and community-level data sources, and that measure-specific risk adjustment methodologies are appropriate. Finally, one commenter noted that risk adjustment should balance fair measurement with ensuring that disparities are not masked.

Response: We appreciate all the comments and interest in this topic. As we have previously stated regarding risk adjustment of publicly reported data for these factors, we are concerned about holding providers and suppliers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities or minimize incentives to improve outcomes for disadvantaged populations. With respect to public reporting, while we agree with commenters and believe it is important to avoid a scenario in which underlying disparities are masked rather than addressed, we also agree with commenters who support the public reporting of risk-adjusted data. We appreciate the need to balance risk adjustment as a strategy to account for social risk factors with the concern that risk adjustment could minimize incentives and reduce efforts to address disparities for patients with social risk factors. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have access to excellent care. We will consider all suggestions as we continue to assess the issue of accounting for social risk factors within individual measures and the program as a whole, and will actively perform

[78] Ibid.

[79] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

[80] NQF. NQF Initiative to Determine the Impact of Adjusting Healthcare Performance Measures for Social Risk Factors Highlights Successes, Opportunities. Available at: *https://www.qualityforum.org/News_And_Resources/Press_Releases/2017/NQF_Initiative_to_Determine_the_Impact_of_Adjusting_Healthcare_Performance_Measures_for_Social_Risk_Factors_Highlights_Successes,_Opportunities.aspx.*

additional research and monitor for trends to prevent unintended consequences. We intend to conduct further analyses on the impact of different approaches to accounting for social risk factors in quality programs.

Comment: Many commenters recommended several social variables and comorbidities, including: Body mass index; race; smoking status; age; gender; back pain; pain in non-operative lower extremity joint; health risk status; mental health factors; chronic narcotic use; socioeconomic status; and pre-procedure ambulatory status. Commenters also recommended that future risk variables could include literacy, marital status, live-in home support, family support structure, and home health resources. One commenter recommended that the following variables not be used: American Society of Anesthesiologists score; range of motion; and mode of patient-reported outcome measure collection. One commenter expressed concern with the use of dual eligible status as a factor, noting that it does not identify or address the specific factors that result in higher spending and/or poorer health outcomes.

Response: We appreciate commenters' recommendations regarding specific social risk factor variables and will consider them as we continue exploring options for accounting for social risk factors in the ASCQR Program.

Comment: Several commenters recommended that CMS consider potential administrative complexities as well as patient impact when implementing risk-adjustment methodologies.

Response: As we consider the feasibility of collecting patient-level data and the impact of strategies to account for social risk factors through further analysis, we will also continue to evaluate the reporting burden on patients and providers. We reiterate that we are committed to ensuring that CMS beneficiaries have access to and receive excellent care and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

Comment: Some commenters recommended that CMS consider recommendations from NQF, ASPE, and the Agency for Healthcare Research and Quality (AHRQ).

Response: Any proposals would be made in future rulemaking after further research and continued stakeholder engagement including from NQF. In addition, we look forward to working with all stakeholders, including NQF, ASPE, the National Academy of Medicine, and AHRQ.

We thank all of the commenters for their input and will consider all suggestions as we continue to assess the issue of accounting for social risk factors within individual measures, the ASCQR Program as a whole, and across CMS quality programs.

3. Policies for Retention and Removal of Quality Measures From the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously adopted a policy that quality measures adopted for an ASCQR Program measure set for a previous payment determination year be retained in the ASCQR Program for measure sets for subsequent payment determination years, except when they are removed, suspended, or replaced as indicated (76 FR 74494 and 74504; 77 FR 68494 through 68495; 78 FR 75122; and 79 FR 66967 through 66969). We did not propose any changes to this policy.

b. Measure Removal

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66969) and 42 CFR 416.320 for a detailed discussion of the process for removing adopted measures from the ASCQR Program. We did not propose any changes to this process.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33687), we proposed to remove a total of three measures for the CY 2019 payment determination and subsequent years: (1) ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing; (2) ASC–6: Safe Surgery Checklist Use; and (3) ASC–7: ASC Facility Volume Data on Selected Procedures. These proposals are discussed in more detail below.

(1) Removal of ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing Beginning With the CY 2019 Payment Determination

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74499 through 74501) where we adopted ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing measure (formerly NQF #0264) beginning with the CY 2014 payment determination and finalized the measure's data collection and data submission timelines (76 FR 74515 through 74516). This measure assesses whether intravenous antibiotics given for prevention of surgical site infection were administered on time per clinical guidelines.

Based on our analysis of ASCQR Program measure data for CY 2014 through 2016 encounters, ASC performance on this measure is so high and unvarying that meaningful distinctions in improvement cannot be made; as a result, we believe this measure meets removal criterion number one under the ASCQR Program's finalized measure removal criteria. The ASCQR Program previously finalized two criteria for determining when a measure is ''topped out:'' (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (COV) is less than or equal to 0.10 (79 FR 66968 through 66969). These analyses are captured in the table below.

ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing Topped Out Analysis

Encounters	Number of ASCs	75th percentile	90th percentile	Truncated COV
CY 2014	2,206	100.000	100.000	0.02633
CY 2015	2,196	100.000	100.000	0.03289
CY 2016	2,158	100.000	100.000	0.02619

As displayed in the table above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles under the ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing measure, and the truncated coefficient of variation has been below 0.10 since 2014. Therefore, the ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing measure meets both ''topped out'' measure criteria for the ASCQR Program.

Furthermore, we note that the NQF endorsement was removed on February 13, 2015; in its discussion of whether to

continue endorsement for the ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing measure, the Surgery Standing Committee also noted that ASC performance on this measure was very high, with 99 percent of facilities meeting the timely antibiotic administration threshold in CY 2013.[81] We believe that removal of this measure from the ASCQR Program measure set is appropriate, as there is little room for improvement and removal would alleviate maintenance costs and administrative burden to ASCs. As such, we believe the burdens outweigh the benefits of keeping the measure in the ASCQR Program. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33687), we proposed to remove the ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing measure for the CY 2019 payment determination and subsequent years. Furthermore, we note that a similar measure was removed from the Hospital OQR Program in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66942 through 66944) due to topped-out status.

We invited public comment on our proposal to remove the ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing measure for the CY 2019 payment determination and subsequent years as discussed above.

Comment: Many commenters supported the proposal to remove the ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing measure, and agreed with CMS' rationale that the measure does not add value and that removal of this measure reduces administrative burden.

Response: We thank the commenters for their support.

Comment: One commenter opposed the proposed removal of ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing measure. The commenter noted that the measure provides value and recommended that the measure be retained in the ASCQR Program despite having ''topped-out'' status.

Response: We understand commenter's concern with removing the ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing measure, and agree that the data captured under the ASC–5 measure could be useful in selecting an ASC at which to receive care. However, we believe that removal of this measure from the ASCQR Program measure set is appropriate as there is little room for improvement, as shown by our data in the table above, and removal would alleviate maintenance costs and administrative burden to ASCs. Overall, we believe the burdens outweigh the benefits of keeping the measure in the ASCQR Program, as stated in our proposal. In response to concerns that the measure adds value, we note that Prophylactic Intravenous (IV) Antibiotic Timing measure data are collected and publicly reported by the ASC Quality Collaboration.

After consideration of the public comments we received, we are finalizing the proposal to remove the ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing measure for the CY 2019 payment determination and subsequent years, as proposed.

(2) Removal of ASC–6: Safe Surgery Checklist Use Beginning With the CY 2019 Payment Determination

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74505 through 74507 and 74509), where we adopted the ASC–6: Safe Surgery Checklist Use measure beginning with the CY 2015 payment determination. This structural measure of facility process assesses whether an ASC employed a safe surgery checklist that covered each of the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data collection period.

Based on our analysis of ASCQR Program measure data for CYs 2014 to 2016 encounters, the ASC–6: Safe Surgery Checklist Use measure meets our first criterion for measure removal that measure performance is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. The ASCQR Program previously finalized two criteria for determining when a measure is ''topped out:'' (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation is less than or equal to 0.10 (79 FR 66968 through 66969). These analyses are captured in the table below.

ASC–6—Safe Surgery Checklist Use Performance Analysis

Encounters	Number of ASCs	Rate	75th percentile	90th percentile	Truncated COV
CY 2012	4,356	0.989	100.000	100.000	0.106
CY 2013[82]	(*)	(*)	(*)	(*)	(*)
CY 2014	4,328	0.997	100.000	100.000	0.050
CY 2015	4,305	0.998	100.000	100.000	0.043

Based on the analysis above the national rate of ''Yes'' response for the ASC–6: Safe Surgery Checklist Use measure is nearly 1.0, or 100 percent, nationwide, and has remained at this level for the last 2 years. In addition, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles under measure, and the truncated coefficient of variation has been below 0.10 since 2014. We believe that removal of this measure from the ASCQR Program measure set is appropriate, as there is little room for improvement. In addition, removal of this measure would alleviate the maintenance costs and administrative burden to ASCs associated with retaining the measure. As such, we believe the burdens of this measure outweigh the benefits of keeping the measure in the Program.

Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33688), we proposed to remove ASC–6: Safe Surgery Checklist Use from the ASCQR Program measure set beginning with the CY 2019 payment determination. We also refer readers to section XIII.B.4.c.(6) of this final rule with comment period, where the Hospital OQR Program is removing a similar measure.

[81] NQF. ''NQF-Endorsed Measures for Surgical Procedures.'' Technical Report. Available at: *http://www.qualityforum.org/Publications/2015/02/NQF-Endorsed_Measures_for_Surgical_Procedures.aspx.*

[82] We note that no performance data was collected for CY 2013 events for the Web-based measures; therefore, we lack performance data for the ASC–6 measure for this year of the ASCQR Program. Available at: *https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890196351&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DASC_wbnr_prsntn_121813_1ppg.pdf&blobcol=urldata&blobtable=MungoBlobs.*

We invited public comment on our proposal to remove the ASC–6: Safe Surgery Checklist Use measure for the CY 2019 payment determination and subsequent years as discussed above.

Comment: Many commenters supported the proposal to remove the ASC–6: Safe Surgery Checklist Use measure, and agreed with our rationale that the measure does not add value and that removal would reduce administrative burden.

Response: We thank the commenters for their support.

Comment: A few commenters opposed the proposed removal of the ASC–6: Safe Surgery Checklist Use measure, noting that this measure provides value and recommending retention of this measure in the ASCQR Program. One commenter expressed concern that high performance on the measure does not indicate whether perioperative communication among team members is effective, and recommended that CMS retain the measure until there is further evidence of whether the use of a safe surgery checklist is supporting effective perioperative communication.

Response: While we agree the ASC–6: Safe Surgery Checklist Use measure captures data patients may find useful in comparing ASCs while selecting an ASC for their care, we believe that removal of this measure from the ASCQR Program measure set is appropriate as there is little room for improvement, as shown by our data in the table above. In addition, removal of this measure would alleviate the maintenance costs and administrative burden to ASCs. Therefore, overall, we believe the burden outweighs the benefits of keeping the measure in the ASCQR Program, as stated in our proposal. We also note that high performance on the ASC–6: Safe Surgery Checklist Use measure does not indicate whether perioperative communication among team members is effective; this measure is not specified to assess the effectiveness of a team's communication, only whether a safe surgery checklist is used at the ASC. Therefore, we do not believe continuing to collect—or, conversely, ceasing to collect—data under this measure will assess or affect the effectiveness of perioperative communication within ASCs.

After consideration of the public comments we received, we are finalizing the proposal to remove ASC–6: Safe Surgery Checklist Use from the ASCQR Program measure set beginning with the CY 2019 payment determination, as proposed. We also refer readers to section XIII.B.4.c.(6) of this final rule where we are finalizing removal of a similar measure from the Hospital OQR Program.

(3) Removal of ASC–7: ASC Facility Volume Data on Selected Procedures Beginning With the CY 2019 Payment Determination

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74507 through 74509), where we adopted the ASC–7: ASC Facility Volume Data on Selected Procedures measure beginning with the CY 2015 payment determination. This structural measure of facility capacity collects surgical procedure volume data on six categories of procedures frequently performed in the ASC setting (76 FR 74507).

We adopted the ASC–7: ASC Facility Volume Data on Selected Procedures measure based on evidence that volume of surgical procedures, particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased medical errors and mortality (76 FR 74507). We further stated our belief that publicly reporting volume data would provide patients with beneficial performance information to use in selecting a care provider. However, over time, we have adopted, and intend to continue to adopt, more measures assessing ASCs' performance on specific procedure types, like ASC–14. As stated below, we believe measures on specific procedure types will provide patients with more valuable ASC performance data. These types of measures are also more strongly associated with desired patient outcomes for the particular topic. For example, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79801 through 79803), we adopted ASC–14: Unplanned Anterior Vitrectomy, a measure assessing patient outcomes following ophthalmologic procedures, and proposed to adopt a second ophthalmology-specific measure, ASC–16: Toxic Anterior Segment Syndrome, in the CY 2018 proposed rule (82 FR 33689 through 33691). We believe these procedure-type-specific measures provide patients with more valuable ASC performance data than the ASC–7: ASC Facility Volume Data on Selected Procedures measure in selecting an ASC for their care. For this reason, we believe the ASC–7: ASC Facility Volume Data on Selected Procedures measure meets our second criterion for removal from the program; specifically, that there are other measures available that are more strongly associated with desired patient outcomes for the particular topic. In addition, removal of this measure would alleviate the maintenance costs and administrative burden to ASCs associated with retaining the measure. As such, we believe the burdens of this measure outweigh the benefits of keeping the measure in the ASCQR Program. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33688), we proposed to remove ASC–7: ASC Facility Volume Data on Selected Procedures from the ASCQR Program beginning with the CY 2019 payment determination. We refer readers to section XIII.B.4.c.(2) of this final rule with comment period where we are removing a similar measure from the Hospital OQR Program.

We invited public comment on our proposal to remove the ASC–7: ASC Facility Volume Data on Selected Procedures measure for the CY 2019 payment determination and subsequent years as discussed above.

Comment: Many commenters supported the proposal to remove the ASC–7: ASC Facility Volume Data on Selected Procedures measure and agreed with CMS' rationale that the measure does not add value and that its removal reduces administrative burden.

Response: We thank the commenters for their support.

Comment: A few commenters opposed the proposal to remove the ASC–7: ASC Facility Volume Data on Selected Procedures measure. One commenter cited concern that removal of this measure will limit the availability of important data that informs comparative research, outcomes research, and that this measure provides immediate consumer value. Moreover, the commenter expressed concern that reducing the data available will interfere with the growing acceptance of ASC-based procedures. Another commenter noted that the measure is not overly burdensome and that it is helpful for strategic planning.

Response: While we believe that continuing to collect and publicly report facility volume data would provide patients with beneficial performance information to use in selecting a care provider, over time, we have adopted, and intend to continue to adopt, more measures assessing ASCs' performance on specific procedure types. In addition, removal of this measure would alleviate the maintenance costs and administrative burden to ASCs associated with retaining the measure. As such, although we recognize the value of the measure for research, strategic planning, and in demonstrating the value of ASC-based procedures, overall we believe the burden of this measure outweighs the benefits of

keeping the measure in the ASCQR Program as stated in our proposal.

After consideration of the public comments we received, we are finalizing our proposal to remove ASC–7: ASC Facility Volume Data on Selected Procedures from the ASCQR Program beginning with the CY 2019 payment determination, as proposed.

4. Delaying Implementation of ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With the CY 2020 Payment Determination

We refer readers to the CY 2017 OPPS/ASC final rule with comment period where we adopted ASC–15a–e (81 FR 79803 through 79817), and finalized data collection and data submission timelines (81 FR 79822 through 79824). These measures assess patients' experience with care following a procedure or surgery in an ASC by rating patient experience as a means for empowering patients and improving the quality of their care.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33688), we proposed to delay implementation of the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based Measures (ASC–15a–e) beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking. Since our adoption of these measures, we have come to believe that we need to collect more operational and implementation data. Specifically, we want to ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; reaffirm the reliability of national implementation of OAS CAHPS Survey data; and appropriately account for the burden associated with administering the survey in the outpatient setting of care. We note that commenters expressed concern over the burden associated with the survey in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79810). We believe that the voluntary national implementation of the survey, which began in January 2016, would provide valuable information moving forward. We plan to conduct analyses of the national implementation data to undertake any necessary modifications to the survey tool and/or CMS systems. We believe it is important to allow time for any modifications before requiring the survey under the ASCQR Program. However, we continue to believe that these measures address an area of care that is not adequately addressed in our current measure set and will be useful to assess aspects of care where the patient is the best or only source of information.

Further, we continue to believe these measures will enable objective and meaningful comparisons between ASCs. Therefore, we proposed to delay implementation of ASC–15a–e beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking. We also refer readers to section XIII.B.5. of this final rule with comment period where we are finalizing a similar policy in the Hospital OQR Program.

We invited public comment on our proposal to delay the OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination as discussed above.

Comment: Many commenters supported the proposal to delay implementation of the OAS CAHPS Survey and noted that if the survey could be improved, ASCs would benefit from having their scores available for comparison to hospital outpatient departments. One commenter agreed that an analysis of the national implementation will provide valuable information. Another commenter noted that the high volume of facilities and hospitals participating in the voluntary national implementation indicates that the data collection burden of the survey is low.

Response: We thank the commenters for their support, and agree that an analysis of the national implementation of OAS CAHPS Survey will provide valuable information as we continue to assess the survey. We also acknowledge that comparing scores between ASCs and hospital outpatient departments may be useful to ASCs and that some ASCs may find the survey to have only limited burden. However, as discussed below, in order to be responsive to concerns about vendor costs and to review the results of the national implementation, we are finalizing our proposal to delay implementation of the OAS CAHPS Survey.

Comment: A few commenters opposed the proposal to delay implementation of the OAS CAHPS Survey, noting the importance of patient experience data. One commenter noted that the survey assesses areas of care not yet adequately addressed and that patient experience of care is a priority area. Another commenter noted a belief that the use of surveys about patient experience in health care settings is the best way to examine whether high-quality, patient-centered care actually takes place.

Response: We agree that patient experience of care data is valuable in assessing the quality of care provided at an ASC and assisting patients in selecting a provider or supplier for their care. However, we seek to ensure the value of this data is appropriately balanced against the implementation and operational burdens imposed to collect and submit these data. As we stated in the proposed rule, we believe delaying implementation of the OAS CAHPS Survey will provide additional time to assess these issues before moving forward.

Comment: A few commenters recommended that the survey be voluntary indefinitely or until implementation issues with the survey are addressed. One commenter recommended that CMS delay implementation of the OAS CAHPS indefinitely and instead increase the number of surveyors that inspect ASCs. Another commenter recommended that CMS adopt the CAHPS surgical care survey as a survey option.

Response: We thank the commenters for their recommendations, and we will take these comments under consideration as we craft future policy. We do not believe that inspectors replace a patient-experience-of-care survey, because inspections and surveys collect different information. Specifically, we believe that patient experience data is an important category of information to collect and would not be captured by surveyors. Further, we believe a patient experience of care survey will provide important information to not just providers, but also patients and the general public. Therefore, we will continue to work towards a successful implementation of a patient experience survey. In addition, we acknowledge the commenter's suggestion that we adopt the surgical CAHPS survey and we will consider this recommendation.

Comment: A few commenters expressed concern about the burden associated with collecting 300 surveys and requested that only 100 surveys be required. Other commenters noted that the survey is unnecessarily long, which could reduce response rates or skew results if only patients with negative feedback respond, and that not all of the questions are relevant. Some commenters noted that the use of a third-party vendor is too costly and could lead to more impersonal contacts with patients than if ASCs surveyed patients directly. Several commenters recommended that vendors should provide electronic or email options for

conducting the OAS CAHPS Survey in order to increase response rates. Other commenters recommended that CMS administer the survey on its Web site. One commenter noted concern that timely results are not provided. A few commenters expressed concern that the CPT codes included in the eligibility criteria for the survey are not always applicable.

Response: While Web-based surveys are not available survey modes at present, we are actively investigating these modes as possible options for the future. We are exploring whether hospitals and ASCs receive reliable email addresses from patients and whether there is adequate access to the internet across all types of patients. Ultimately, the purpose of the investigation is to ensure that any future survey administration method does not introduce bias in the survey process and reduces length and burden if at all possible. Although we are investigating other modes of survey administration, we do not expect that CMS will directly administer the survey; the survey would still be administered through vendors. In addition, we acknowledge commenters concerns that ASCs would not receive immediate feedback from patients that is obtained through the survey. Finally, we acknowledge the concern about the use of CPT codes, including those for procedures that patients may not perceive as surgery. We note that many CPT codes have been excluded from inclusion in the OAS CAHPS, including services like application of a cast or splint, in order to ensure that only patients receiving applicable procedures are surveyed.[83] We thank the commenters and will take all comments under consideration as we craft future policy for the OAS CAHPS Survey.

After consideration of the public comments we received, we are finalizing the proposal to delay implementation of the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based Measures (ASC–15a–e) beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking, as proposed. We refer readers to section XIII.B.5. of this final rule with comment where we are also finalizing delay of the OAS CAHPS Survey-based measures in the Hospital OQR Program.

5. ASCQR Program Quality Measures Adopted in Previous Rulemaking

For the CY 2020 payment determination and subsequent years, we have previously finalized the following measure set. We note that this chart still includes the ASC–5, ASC–6, and ASC–7 measures, which are being finalized for removal beginning with the CY 2019 payment determination as discussed above, as well as the ASC–15a–e measures, which are being finalized for delay beginning with the CY 2020 payment determination and until further action as discussed above:

ASCQR Program Measure Set Previously Finalized for the CY 2020 Payment Determination and Subsequent Years

ASC No.	NQF No.	Measure name
ASC–1	0263	Patient Burn.
ASC–2	0266	Patient Fall.
ASC–3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4	0265†	All-Cause Hospital Transfer/Admission.
ASC–5	0264†	Prophylactic Intravenous (IV) Antibiotic Timing.*
ASC–6	None	Safe Surgery Checklist Use.*
ASC–7	None	ASC Facility Volume Data on Selected Procedures.*
ASC–8	0431	Influenza Vaccination Coverage Among Healthcare Personnel.
ASC–9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use.
ASC–11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**
ASC–12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
ASC–13	None	Normothermia Outcome.
ASC–14	None	Unplanned Anterior Vitrectomy.
ASC–15a	None	OAS CAHPS—About Facilities and Staff.***
ASC–15b	None	OAS CAHPS—Communication About Procedure.***
ASC–15c	None	OAS CAHPS—Preparation for Discharge and Recovery.***
ASC–15d	None	OAS CAHPS—Overall Rating of Facility.***
ASC–15e	None	OAS CAHPS—Recommendation of Facility.***

† We note that NQF endorsement for this measure was removed.

* Measure finalized for removal beginning with the CY 2019 payment determination, as discussed in section XIV.B.3.b. of this final rule with comment period.

** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

*** Measure finalized for delay in reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking as discussed in section XIV.B.4. of this final rule with comment period.

[83] *OASCAHPS.org.* Additional Procedural Codes for Exclusion from the OAS CAHPS Survey. Available at: *https://oascahps.org/General-Information/Announcements/EntryId/80/Additional-Procedural-Codes-for-Exclusion-from-the-OAS-CAHPS-Survey.*

6. New ASCQR Program Quality Measures for the CY 2021 and CY 2022 Payment Determinations and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124) for a detailed discussion of our approach to measure selection for the ASCQR Program. In the CY 2018 OPPS/ASC proposed rule (82 FR 33689 through 33698), we proposed to adopt a total of three new measures for the ASCQR Program: one measure collected via a CMS web-based tool for the CY 2021 payment determination and subsequent years (ASC–16: Toxic Anterior Segment Syndrome), and two measures collected via claims for the CY 2022 payment determination and subsequent years (ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures). These measures are discussed in detail below.

a. Proposal To Adopt ASC–16: Toxic Anterior Segment Syndrome Beginning With the CY 2021 Payment Determination

(1) Background

Toxic Anterior Segment Syndrome (TASS), an acute, noninfectious inflammation of the anterior segment of the eye, is a complication of anterior segment eye surgery that typically develops within 24 hours after surgery.[84] The TASS measure assesses the number of ophthalmic anterior segment surgery patients diagnosed with TASS within two days of surgery. Although most cases of TASS can be treated, the inflammatory response associated with TASS can cause serious damage to intraocular tissues, resulting in vision loss.[85] Prevention requires careful attention to solutions, medications, and ophthalmic devices and to cleaning and sterilization of surgical equipment because of the numerous potential etiologies.[86] Despite a recent focus on prevention, cases of TASS continue to occur, sometimes in clusters.[87] With millions of anterior segment surgeries being performed in the United States each year, measurement and public reporting have the potential to serve as an additional tool to drive further preventive efforts.

TASS is of interest to the ASCQR Program because cataract surgery is an anterior segment surgery commonly performed at ASCs. In addition, the TASS measure addresses the MAP-identified priority measure area of procedure complications for the ASCQR Program.[88]

(2) Overview of Measure

We believe it is important to monitor the rate of TASS in the ASC setting because ophthalmologic procedures such as anterior segment surgery are commonly performed in this setting of care. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33690), we proposed to adopt the ASC–16: Toxic Anterior Segment Syndrome measure, which is based on aggregate measure data collected by the ASC and submitted via a CMS online data submission tool (QualityNet), in the ASCQR Program for the CY 2021 payment determination and subsequent years. We expect the measure would promote improvement in patient care over time, because measurement coupled with transparency in publicly reporting of measure information would make patient outcomes following anterior segment procedures more visible to ASCs and patients and incentivize ASCs to incorporate quality improvement activities to reduce the incidence of TASS where necessary.

Section 1890A of the Act requires the Secretary to establish a prerulemaking process with respect to the selection of certain categories of quality and efficiency measures. Under section 1890A(a)(2) of the Act, the Secretary must make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering for the Medicare program. The ASC–16 measure was included on the 2015 MUC list [89] and reviewed by the MAP. The MAP reviewed the measure (MUC15–1047) and conditionally supported it for the ASCQR Program pending NQF review and endorsement.[90] The MAP noted the high value and urgency of this measure, given many new entrants to the ambulatory surgical center space, as well as the clustering outbreaks of TASS. The MAP also cautioned that the measure be reviewed and endorsed by NQF before adoption into the ASCQR Program, so that a specialized standing committee can evaluate the measure for scientific acceptability.[91] A summary of the MAP recommendations can be found at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

Sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, when read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care furnished by ASCs that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. However, we note that section 1833(i)(7)(B) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, under section 1833(i)(7)(B) of the Act, section 1833(t)(17)(C)(i) of the Act applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment. We believe this measure meets these statutory requirements.

The proposed ASC–16: Toxic Anterior Segment Syndrome measure is not NQF-endorsed. However, this measure is maintained by the ASC Quality Collaboration,[92] an entity recognized within the community as an expert in measure development for the ASC

[84] Centers for Disease Control and Prevention. Toxic Anterior Segment Syndrome after Cataract Surgery—Maine, 2006. MMWR. Morbidity and Mortality Weekly Report. 2007 Jun 29;56(25):629–630.

[85] Breebaart AC, Nuyts RM, Pels E, Edelhauser HF, Verbraak FD. Toxic Endothelial Cell Destruction of the Cornea after Routine Extracapsular Cataract Surgery. Archives of Ophthalmology 1990;108:1121–1125.

[86] Hellinger WC, Bacalis LP, Erdhauser HF, Mamalis N, Milstein B, Masket S. ASCRS Ad Hoc Task Force on Cleaning and Sterilization of Intraocular Instruments: Recommended Practices for Cleaning and Sterilizing Intraocular Surgical Instruments. Journal of Cataract and Refractive Surgery. 2007 Jun;33(6):1095–1100.

[87] Moyle W, Yee RD, Burns JK, Biggins T. Two Consecutive Clusters of Toxic Anterior Segment Syndrome. Optometry and Vision Science. 2013 Jan;90(1):e11–23.

[88] National Quality Forum. ''MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals.'' Report. 2017. Available at: *http://www.qualityforum.org/map/* under ''Hospitals—Final Report.''

[89] National Quality Forum. *2015 Measures Under Consideration List.* National Quality Forum, Dec. 2016. Available at: *http://www.qualityforum.org/2015_Measures_Under_Consideration.aspx*, under ''2015 Measures Under Consideration List (PDF).''

[90] National Quality Forum. *2016 Spreadsheet of Final Recommendations to HHS and CMS.* Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

[91] Ibid.

[92] ASC Quality Collaboration. ''ASC Quality Collaboration.'' Available at: *http://www.ascquality.org/.*

setting. We believe that this measure is appropriate for the measurement of quality care furnished by ASCs because ophthalmologic procedures are commonly performed in ASCs and, as discussed above, the inflammatory response associated with TASS can cause serious damage to patients' vision, but TASS is also preventable through careful attention to solutions, medications, ophthalmic devices, and to cleaning and sterilization of surgical equipment. While the ASC–16: Toxic Anterior Segment Syndrome measure is not NQF-endorsed, we believe this measure reflects consensus among affected parties, because the MAP, which represents stakeholder groups, reviewed and conditionally supported the measure [93] for use in the ASCQR Program. The MAP agreed that this measure is high-value and urgent in the current healthcare marketplace and the number of new entrants to the surgical center place, as well as the clustering outbreaks of TASS.[94] Furthermore, we believe that this measure is scientifically acceptable, because the measure steward has completed reliability testing and validity assessment of the measure.[95] Specifically, an internal retrospective chart audit of the ASCs participating in measurement testing found no differences between the originally submitted and re-abstracted TASS rates, providing strong evidence the measure is reliable. The measure steward also conducted a formal consensus review to assess the measure's validity; the results of this assessment showed participants believe the measure appears to measure what it is intended to, and is defined in a way that will allow for consistent interpretation of the inclusion and exclusion criteria from ASC to ASC.

(3) Data Sources

This measure is based on aggregate measure data collected via chart-abstraction by the ASC and submitted via a CMS online data submission tool (that is, QualityNet).

We proposed that the data collection period for the proposed ASC–16 measure would be the calendar year two years prior to the applicable payment determination year. For example, for the CY 2021 payment determination, the data collection period would be CY 2019. We also proposed that ASCs submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 2021 payment determination, the submission period would be January 1, 2020 to May 15, 2020. We refer readers to section XIV.D.3.b. of this final rule with comment period for a more detailed discussion of the requirements for data submitted via a CMS online data submission tool.

(4) Measure Calculation

The outcome measured in the proposed ASC–16: Toxic Anterior Segment Syndrome measure is the number of ophthalmic anterior segment surgery patients diagnosed with TASS within 2 days of surgery. The numerator for this measure is all anterior segment surgery patients diagnosed with TASS within 2 days of surgery. The denominator for this measure is all anterior segment surgery patients. The specifications for this measure for the ASC setting can be found at: *http://ascquality.org/documents/ASC%20QC%20Implementation%20Guide%203.2%20October%202015.pdf*.

(5) Cohort

The measure includes all patients, regardless of age, undergoing anterior segment surgery at an ASC. Additional methodology and measure development details are available at: *http://www.ascquality.org/qualitymeasures.cfm* under ''ASC Quality Collaboration Measures Implementation Guide.''

(6) Risk Adjustment

The proposed ASC–16: Toxic Anterior Segment Syndrome measure is not risk-adjusted; risk adjustment for patient characteristics is not appropriate for this measure.

We invited public comment on our proposal to adopt the ASC–16: Toxic Anterior Segment Syndrome measure for the CY 2021 payment determination and subsequent years as discussed above.

Comment: Some commenters supported CMS' proposal to adopt ASC–16: Toxic Anterior Segment Syndrome beginning with the CY 2021 payment determination, citing the measure's clinical significance and impact on patients. One commenter specifically noted the measure could improve patient care while adding little administrative burden. One commenter noted the measure's potential to promote collaboration between surgeons and facilities and ensure that prevention guidelines are appropriately followed. Another commenter noted this measure is currently in use as part of the ASC Quality Collaboration's public report of ASC quality data, and expressed particular support for submission of aggregated measure data for the proposed ASC–16: Toxic Anterior Segment Syndrome measure via QualityNet.

Response: We thank the commenters for their support.

Comment: Another commenter specifically noted the measure could improve patient care while adding little administrative burden, but also expressed concern about an ASC's ability to collect measure data if patients do not present back to the ASC where their procedure was performed.

Response: We thank the commenter for their feedback and acknowledge that it may be difficult to collect data based on where patients present.

Comment: One commenter expressed conditional support for the proposed ASC–16: Toxic Anterior Segment Syndrome measure pending NQF endorsement prior to adoption. Other commenters expressed concern that the measure is not NQF-endorsed and recommended CMS secure NQF endorsement for the measure prior to adopting it for use in the ASCQR Program.

Response: Sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, when read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care furnished by ASCs that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. However, we note that section 1833(i)(7)(B) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, under section 1833(i)(7)(B) of the Act, section 1833(t)(17)(C)(i) of the Act applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non NQF-endorsed measures. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of

[93] National Quality Forum. *2016 Spreadsheet of Final Recommendations to HHS and CMS.* Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

[94] Ibid.

[95] AHRQ Measure Summary. Available at: *https://www.qualitymeasures.ahrq.gov/summaries/summary/49582/ambulatory-surgery-percentage-of-ophthalmic-anterior-segment-surgery-patients-diagnosed-with-toxic-anterior-segment-syndrome-tass-within-2-days-of-surgery.*

measures, and consensus through public comment. This measure is maintained by the ASC Quality Collaboration,[96] an entity recognized within the community as an expert in measure development for the ASC setting. Furthermore, the ASC–16 measure was included on the 2015 MUC list [97] and reviewed by the MAP. While the ASC–16: Toxic Anterior Segment Syndrome measure is not NQF-endorsed, we believe this measure reflects consensus among affected parties, because the MAP, which represents stakeholder groups, reviewed and conditionally supported the measure [98] for use in the ASCQR Program. The MAP agreed that this measure is high-value and urgent in the current healthcare marketplace and the number of new entrants to the surgical center place, as well as the clustering outbreaks of TASS.[99]

Comment: Several commenters did not support adoption of the proposed ASC–16: Toxic Anterior Segment Syndrome measure. Two commenters noted it may not be feasible for ASCs to implement the measure due to the small number of patients experiencing TASS. Other commenters similarly asserted ASCs will encounter operational difficulties incorporating the measure into their clinical workflow, because the measure requires information sharing across clinicians in order to collect accurate data, making accurate data collection both expensive and labor-intensive. A commenter also expressed concern that patients may not understand the difference between TASS and infection, leading to inaccurate data being present in charts. Another commenter expressed concern that the measure's reliance on self-reported data may lead to subjective results or manipulation, and that the measure is limited to a segment of the larger ASC industry, as only very few ASCs will have patients presenting with TASS. One commenter expressed concern that the proposed ASC–16: Toxic Anterior Segment Syndrome measure will not improve healthcare quality because the measure provides data that is retrospective in nature and the commenter believes the measure will not assist ASCs in implementing improvement activities.

Response: We thank the commenters for their suggestions and note the concerns about the proposal to adopt ASC–16: Toxic Anterior Segment Syndrome beginning with the CY 2021 payment determination. While we believe the measure is reliable, we recognize that there are concerns over the feasibility of implementing the TASS measure. Some commenters expressed concern that ASCs will have difficulty reporting the measure if patients present to another facility with TASS within 2 days of a procedure and we acknowledge that some cases could be missing from inclusion in the measure especially given the very low incidence of TASS. In response to concerns that ASCs will receive retrospective data on the measure, rather than during the time that a patient is experiencing TASS, we note our belief that tracking TASS for the purpose of the measure reporting would increase facility awareness of potential outbreaks. In addition, we disagree with commenters that the measure relies on subjective or self-reported data, as data sources for this measure include physician diagnosis and report, clinical administrative data, paper medical records, or incident/occurrence reports.[100]

Regarding concerns about the low volume of procedures, although data show that TASS occurs in clusters, these clusters do indeed include low numbers, ranging from just a few cases to up to 20 cases during a year's time.[101] As a result of this low volume, we agree that this measure may not be appropriate for national implementation in the ASCQR Program. Upon further consideration of the difficulty of implementing the measure, the likelihood of applicability to only very specific ASC facilities where TASS occurs, and from incoming comments, we believe that the burden of the measure would outweigh the benefits and no longer believe that the measure is appropriate for the ASCQR Program at this time. Therefore, we are not finalizing this measure. However, we refer readers to the ASC Quality Collaboration, the measure steward, which is independently collecting and publicly reporting this TASS measure: *http://ascquality.org/documents/ASC-QC-Implementation-Guide-4.0-September-2016.pdf*.

Comment: One commenter recommended CMS instead enable ASCs to learn best practices and techniques from other facilities by facilitating data-sharing among facilities.

Response: We agree that data-sharing among facilities could inform quality improvement activities. We will consider opportunities to further promote the sharing of best practices across ASCs.

After consideration of the public comments we received, we are not finalizing the proposal to adopt the ASC–16: Toxic Anterior Segment Syndrome measure for the CY 2021 payment determination and subsequent years for reasons discussed in our responses above.

The measure set for the ASCQR Program CY 2021 payment determination and subsequent years is as listed below. We note that the measures we are finalizing for removal in this final rule with comment period are not included in this chart.

ASCQR Program Measure Set Finalized for the CY 2021 Payment Determination and Subsequent Years ***

ASC No.	NQF No.	Measure name
ASC–1	0263	Patient Burn.
ASC–2	0266	Patient Fall.
ASC–3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4	0265 †	All-Cause Hospital Transfer/Admission.
ASC–8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
ASC–9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.

[96] ASC Quality Collaboration. ''ASC Quality Collaboration.'' Available at: *http://www.ascquality.org/*.

[97] National Quality Forum. *2015 Measures Under Consideration List.* National Quality Forum, Dec. 2016. Available at: *http://www.qualityforum.org/2015_Measures_Under_Consideration.aspx*, under ''2015 Measures Under Consideration List (PDF).''

[98] National Quality Forum. *2016 Spreadsheet of Final Recommendations to HHS and CMS.* Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

[99] Ibid.

[100] ASC Quality Measures Implementation Guide. Available at: *http://ascquality.org/documents/ASC–QC-Implementation-Guide-4.0-September-2016.pdf*.

[101] Moyle W, Yee RD, Burns JK, Biggins T. Two Consecutive Clusters of Toxic Anterior Segment Syndrome. Optometry and Vision Science. 2013 Jan;90(1):e11–23.

ASCQR PROGRAM MEASURE SET FINALIZED FOR THE CY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS ***—Continued

ASC No.	NQF No.	Measure name
ASC–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use.
ASC–11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.*
ASC–12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
ASC–13	None	Normothermia Outcome.
ASC–14	None	Unplanned Anterior Vitrectomy.
ASC–15a	None	OAS CAHPS—About Facilities and Staff.**
ASC–15b	None	OAS CAHPS—Communication About Procedure.**
ASC–15c	None	OAS CAHPS—Preparation for Discharge and Recovery.**
ASC–15d	None	OAS CAHPS—Overall Rating of Facility.**
ASC–15e	None	OAS CAHPS—Recommendation of Facility.**

† We note that NQF endorsement for this measure was removed.

* Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

** Measure reporting delayed beginning with the CY 2020 payment determination (CY 2018 data collection) and until further action in future rulemaking, as discussed in section XIV.B.4. of this final rule with comment period.

*** The ASC–5, ASC–6 and ASC–7 measures are finalized for removal beginning with the CY 2019 payment determination, as discussed in section XIV.B.3.b. of this final rule with comment period.

b. Adoption of ASC–17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures Beginning With the CY 2022 Payment Determination

(1) Background

Reporting the quality of care provided at ASCs is a key priority in the context of growth in the number of ASCs and the number of procedures performed in this setting. More than 60 percent of all medical or surgical procedures performed in 2006 were performed at ASCs; this represents a three-fold increase from the late 1990s.[102] In 2015, more than 3.4 million fee-for-service Medicare beneficiaries were treated at 5,475 Medicare-certified ASCs, and spending on ASC services by Medicare and its beneficiaries amounted to 4.1 billion dollars.[103] The patient population served at ASCs has increased not only in volume, but also in age and complexity, which can be partially attributed to improvements in anesthetic care and innovations in minimally invasive surgical techniques.[104] [105] As such, ASCs have become the preferred setting for the provision of low-risk surgical and medical procedures in the United States, as many patients experience shorter wait times, prefer to avoid hospitalization, and are able to return to work more quickly.[106] As the number of orthopedic procedures performed in ASCs increases, it is increasingly important to report the quality of care for patients undergoing these procedures. According to Medicare claims data, approximately seven percent of surgeries performed in ASCs in 2007 were orthopedic in nature, which reflects a 77-percent increase in orthopedic procedures performed at ASCs from 2000 to 2007.[107]

We believe measuring and reporting seven-day unplanned hospital visits following orthopedic ASC procedures will incentivize ASCs to improve care and care transitions. Patients that have hospital visits that occur at or after discharge from the ASC and may not be readily visible to clinicians because such patients often present to alternative facilities, such as emergency departments where patient information is not linked back to the ASC. Furthermore, many of the reasons for hospital visits following surgery at an ASC are preventable; patients often present to the hospital for complications of medical care, including infection, post-operative bleeding, urinary retention, nausea and vomiting, and pain. One study found that of 10,032 patients who underwent orthopedic surgery in an ASC between 1993 and 2012, 121 (1.2 percent) needed attention in the emergency department in the first 24 hours after discharge due to pain or bleeding, while others were admitted later for issues related to pain and swelling.[108] Therefore, we believe tracking and reporting these events would facilitate efforts to lower the rate of preventable adverse events and to improve the quality of care following orthopedic surgeries performed at an ASC.

(2) Overview of Measure

Based on the increasing prevalence of orthopedic surgery in the ASC setting, we believe it is important to minimize adverse patient outcomes associated with these orthopedic ASC surgeries. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33692), we proposed to adopt the ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures measure into the ASCQR Program for the CY 2022 payment determination and subsequent years. We expect the measure would promote improvement in patient care over time, because measurement coupled with transparency in publicly reporting measure information would make the rate of unplanned hospital visits (emergency department visits, observation stays, and unplanned inpatient admissions) following orthopedic surgery at ASCs more visible to both ASCs and patients and would incentivize ASCs to incorporate quality improvement activities to reduce these unplanned hospital visits. The measure also addresses the CMS National Quality Strategy domains of making care safer by reducing harm caused in the delivery of care and promoting effective

[102] Cullen KA, Hall MJ, Golosinskiy A, Statistics NFcH. Ambulatory Surgery in the United States, 2006. National Health Statistics Report; 2009.

[103] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Medicare Payment Policy. March 2017; Available at: *http://www.medpac.gov/docs/default-source/reports/mar17_entirereport.pdf?sfvrsn=0*.

[104] Bettelli G. High Risk Patients in Day Surgery. Minerva Anestesiologica. 2009;75(5):259–268. *See also* Fuchs K. Minimally Invasive Surgery. Endoscopy. 2002;34(2):154–159.

[105] Fuchs K. Minimally invasive surgery. Endoscopy. 200234(2):154159.

[106] Cullen KA, Hall MJ, Golosinskiy A, Statistics NFcH. Ambulatory Surgery in the United States, 2006. National Health Statistics Report; 2009.

[107] Goyal KS, Jain S, Buterbaugh GA, et al. The Safety of Hang and Upper-Extremity Surgical Procedures at a Freestanding Ambulatory Surgical Center. The Journal of Bone and Joint Surgery. 2016;90:600–604.

[108] Martín-Ferrero MA, Faour-Martín O. Ambulatory surgery in orthopedics: experience of over 10,000 patients. Journal of Orthopaedic Surgery. 2014;19:332–338.

communication and coordination of care.

Section 1890A of the Act requires the Secretary to establish a prerulemaking process with respect to the selection of certain categories of quality and efficiency measures. Under section 1890A(a)(2) of the Act, the Secretary must make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering for the Medicare program. The ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures measure was included on a publicly available document entitled ''List of Measures under Consideration for December 1, 2016.'' [109] The MAP reviewed this measure (MUC16–152) and recommended this measure be refined and resubmitted prior to adoption, stating that testing results should demonstrate reliability and validity at the facility level in the ambulatory surgical setting.[110] MAP also recommended that this measure be submitted to NQF for review and endorsement.[111] At the time of the MAP's review, this measure was still undergoing field testing.

Since the MAP's review and recommendation of 'Refine and Resubmit' in 2016, we have completed testing for this measure and continued to refine this proposed measure in response to the MAP's recommendations. Results of continued development activities, including stakeholder feedback from the public comment period and pilot test findings will be presented to the MAP during the MAP feedback loop meeting in fall 2017. The proposed measure is consistent with the information submitted to the MAP, and the original MAP submission and our continued refinements support its scientific acceptability for use in quality reporting programs. Facility-level testing showed variation in unplanned hospital visits among ASCs after adjusting for case-mix differences, which suggests variation in quality of care and opportunities for quality improvement; and reliability testing showed fair measure score reliability.[112] As expected, the reliability increased for ASCs with more patients; ASCs with at least 250 cases showed moderate reliability, consistent with other publicly reported Medicare claims-based, risk-adjusted outcome measures.[113] The validity testing results demonstrated that the measure scores are valid and useful measures of ASC orthopedic surgical quality of care and will provide ASCs with information that can be used to improve their quality of care. Detailed testing results are available in the technical report for this measure, located at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, when read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care furnished by ASCs that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. However, we note that section 1833(i)(7)(B) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, under section 1833(i)(7)(B) of the Act, section 1833(t)(17)(C)(i) of the Act applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-NQF-endorsed measures. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment. We believe this proposed measure meets these statutory requirements.

The proposed ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures measure is not currently NQF-endorsed. However, we intend to submit this measure for review and endorsement by NQF once an appropriate NQF project has a call for measures. We believe that this measure is appropriate for the measurement of quality care furnished by ASCs, because surgeries are becoming increasingly common in ASCs and, as discussed above, can signify unanticipated admissions after care provided in ASCs. Such visits are an unexpected and potentially preventable outcome for patients with a low anticipated perioperative risk. We also believe this proposed measure reflects consensus among affected parties, because it was developed with stakeholder input from a Technical Expert Panel convened by a CMS contractor as well as from the measure development public comment period.[114] During the MAP and measure development processes, public commenters supported the measure's focus on assessing patient outcomes after orthopedic surgery performed in ASC setting of care, and agreed that the measure would be meaningful and improve quality of care. In addition, the ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures measure addresses the MAP-identified priority measure area of surgical complications for the ASCQR Program.[115] Therefore, we believe it is appropriate to incorporate this measure into the ASCQR Program measure set because collecting and publicly reporting these data will improve transparency, inform patients and providers, and foster quality improvement efforts.

(3) Data Sources

This measure is claims-based and uses Part A and Part B Medicare administrative claims and Medicare enrollment data to calculate the measure.

We proposed that the data collection period for the proposed ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures measure would be the two calendar years ending two years prior to the applicable payment determination year. For example, for the CY 2022 payment determination, the data collection period would be CY 2019 to 2020. Because the measure data are collected via claims, ASCs will not need to submit any additional data directly to CMS. We refer readers to section XIV.D.4. of this final rule with comment period for a more detailed discussion of

[109] National Quality Forum. *List of Measures under Consideration for December 1, 2016.* National Quality Forum, Dec. 2016. Available at: *http://www.qualityforum.org/map/*.

[110] National Quality Forum. *2016–2017 Spreadsheet of Final Recommendations to HHS and CMS.* Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

[111] Ibid.

[112] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159–174.

[113] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE). Measure Technical Report: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf*.

[114] National Quality Forum. ''MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals.'' Report. 2017. Available at: *http://www.qualityforum.org/map/* under ''Hospitals—Final Report.''

[115] Ibid.

the requirements for data submitted via claims.

(4) Measure Calculation

The measure outcome is all-cause, unplanned hospital visits within seven days of an orthopedic procedure performed at an ASC. For the purposes of this measure, ''hospital visits'' include emergency department visits, observation stays, and unplanned inpatient admissions. When there are two or more qualifying surgical procedures within a 7-day period, the measure considers all procedures as index procedures; however, the timeframe for outcome assessment is defined as the interval between procedures (including the day of the next procedure) and then 7 days after the last procedure.

The facility-level score is a risk-standardized hospital visit rate, calculated by multiplying the ratio of the predicted to the expected number of post-surgical hospital visits among the given ASC's patients by the national observed hospital visit rate for all ASCs. For each ASC, the numerator of the ratio is the number of hospital visits predicted for the ASC's patients accounting for its observed rate, the number of the orthopedic surgeries performed at the ASC, the case-mix, and the surgical complexity mix. The denominator of the ratio is the expected number of hospital visits given the ASC's case-mix and surgical complexity mix. A ratio of less than one indicates the ASC facility's patients were estimated as having fewer post-surgical visits than expected compared to ASCs with similar surgical complexity and patients; and a ratio of greater than one indicates the ASC facility's patients were estimated as having more visits than expected. The national observed hospital visit rate is the national unadjusted proportion of patients who had a hospital visit following an orthopedic ASC surgery. For more information on measure calculations, we refer readers to: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(5) Cohort

The patient cohort for the proposed ASC–17 measure includes all Medicare beneficiaries ages 65 and older undergoing outpatient orthopedic surgery at an ASC who have 12 prior months of Medicare fee-for-service Parts A and B enrollment. The target group of procedures includes those that: (1) Are routinely performed at ASCs; (2) involve some increased risk of post-surgery hospital visits; and (3) are routinely performed by orthopedists.

Procedures included in the measure cohort are on Medicare's list of covered ambulatory surgical center (ASC) procedures.[116] Medicare developed this list to identify surgeries that have a low to moderate risk profile. Surgeries on the ASC list of covered procedures do not involve or require major or prolonged invasion of body cavities, extensive blood loss, major blood vessels, or care that is either emergent or life threatening. Medicare annually reviews and updates this list, and includes a transparent public comment submission and review process for addition and/or removal of procedures codes.[117] The current list is accessible in the Downloads section at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html*.

In addition, to focus the measure only on the subset of surgeries on Medicare's list of covered ASC procedures that impose a meaningful risk of post-orthopedic ASC surgery hospital visits, the measure includes only ''major'' and ''minor'' procedures, as indicated by the Medicare Physician Fee Schedule global surgery indicator (GSI) values of 090 and 010, respectively. This list of GSI values is publicly available at: *https://www.cms.gov/Medicare/Medicare-fee-for-service-payment/physicianfeesched/pfs-federal-regulation-notices-items/cms-1590-fc.html* (download Addendum B). Moreover, to identify the subset of ASC procedures typically performed by orthopedists, we used the Clinical Classifications Software (CCS) developed by the Agency for Healthcare Research and Quality (AHRQ) and include in this measure procedures from AHRQ's ''operations on the musculoskeletal system'' group of procedures.[118] For more cohort details, we refer readers to the measure technical report located at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

The measure excludes patients who survived at least 7 days following orthopedic surgery at an ASC, but were not continuously enrolled in Medicare fee-for-service Parts A and B in the 7 days after surgery. These patients are excluded to ensure all patients captured under this measure have full data available for outcome assessment. There are no additional inclusion or exclusion criteria for the proposed ASC–17 measure. Additional methodology and measure development details are available at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(6) Risk Adjustment

The statistical risk-adjustment model includes 29 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within seven days following ASC orthopedic surgery. The measure risk adjusts for age, 27 comorbidities, and a variable for work Relative Value Units (RVUs) to adjust for surgical complexity.[119] Additional risk adjustment details are available in the technical report at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(7) Public Reporting

As stated above, facility-level testing showed variation in unplanned hospital visits among ASCs after adjusting for case-mix differences, which suggests variation in quality of care and opportunities for quality improvement.[120] Reliability testing showed fair measure score reliability.[121] As expected, the reliability increased for ASCs with more patients; ASCs with at least 250 cases showed moderate reliability, consistent with other publicly reported Medicare claims-based, risk-adjusted outcome measures. We proposed that if this measure were adopted, we would publicly report results only for facilities with sufficient case numbers to meet moderate reliability standards.[122] CMS will determine the case size cutoff for meeting moderate reliability standards using the intraclass correlation (ICC)

[116] Centers for Medicare and Medicaid Services. ''Ambulatory Surgical Center (ASC) Payment: Addenda Updates.'' Available at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html*.

[117] Ibid.

[118] Healthcare Cost and Utilization Project. *Clinical Classifications Software for Services and Procedures.* Available at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcproc.jsp*.

[119] S. Coberly. The Basics; Relative Value Units (RVUs). National Health Policy Forum. January 12, 2015. Available at: *http://www.nhpf.org/library/the-basics/Basics_RVUs_01-12-15.pdf*.

[120] Yale New Haven Health Services Corporation. Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf*.

[121] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159–174.

[122] Ibid.

during the measure dry run (discussed below) by testing the reliability of the scores at different case sizes in the dry run data. However, we would also provide confidential performance data directly to smaller facilities, which do not meet the criteria for sufficient case numbers for reliability considerations that would benefit from seeing their measure results and individual patient-level outcomes. These data are currently largely unknown to ASCs and providers. The validity testing results demonstrated that the measure scores are valid and useful measures of ASC orthopedic surgical quality of care and will provide ASCs with information that can be used to improve their quality of care. Detailed testing results are available in the technical report for this measure, located at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(8) Provision of Facility-Specific Information Prior To Public Reporting

In the CY 2018 OPPS/ASC proposed rule (82 FR 33694), we stated that if this proposed measure is finalized as proposed, we intend to conduct a dry run before the official data collection period or any public reporting. A dry run is a period of confidential reporting and feedback during which ASCs may review their dry-run measure results, and in addition, further familiarize themselves with the measure methodology and ask questions. For the dry-run, we intend to use the most current 2-year set of complete claims (usually 12 months prior to the start date) available at the time of dry run. For example, if the dry run began in June 2018, the most current 2-year set of data available would likely be July 2015 to June 2017. Because we use paid, final action Medicare claims, ASCs would not need to submit any additional data for the dry run. The dry run would generate confidential feedback reports for ASCs, including patient-level data indicating whether the patient had a hospital visit and, if so, the type of visit (emergency department visit, observation stay, or unplanned inpatient admission), the admitting facility, and the principal discharge diagnosis. Further, the dry run would enable ASCs to see their risk-standardized hospital visit rate prior to the measure being implemented. General information about the dry run as well as confidential facility-specific reports would be made available for ASCs to review on their accounts at: *http://www.qualitynet.org*. We plan to continue to generate these reports for ASCs after we implement the measure so ASCs can use the information to identify performance gaps and develop quality improvement strategies.

These confidential dry run results are not publicly reported and do not affect payment. We expect the dry run to take approximately one month to conduct, during which facilities would be provided the confidential report and the opportunity to review their performance and provide feedback to us. However, after the dry run, measure results would have a payment impact and be publicly reported beginning with the CY 2022 payment determination and for subsequent years as proposed. Although not previously stated in the CY 2018 OPPS/ASC proposed rule (82 FR 33694), we note that the primary purpose of the records maintained in the National Claims History system of records (SOR) is for evaluating and studying the operation and effectiveness of the Medicare program, which aligns with the purposes of the ASCQR Program and a permissible use of beneficiary information. In addition, under 45 CFR 164.506(c)(4) of the HIPAA Privacy Rule, we may disclose protected health information to another covered entity, such as the ASCs, provided that both the ASC and CMS have or had a relationship with each individual who is the subject of the PHI being requested, the PHI pertains to such relationship, and the disclosure is for the purposes of conducting quality assessment and improvement activities listed in paragraph (1) or (2) of the definition of ''health care operations'' at 45 CFR 164.501. We believe that this provision is extensive enough to cover the uses that we would expect an ASC to make of the PHI.

We invited public comment on our proposal to adopt the ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures measure beginning with the CY 2022 payment determination as discussed above.

Comment: A few commenters supported the proposed adoption of the ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures in the ASCQR Program. One of the commenters noted that these measures will provide patients with valuable data and address clinical areas critical to providers.

Response: We thank the commenters for their support. We agree that measuring quality of care associated with orthopedic procedures performed at ASCs is patient-centered and is an important clinical care area to evaluate.

Comment: Two commenters believed that the measure should be refined and resubmitted prior to rulemaking, as suggested by the MAP. Several commenters noted or were concerned that the measure lacks NQF endorsement. A few commenters also suggested that CMS seek input from the MAP on the finalized measure prior to including the measure in the program.

Response: Section 1833(h)(7)(B) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or the NQF specifically. Under this provision, the Secretary has further authority to adopt non-endorsed measures. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, broad acceptance and use of the measure, and public comments. As part of the measure development process, a national Technical Expert Panel (TEP), clinical experts, and stakeholders provided input at multiple points during development. We believe the ASC–17 measure meets these statutory requirements.

We strive to adopt NQF-endorsed measures when possible. Although ASC–17 is not currently NQF-endorsed, our research and analysis conducted during development demonstrate that the measure is accurate, valid, and actionable. We refer readers to the technical report for more information about the measure and testing results: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf*. We will submit this measure, with complete evidence, specifications, and testing results, to NQF for endorsement when an appropriate NQF project has a call for the measure.

In addition, in December 2016, the MAP Hospital Workgroup reviewed and classified the measure as ''Refine and Resubmit Prior to Rulemaking.'' [123] We understand that the measure received this classification because: (1) The measure was still undergoing field testing at the time, and (2) the MAP also recommended that the measure be submitted to the NQF for review and endorsement. Between that initial MAP review in December 2016 and the CY 2018 OPPS/ASC proposed rule, we

[123] Spreadsheet of MAP 2017 Final Recommendations. February 1, 2017. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452*.

completed field testing and refined the measure.[124] The final methodology report, which was presented in the proposed rule, included the final results of measure testing and completed measure specifications that occurred between the MAP's review in December 2016 and CMS' proposal to adopt the measure in the ASCQR Program.[125] We also intend to update the MAP at the next appropriate opportunity. As stated above, we also intend to submit the measure to the NQF for endorsement during the next appropriate call for measures.

Comment: A few commenters expressed concerns over the measure outcome. One commenter stated that it is not well proven that a hospital visit within 7 days of ASC procedure is a sign of poor quality. Similarly, one commenter suggested that CMS should adopt a measure that captures hospital visits directly tied to complications arising from orthopedic procedures performed in an ASC, and another commenter suggested that CMS exclude unrelated hospital visits. A commenter suggested that CMS remove ED visits and observation stays from the measure outcome because the ED is seen not as a healthcare resource to be avoided, but a key stabilization and decision point for patient disposition. Another commenter expressed concern about the attribution of outcomes. Specifically, the commenter flagged four of the top reasons for hospital visits within 7 days of orthopedic procedures that likely reflect routine follow-up rather than quality of care as intended by the measure.

Response: We have designed the measure to capture all unplanned hospital visits that may be a signal of poor quality of care and encourage ASCs to minimize the risk of follow-up hospital visits. The outcome captures the full range of adverse events related to undergoing orthopedic ASC surgery. We believe that the measure, as specified, has the potential to illuminate differences in quality, inform patient choice, drive quality improvement, enhance care coordination, and ultimately to minimize acute complications and reduce unplanned hospital visits following orthopedic procedures performed at ASCs.

The measure was purposely designed to evaluate all-cause hospital visits to broadly capture serious adverse events experienced by patients after undergoing orthopedic ASC procedures, rather than a narrow set of identifiable complications, for many reasons. The outcome of all-cause hospital visits is consistent with a patient-centric view of care that is designed to prompt ASC providers to minimize the risk and reduce the need for a broad range of outcomes after undergoing orthopedic ASC procedures, including the risk of dehydration, nausea and vomiting, dizziness, and urinary retention. Measuring only hospital visits that are overtly related to a procedure, such as visits for pain and bleeding, would limit the measure's intended broad impact on quality improvement efforts.

Furthermore, the rate of hospital visits is not expected to be zero, since some patients will have visits for reasons unrelated to the procedure. In designing the measure, we narrowed the measure to include surgical procedure that: (1) Are routinely performed at ASCs; (2) involve increased risk of post-surgery hospital visits; and (3) are routinely performed by orthopedists. In addition, the measure is risk adjusted for patient demographics, clinical characteristics, and surgical procedural complexity, so that facilities that experience more unrelated visits due to a generally higher-risk patient mix will not be disadvantaged. We refer readers to the methods section in the measure specifications for more information about the risk-adjustment methodology.

In addition, we only measure the rate of *unplanned* hospital admissions; ED visits and observation stays are never considered planned.[126] [127] This approach removes from the outcome admissions that are not a signal of quality of care, because they represent: (1) A condition or diagnosis that is considered to be always planned (such as transplants or maintenance chemotherapy); or (2) that are considered potentially planned (such as cardiovascular procedures) and are not accompanied by an acute diagnosis. The planned admission algorithm is based on CMS' widely-used Planned Readmission Algorithm v4.0.[128] We refer readers to the measure methodology report at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* for more details.

Furthermore, we disagree with the commenter's suggestion that we remove ED visits and observation stays from the measure outcome, because these are unplanned visits for patients undergoing low- to moderate-risk outpatient procedures. From a patient perspective, we believe that ED visits and observation stays are an undesirable outcome. We believe a quality measure assessing hospital visits following ASC surgery will serve to improve transparency, inform patients and providers, and foster quality improvement, because providers at ASCs are often unaware of patients' subsequent acute care visits given that patients tend to present to the emergency department or to hospitals unaffiliated with the ASC. Moreover, the measure outcome of hospital visits within 7 days after a procedure aligns with the NQF-endorsed measure Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy Measure (NQF #2539).

Regarding the commenter's concerns about the attribution of outcomes and whether hospital visits within 7 days of ASC procedure is a sign of poor quality, we believe that the measure captures the full range of potentially serious adverse events related to orthopedic procedures performed as ASCs. We limited the outcome timeframe for hospital visits (ED visits, observation stays, and unplanned admissions) to 7 days because existing literature suggests that the vast majority of adverse events after an orthopedic procedure occur within the first 7 days following the procedure and because the highest rates of hospital visits were observed in claims data within 7 days following the procedure.[129] [130] A 7-day timeframe helps to ensure that the measure will capture adverse events following the procedure, but will not capture events impacted by factors unrelated to the

[124] MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals. Final Report. February 15, 2017. Available at: *http://www.qualityforum.org/Publications/2017/02/2017_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx*.

[125] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE). Measure Technical Report: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf*.

[126] Horwitz, Leora I., et al. ''Development and validation of an algorithm to identify planned readmissions from claims data.'' *Journal of hospital medicine* 10.10 (2015): 670–677.

[127] Ranasinghe, Isuru, et al. ''Differences in colonoscopy quality among facilities: development of a post-colonoscopy risk-standardized rate of unplanned hospital visits.'' *Gastroenterology* 150.1 (2016): 103–113.

[128] Ibid.

[129] Mattila K, Toivonen J, Janhunen L, Rosenberg PH, Hynynen M. Postdischarge symptoms after ambulatory surgery: First-week incidence, intensity, and risk factors. Anesthesia and Analgesia. 2005;101(6):1643–1650.

[130] Fleisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly patients: Importance of patient and system characteristics and location of care. Archives of Surgery. 2004;139(1):67–72.

care patients received.[131] We appreciate the commenter's careful review of the top hospital visit diagnoses within seven days of orthopedic procedures. We welcome specific examples of potentially planned admissions following outpatient orthopedic procedures.

Comment: One commenter suggested that CMS provide a detailed clinical review of all the measure results by several seasoned orthopedic surgeons to ensure the measure algorithm is appropriate.

Response: In developing the measure, we incorporated significant input from various experts and stakeholders. In addition to the MUC and MAP processes described above, a multidisciplinary team of clinicians, health services researchers, and statisticians were informed, in part, by a national TEP consisting of patients, methodologists, researchers, and providers, including orthopedists who conducted a detailed clinical review of all the measure results to ensure the measure algorithm is appropriate. We also held a public comment period soliciting stakeholder input on the measure methodology, including the planned admission algorithm. However, we will continue to evaluate the measure as our goal is to ensure that the measure accurately reflects the quality of care provided in ASCs.

We appreciate the commenter's careful review of the top hospital visit diagnoses within seven days of orthopedic procedures. We welcome specific examples of potentially planned admissions following outpatient orthopedic procedures.

Comment: Some commenters were concerned that ASCs may not have actionable information generated from ASC–17. Specifically, some commenters did not support adoption of the measure, because measure score calculation relies on retrospective claims data. The commenters expressed concerns that the delay in providing data to facilities would provide limited usefulness for quality improvement or for consumers in choosing an ASC facility. Regarding a similar measure, ASC–12 Facility Risk-Standardized Visit Rate after Outpatient Colonoscopy, one commenter noted that in their members' experience with the confidential feedback reports, facilities were already aware of most of the visits in the claims detail report and did not review the reports unless the facilities were categorized as underperforming. The commenter also questioned the usefulness of the measure to make distinction among facilities and to consumers, because the performance for the overwhelming majority of the facilities would be no different than expected.

Response: We acknowledge the commenters' concerns regarding the use of claims data for the ASC–17 measure; however, the measure would provide facilities with the most recently available, patient-level data to help guide quality improvement efforts that would also be low burden.

Further, we believe that measures of hospital events following specific types of surgical procedures fully based on Medicare FFS claims recently adopted (for example, ASC–12: Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy Measure) and including those newly finalized in this final rule with comment period (that is, ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures and ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures) will better inform Medicare beneficiaries and other consumers about post-procedure complication rates. Existing ASC quality measures tend to focus on very rare, patient safety-related events. For example, ASC–3 counts cases in which a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant event occurred (76 FR 74499).[132] Measures designed to capture more common adverse outcomes that patients experience, such as pain, bleeding, urinary retention, and other complications, prompting acute care hospital visits or admissions are lacking at this time, and this is what this measure is intended to accomplish.

While we appreciate the commenter's feedback that some ASCs were already aware of most of the visits in the claims detail report and did not review the reports unless the facilities were categorized as underperforming, that is not always the case. Providers at ASCs are often unaware of patients' subsequent acute care visits given that separate providers (for example, emergency department physicians) tend to provide post-surgical care when it is required.[133] This measure is intended to bring greater awareness to a larger number of ASCs and patients, in addition to actionable information to lower the rate of preventable adverse events and to improve the quality of care following procedures performed at an ASC.

Although the majority of ASCs would be expected to have risk-standardized rates that would be classified as ''no different than the national rate'' on *Hospital Compare,* we believe that the measure will be able to make distinction among facilities and to consumers because the variation in risk-standardized hospital visit rates across ASCs nationally suggests that there is still room for quality improvement. *Hospital Compare* will also report facilities' risk-standardized rates, and facilities will receive confidential feedback reports to support quality improvement efforts. Furthermore, feedback from national TEP members showed that the ASC–17 measure, as specified, can be used to distinguish between better and worse quality facilities.[134] This shows TEP agreement with the overall face validity of the measure.

Comment: A few commenters expressed concerns about risk adjustment. A commenter noted that the measure is not risk adjusted to account for socioeconomic status and other factors beyond an ASC's control. Another commenter noted that successful application of risk stratification methods must be accomplished before using claims data, especially with the move from traditionally inpatient procedures to the outpatient and ambulatory settings. A third commenter expressed a concern about including condition category (CC 82), Respirator dependence/tracheostomy status, on the list of condition categories that are not risk-adjusted if the condition occurs only at the time of the procedure. The commenter noted that this type of condition is not something that develops acutely within the timeframe of an ASC procedure, but rather is reflective of a more chronic patient condition.

Response: We understand the important role that factors outside of an ASC's control, for example, socioeconomic and sociodemographic status, play in the care of patients.

[131] Parry, Nicola. ''7-Day Readmissions: Better Indicators of Patient Care.'' *Medscape,* 2016.

[132] Centers for Medicare & Medicaid Services. Ambulatory Surgical Center Quality Reporting Specifications Manual Release Notes Version: 6.0. 2016; *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754.* Accessed July 13, 2016.

[133] Mezei G, Chung F. Return hospital visits and hospital readmissions after ambulatory surgery. Annals of Surgery. 1999;230(5):721–727.

[134] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE). Measure Technical Report: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf.*

Although the risk-adjustment methodology does not stratify by social risk factors, it does account for risk by adjusting for risk factors associated with increased risk for hospital visits after surgery. In developing this measure, we evaluated the potential effects of risk adjusting for three socioeconomic status (SES) factors that are available in CMS claims (Medicaid dual-eligibility status, African-American race, and the AHRQ SES index). Our results show that adjusting for these three factors at the patient level do not change the measure scores. We assessed the relationship of SES to hospital visits at the patient and facility levels. Unadjusted and adjusted ASC-level risk-standardized hospital visit rates were highly correlated (Spearman correlation coefficients of nearly 1.0) when calculated with and without the addition of the three SES variables (Medicaid dual-eligibility status, African-American race, and the AHRQ SES index). This indicates that including SES variables in the ASC-level risk-adjusted measure score will result in limited differences in measure results after accounting for other risk factors, such as age and comorbidities. We refer readers to the methodology in the measure specifications for more information about SES testing for this measure at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. We also refer readers to section XIV.B.2. of this final rule with comment period where we discuss social risk factors in the ASCQR Program in more detail.

In addition, analyses of ASCs categorized into quartiles based on proportions of Medicaid dual-eligible patients, of African-American patients, and of low-SES patients (as identified by the AHRQ SES index),[135] showed largely overlapping distributions (with similar median values) of the risk-standardized hospital visit rates (RSHVRs) by quartile. This means that facilities serving larger proportions of low-SES patients perform similarly to facilities serving lower proportions of low-SES patients.

Furthermore, we appreciate the commenter's concern about including condition category (CC) 82 on the list of condition categories that are not risk-adjusted for if they occur only at the time of the procedure.[136] Condition categories are used to classify diagnoses into clinically coherent groups.[137] We consolidated like risk factors into candidate variables, which were the variables that we considered for the risk-adjustment model. We agree with the commenter for noting that CC 82 is unlikely to develop acutely during the timeframe of a procedure; we will review this group of codes and will consider revising the list of CCs that are not risk-adjusted for if the condition occurs at the time of the procedure. As explained above, this measure was reviewed using a consensus-driven approach, with input from a national TEP and surgeons, including orthopedists, providing care in the ASC setting. Potential candidate risk factors and condition categories were identified from related quality measures and the literature; [138] [139] a preliminary list of risk factors was developed and then revised based on national TEP and clinical expert review that included several orthopedists. These risk variables were further released and reviewed during the measure development public comment period prior to the selection of the final model.[140] This consensus-based approach was used to achieve clinical face validity prior to the model selection.

Comment: One commenter suggested that the ASC–17 should not be tied to payment or measure procedures until after the first year of provision in the ASC setting and noted concern that doing so at the outset would not accurately reflect quality and risks incentivizing hospital services over ASCs. Another commenter noted that ASCs still receive a full payment update even if the ASCs are not involved in the measure.

Response: We thank the commenters for their suggestions regarding the link of the ASC–17 measure to payment. We do not believe that the measure risks incentivizing hospital services over ASCs. The ASCQR Program is a pay-for-reporting quality data program. This means that payments under our pay-for-reporting quality data program are tied to reporting of the measures in the form and manner specified, not to specific performance on the measures, like for pay-for-performance programs (for example, the Hospital VBP Program (82 FR 38240)). In addition, we believe that the measure does indeed reflect quality. Feedback from national TEP members showed that the ASC–17 measure, as specified, can be used to distinguish between better and worse quality facilities.[141] This shows TEP agreement with the overall face validity of the measure.

We note that while ASCs will not be required to submit additional data for measure calculation, because this is a claims-based measure, we strongly encourage ASCs to review measure scores to improve quality of care and patient outcomes. The detailed feedback reports, which provide information on every procedure performed during the performance period and the details of the hospital visits within seven days of the orthopedic procedure, will enable ASCs to understand the post-surgical hospital visit patterns. We believe this will help to facilitate ASCs to tailor clinical and educational interventions with the goal of reducing or eliminating the risk of hospital visits for complication of an orthopedic surgery. We also believe that the measure will facilitate improvements via public reporting by informing the general public and ASCs even if particular ASCs are not active in the measure.

Comment: A few commenters expressed concerns about the reliability of the measure. One commenter noted that low-volume situations tend to produce measure scores that lack reliability. The commenter noted that the measure is only ''fairly'' reliable and suggested the reliability for a measure intended for public reporting should be substantially reliable, or have an ICC of 0.61 to 0.80. Furthermore, the commenter noted that the measure also suffers from limited discriminatory power because the number of underperforming facilities is very small.

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[135] Bonito A, Bann C, Eicheldinger C, Carpenter L. Creation of new race-ethnicity codes and socioeconomic status (SES) indicators for Medicare beneficiaries. RTI International, *Agency for Healthcare Research and Quality*. 2008.

[136] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE). Measure Technical Report: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf*.

[137] HCUP CCS Fact Sheet. Healthcare Cost and Utilization Project (HCUP). January 2012. Agency for Healthcare Research and Quality, Rockville, MD. *https://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccsfactsheet.jsp*.

[138] Sherman SL, Lyman S, Koulouvaris P, Willis A, Marx RG. Risk factors for readmission and revision surgery following rotator cuff repair. Clinical Orthopaedics and Related Research. 2008;466(3):608–613.

[139] Fleisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly patients: Importance of patient and system characteristics and location of care. Archives of Surgery. 2004;139(1):67–72.

[140] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE). Measure Technical Report: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf*.

[141] Ibid.

The commenter urged CMS to ensure that the publicly reported scores are reliable. A few commenters expressed concern about the reliability of the measure for public reporting.

Response: We thank the commenters for their feedback about the measure reliability. We disagree with the commenters and believe that ASC–17 is sufficiently reliable to be included in the ASCQR Program. Our calculated intraclass correlation coefficient (ICC),[142] a measure of reliability or the degree to which the measure can produce accurate and consistent results across multiple measurements of the same entities in a time period, for this measure was 0.226.[143] The NQF considers ICC values ranging from 0.01–0.20 as ''slight'' reliability, 0.21–0.40 as ''fair'' reliability, 0.41 to 0.60 as ''moderate'' reliability, and 0.61 to 0.80 as ''strong'' reliability.[144] Although this value indicates fair measure score reliability,[145] we recognize that it is lower than for other claims-based outcomes measures developed by CMS.[146] However, as we would expect, the ICC increases for ASCs with more patients.[147] We disagree that the measure reliability should be ''substantially'' reliable, or have an ICC of 0.61 to 0.80, and believe the publicly reported scores will be sufficiently reliable based on results showing increased reliability with increased case numbers.[148] Specifically, for ASCs with at least 250 cases in each of the two samples, the ICC was 0.359, which reflects better reliability that is more consistent with previously developed measures.[149] During the measure dry run, we intend to determine the case size cutoff for meeting moderate reliability standards using the ICC by testing the reliability of the scores at different case sizes in the dry run data. In the 4-year data set, of the 3,075 ASCs, 467 (15.2 percent) had 250 or more procedures, accounting for 57.3 percent of all procedures in the measure cohort.[150]

Regarding the comment about lack of discriminatory power, we agree that the many small-volume ASCs will limit the ability to make distinctions in performance between facilities. ASCs with few cases in a given year limit our ability to capture variation in ASC-level measure scores because our modeling methodology is conservative and will estimate measure scores toward the national mean for facilities with small volumes. Specifically, ASCs with relatively few cases in the performance period may have a true rate that is worse/better than the national average. However, the model estimates their rate as close to the mean because their low volume does not provide enough information to accurately estimate a value near their true rate. As a result, the model may capture less variation than truly exists due to low case sizes. To improve the measure's ability to detect quality differences, we crafted our proposal to use 2 years of data for public reporting to expand the number of cases available for estimating rates across all facilities and to increase both the reliability of the measure score and the ability to discriminate performance across facilities. Furthermore, ASC facilities that have too few cases to reliably estimate a measure score (moderate reliability as discussed in the prior paragraph) would be treated in the same way as other facilities with too few cases and would not have their scores posted on *Hospital Compare;* their data would be replaced with a footnote. We discuss our *Hospital Compare* footnotes at: *https://www.medicare.gov/hospitalcompare/data/Footnotes.html.* However, these facilities will still receive confidential feedback reports/facility-specific reports providing valuable information about post-surgery events. We refer readers to section XIV.B.6.b.(7) of this final rule with comment period for more details about public reporting of this measure. We expect that smaller ASCs will still benefit from confidentially reviewing their measure results and individual patient-level outcomes in the facility-specific report, as these data are currently largely unknown to ASCs and providers.

Comment: One commenter requested that the dry run results be aggregated and made available in its entirety to the public for review and comment if the measure is finalized. The commenter also suggested that CMS conduct pilot testing for the measure with volunteer ASCs rather than conduct national dry runs.

Response: We refer readers to section XIV.B.6.b.(7) of this final rule with comment period where we discuss our dry run. The intent of the dry run is to test production of the measure and for ASCs to familiarize themselves with the measure and provide feedback to us. The dry run will generate confidential feedback reports for ASCs on measure performance and risk-standardized hospital visit rates, among other data. We plan to perform a dry run of the measure prior to implementation. The confidential dry run results will not be publicly reported or used for payment determination. We believe a dry run will be more beneficial than pilot testing. The dry run will include all ASCs rather than just a subset of volunteer ASCs and will enable all ASCs to gain familiarity with the measure and processes, as well as provide feedback to CMS on both the measure itself and the reports. This will also enable CMS to learn about any unanticipated nuances associated with measure implementation.

As proposed, we will not publicly report data for this measure until the CY 2022 payment determination and subsequent years. We do not believe publicly reporting data from the dry run is appropriate as we might still be working out unanticipated nuances; the data is preliminary and is therefore subject to change based on feedback provided by ASCs.

Comment: A commenter noted that although CMS believes that there would not be any additional burden because ASCs are not required to submit additional data, reviewing claims detail reports and measure scores would be associated with additional burden for someone at ASCs, likely a clinician.

Response: We thank the commenter for providing this input and acknowledge that this measure will be calculated completely from data already obtained from paid Medicare FFS claims submitted by ASCs, hospitals,

[142] Landis J, Koch G. The measurement of observer agreement for categorical data, Biometrics 1977;33:159–174.

[143] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE). Measure Technical Report: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf.*

[144] Landis J, Koch G. The measurement of observer agreement for categorical data, Biometrics 1977;33:159–174.

[145] The NQF considers ICC values ranging from 0.01–0.20 as ''slight'' reliability, 0.21–0.40 as ''fair'' reliability, 0.41 to 0.60 as ''moderate'' reliability, and 0.61 to 0.80 as ''strong'' reliability. *http://www.qualityforum.org/Measuring_Performance/Improving_NQF_Process/Measure_Testing_Task_Force_Final_Report.aspx.*

[146] See the Risk-Standardized Hospital Visits within 7 Days After Hospital Outpatient Surgery Measure. For ICC score of 0.50: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Hospital-Visits-after-Hospital-Outpatient-Surgery-Measure.pdf.*

[147] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE). Measure Technical Report: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf.*

[148] Ibid.

[149] Ibid.

[150] Ibid.

and physicians for billing purposes. Because claims data are used, there is no burden on the part of ASCs to submit additional data for measure calculation. We strongly suggest that facilities allocate time to review their feedback report, because they contain actionable information to identify performance gaps and further develop quality improvement strategies. However, we note that these activities do not represent burden related to program requirements.

After consideration of the public comments we received, we are finalizing the proposal to adopt the ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures measure in the ASCQR Program for the CY 2022 payment determination and subsequent years, as proposed.

c. Adoption of ASC–18: Hospital Visits After Urology Ambulatory Surgical Center Procedures Beginning With the CY 2022 Payment Determination

(1) Background

As the number of urology procedures performed in ASCs increases, it is of increasing importance to report the quality of care provided to patients undergoing these procedures. One study found that urology procedures accounted for 4.8 percent of unanticipated admissions, and that urology surgery patients were almost twice as likely as orthopedics, plastic surgery, or neurosurgery to be admitted following surgery.[151] Similarly, a recent study found outpatient urology surgery has an overall 3.7 percent readmission rate.[152] A third study using a 5-percent national sample of Medicare beneficiaries ages 65 and older who underwent one of 22 common outpatient urologic procedures at ASCs from 1998 to 2006 found a 7.9 percent 30-day risk-adjusted rate of inpatient admission following surgery, with more frequent same-day admissions following outpatient surgery at ASCs than at hospitals.[153]

Because urology surgery performed at an ASC is a significant predictive factor for unanticipated admissions compared to other procedures,[154] we believe measuring and reporting 7-day unplanned hospital visits following urology procedures will incentivize ASCs to improve care and care transitions. Many of the reasons for hospital visits following surgery at an ASC are preventable; patients often present to the hospital following urology surgery for complications of medical care, including urinary tract infection, calculus of the ureter, urinary retention, hematuria, and septicemia.[155] However, increased patient and staff education present opportunities to improve the success rate of urology surgeries in ASCs.[156] Therefore, we believe tracking and reporting these events would facilitate efforts to lower the rate of preventable adverse events and to improve the quality of care following urology procedures performed at an ASC.

(2) Overview of Measure

We believe it is important to minimize adverse patient outcomes associated with urology ASC surgeries. Therefore, in the CY 2018 OPPS/ASC proposed rule (82 FR 33695), we proposed to adopt the ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures measure in the ASCQR Program for the CY 2022 payment determination and subsequent years. We expect the measure would promote improvement in patient care over time, because measurement coupled with transparency in publicly reporting measure information would make the rate of unplanned hospital visits (emergency department visits, observation stays, and unplanned inpatient admissions) following urology procedures at ASCs more visible to both ASCs and patients, and would incentivize ASCs to incorporate quality improvement activities to reduce these unplanned hospital visits. The measure also addresses the CMS National Quality Strategy domains of making care safer by reducing harm caused in the delivery of care and promoting effective communication and coordination of care.

Section 1890A of the Act requires the Secretary to establish a prerulemaking process with respect to the selection of certain categories of quality and efficiency measures. Under section 1890A(a)(2) of the Act, the Secretary must make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering for the Medicare program. The ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures measure was included on a publicly available document entitled ''List of Measures under Consideration for December 1, 2016.'' [157] The MAP reviewed this measure (MUC16–153) and recommended that this measure be refined and resubmitted prior to adoption by the ASCQR Program because, at the time of the MAP's review, this measure was still undergoing field testing. The Workgroup stated testing results should demonstrate reliability and validity at the facility level in the ambulatory surgical setting, and recommended this measure be submitted to NQF for review and endorsement.[158]

Since the MAP's review and recommendation of 'Refine and Resubmit' in 2016, we have completed testing for this measure and continued to refine this proposed measure in response to the MAP's recommendations. Results of continued development activities, including stakeholder feedback from the public comment period and pilot test findings will be presented to the MAP during the MAP feedback loop meeting in fall 2017. The proposed measure is consistent with the information submitted to the MAP, and the original MAP submission and our continued refinements support its scientific acceptability for use in quality reporting programs. Facility-level testing showed significant variation in unplanned hospital visits among ASCs after adjusting for case-mix differences, which suggests variation in quality of care. Our testing found moderate measure score reliability [159] for this measure, which is consistent with existing measures of patient outcomes in the ASC setting, such as ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (described in the CY 2015 OPPS/ASC final rule with comment period at 79 FR 66973). Validity testing demonstrated that the measure scores

[151] Fortier J. Unanticipated Admission after Ambulatory Surgery—A Prospective Study. Canadian Journal of Anaesthesia. 1998;45(7):612–619.

[152] Rambachan A. Predictors of Readmission Following Outpatient Urological Surgery, Annals of the Royal College of Surgeons of England. Journal of Urology. 2014;192(1):183–188.

[153] Hollingsworth JM. Surgical Quality Among Medicare Beneficiaries Undergoing Outpatient Urological Surgery. The Journal of Urology. 2012;188(4):1274–1278.

[154] Fortier J. Unanticipated Admission after Ambulatory Surgery—A Prospective Study. Canadian Journal of Anaesthesia. 1998;45(7):612–619.

[155] Paez A. Adverse Events and Readmissions after Day-Care Urological Surgery. International Brazilian Journal of Urology. 2007;33(3):330–338.

[156] Ibid.

[157] National Quality Forum. *List of Measures under Consideration for December 1, 2016.* National Quality Forum, Dec. 2016. Available at: *http://www.qualityforum.org/map/.*

[158] National Quality Forum. 2016–2017 Spreadsheet of Final Recommendations to HHS and CMS, available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

[159] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159–174.

identify differences in quality across facilities. Detailed testing results are available in the technical report for this measure, located at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

Sections 1833(i)(7)(B) and 1833(t)(17)(C)(i) of the Act, when read together, require the Secretary, except as the Secretary may otherwise provide, to develop measures appropriate for the measurement of the quality of care furnished by ASCs that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by one or more national consensus building entities. However, we note that section 1833(i)(7)(B) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or by the NQF specifically. Further, under section 1833(i)(7)(B) of the Act, section 1833(t)(17)(C)(i) of the Act applies to the ASCQR Program, except as the Secretary may otherwise provide. Under this provision, the Secretary has further authority to adopt non-endorsed measures. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe that consensus among affected parties can be reflected through means other than NQF endorsement, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment. We believe this proposed measure meets these statutory requirements.

The proposed ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures measure is not currently NQF-endorsed. However, we intend to submit this measure for review and endorsement by the NQF once an appropriate measure endorsement project has a call for measures. We believe that this measure is appropriate for the measurement of quality care furnished by ASCs because urology procedures are becoming increasingly common in ASCs and, as discussed above, can signify unanticipated admissions after care provided in ASCs. Such visits are an unexpected and potentially preventable outcome for patients with a low anticipated perioperative risk. We also believe this measure depicts consensus among affected parties, as it was developed with stakeholder input from both a Technical Expert Panel convened by a contractor as well as the measure development public comment period.[160] During the MAP and measure development processes, public commenters supported the measure's focus on assessing patient outcomes after urology ASC and agreed that the measure would be meaningful and improve quality of care. In addition, the ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures measure addresses the MAP-identified priority measure area of surgical complications for the ASCQR Program.[161] Therefore, we believe it is appropriate to incorporate this measure into the ASCQR Program measure set because collecting and publicly reporting this data will improve transparency, inform patients and providers, and foster quality improvement efforts.

(3) Data Sources

This measure is claims-based and uses Part A and Part B Medicare administrative claims and Medicare enrollment data to calculate the measure.

We proposed that the data collection period for the proposed ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures measure would be the 2 calendar years ending 2 years prior to the applicable payment determination year. For example, for the CY 2022 payment determination, the data collection period would be CY 2019 to 2020. Because these measure data are collected via claims, ASCs will not need to submit any additional data directly to CMS. We refer readers to section XIV.D.4. of this final rule with comment period for a more detailed discussion of the requirements for data submitted via claims.

(4) Measure Calculations

The measure outcome is all-cause, unplanned hospital visit occurring within seven days of the urology procedure performed at an ASC. For the purpose of this measure, ''hospital visits'' include emergency department visits, observation stays, and unplanned inpatient admissions. When there are two or more qualifying surgical procedures within a 7-day period, the measure considers all procedures as index procedures. However, the timeframe for outcome assessment is defined as the interval between procedures (including the day of the next procedure) and then 7 days after the last procedure.

The facility-level score is a risk-standardized hospital visit rate, calculated by multiplying the ratio of the predicted to the expected number of postsurgical hospital visits among the given ASC's patients by the national observed hospital visit rate for all ASCs. For each ASC, the numerator of the ratio is the number of hospital visits predicted for the ASC's patients accounting for its observed rate, the number of the urology procedures performed at the ASCs, the case-mix, and the surgical complexity mix. The denominator of the ratio is the expected number of hospital visits given the ASC's case-mix and surgical complexity mix. A ratio of less than one indicates the ASC facility's patients were estimated as having fewer post-surgical visits than expected compared to ASCs with similar surgical complexity and patients; and a ratio of greater than one indicates the ASC facility's patients were estimated as having more visits than expected. The national observed hospital visit rate is the national unadjusted proportion of patients who had a hospital visit following a urology ASC surgery. For more information on measure calculations, we refer readers to: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

(5) Cohort

The patient cohort for the proposed ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures measure includes all Medicare beneficiaries ages 65 and older undergoing outpatient urology procedures at an ASC who have 12 prior months of Medicare fee-for-service Parts A and B enrollment. The target group of procedures are those that: (1) Are routinely performed at ASCs; (2) involve increased risk of post-surgery hospital visits; and (3) are routinely performed by urologists.

Procedures included in the measure cohort are on Medicare's list of covered ambulatory surgical center (ASC) procedures.[162] Medicare developed this

[160] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE). Public Comment Summary Report: Development of Facility-Level Quality Measures of Unplanned Hospital Visits after Selected Ambulatory Surgical Center Procedures. Fall 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html.*

[161] National Quality Forum. ''MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals.'' Report. 2017. Available at: *http://www.qualityforum.org/map/* under ''Hospitals—Final Report.''

[162] Centers for Medicare and Medicaid Services. ''Ambulatory Surgical Center (ASC) Payment: Addenda Updates.'' Available at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html.*

list to identify surgeries have a low to moderate risk profile. Surgeries on the ASC list of covered procedures do not involve or require major or prolonged invasion of body cavities, extensive blood loss, major blood vessels, or care that is either emergent or life threatening.[163] Medicare annually reviews and updates this list, and includes a transparent public comment submission and review process for addition and/or removal of procedures codes.[164] The current list is accessible in the Downloads section at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html*. In addition, to focus the measure only on the subset of surgeries on Medicare's list of covered ASC procedures that impose a meaningful risk of post-urology ASC surgery hospital visits, the measure includes only ''major'' and ''minor'' procedures, as indicated by the MPFS global surgery indicator (GSI) values of 090 and 010, respectively, and therapeutic cystoscopy procedures. This list of GSI values is publicly available at: *https://www.cms.gov/Medicare/Medicare-fee-for-service-payment/physicianfeesched/pfs-federal-regulation-notices-items/cms-1590-fc.html* (download Addendum B). Moreover, to identify the subset of ASC procedures typically performed by urologists, we used the Clinical Classifications Software (CCS) developed by the Agency for Healthcare Research and Quality (AHRQ) and include in this measure procedures from two of AHRQ's categories, ''operations on the urinary system'' and ''operations on the male genital organs.'' [165] For more cohort details, we refer readers to the measure technical report located at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

The measure excludes patients who survived at least 7 days following a urology procedure at an ASC, but were not continuously enrolled in Medicare fee-for-service Parts A and B in the 7 days after surgery. These patients are excluded to ensure all patients captured under this measure have full data available for outcome assessment. There are no additional inclusion or exclusion criteria for the proposed ASC–18 measure. Additional methodology and measure development details are available at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(6) Risk Adjustment

The statistical risk-adjustment model includes nine clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within seven days following ASC urology surgery. The measure risk adjusts for age, six comorbidities, number of qualifying procedures, and work Relative Value Units (RVUs) to adjust for surgical complexity.[166] Additional risk adjustment details are available in the technical report at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(7) Public Reporting

As stated above, facility-level testing showed variation in unplanned hospital visits among ASCs after adjusting for case-mix differences, which suggests variation in quality of care and opportunities for quality improvement.[167] Reliability testing showed fair measure score reliability.[168] As expected, the reliability increased for ASCs with more patients; ASCs with at least 250 cases showed moderate reliability, consistent with other publicly reported Medicare claims-based, risk-adjusted outcome measures. In the CY 2018 OPPS/ASC proposed rule (82 FR 33694), we noted that if this measure is adopted, we proposed to publicly report results only for facilities with sufficient case numbers to meet moderate reliability standards.[169] CMS will determine the case size cutoff for meeting moderate reliability standards using the intraclass correlation (ICC) during the measure dry run (discussed below) by testing the reliability of the scores at different case sizes in the dry run data. However, we would also provide confidential performance data directly to smaller facilities which do not meet the criteria for sufficient case numbers for reliability considerations that would benefit from seeing their measure results and individual patient-level outcomes, as these data are currently largely unknown to ASCs and providers. The validity testing results demonstrated that the measure scores are valid and useful measures of ASC urology surgical quality of care and will provide ASCs with information that can be used to improve their quality of care. Detailed testing results are available in the technical report for this measure, located at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(8) Provision of Facility-Specific Information Prior to Public Reporting

In the CY 2018 OPPS/ASC proposed rule (82 FR 33694), we noted that if this proposed measure is finalized, but before the official data collection period or public reporting for the proposed ASC–18 measure, we intend to conduct a dry run. A dry run is a period of confidential feedback during which ASCs may review their dry-run measure results, and in addition, further familiarize themselves with the measure methodology, and ask questions. For the dry-run, we intend to use the most current 2-year set of complete claims (usually 12 months prior to the start date) available at the time of dry run. For example, if the dry run began in June 2018, the most current 2-year set of data available would likely be July 2015 to June 2017. Because we use paid, final action Medicare claims, ASCs would not need to submit any additional data for the dry run. The dry run would generate confidential feedback reports for ASCs, including patient-level data indicating whether the patient had a hospital visit and, if so, the type of visit (emergency department visit, observation stay, or unplanned inpatient admission), the admitting facility, and the principal discharge diagnosis. Further, the dry run would enable ASCs to see their risk-standardized hospital visit rate prior to the measure being implemented. General information about the dry run as well as confidential facility-specific reports would be made available for ASCs to review on their accounts at: *http://www.qualitynet.org*. We intend to continue to generate these reports for ASCs after we implement the measure so ASCs can use the information to identify performance gaps and develop quality improvement strategies.

The confidential dry run results are not publicly reported and do not affect payment. We expect the dry run to take

[163] Ibid.

[164] Ibid.

[165] Healthcare Cost and Utilization Project. *Clinical Classifications Software for Services and Procedures.* Available at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcproc.jsp*.

[166] S. Coberly. The Basics; Relative Value Units (RVUs). National Health Policy Forum. January 12, 2015. Available at: *http://www.nhpf.org/library/the-basics/Basics_RVUs_01-12-15.pdf*.

[167] Yale New Haven Health Services Corporation. Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf*.

[168] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159–174.

[169] Ibid.

approximately one month to conduct, during which facilities would be provided the confidential report and the opportunity to review their performance and provide feedback to us. However, after the dry run, measure results would have a payment impact and would be publicly reported beginning with the CY 2022 payment determination and for subsequent years as proposed. Although not previously stated in the CY 2018 OPPS/ASC proposed rule (82 FR 33694), we note that the primary purpose of the records maintained in the National Claims History system of records (SOR) is for evaluating and studying the operation and effectiveness of the Medicare program, which aligns with the purposes of the ASCQR Program and a permissible use of beneficiary information. In addition, under 45 CFR 164.506(c)(4) of the HIPAA Privacy Rule, we may disclose protected health information to another covered entity, such as the ASCs, provided that both the ASC and CMS have or had a relationship with each individual who is the subject of the PHI being requested, the PHI pertains to such relationship, and the disclosure is for the purposes of conducting quality assessment and improvement activities listed in paragraph (1) or (2) of the definition of ''health care operations'' at 45 CFR 164.501. We believe that this provision is extensive enough to cover the uses that we would expect an ASC to make of the PHI.

We invited public comment on our proposal to adopt the ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures measure beginning with the CY 2022 payment determination as discussed above.

Comment: A few commenters supported the proposed adoption of the ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures measure in the ASCQR Program. One of the commenters noted that the measure will provide patients with valuable data and address clinical areas critical to providers.

Response: We thank the commenters for their support. We agree that measuring quality of care associated with urology procedures performed at ASCs is patient-centered and is an important clinical care area to evaluate.

Comment: A few commenters believed that the measure should be refined and resubmitted prior to rulemaking, as suggested by the MAP. Several commenters noted or were concerned that the measure lacks NQF endorsement. A few commenters also suggested that CMS seek input from the MAP on the finalized measure prior to proposing for inclusion in the program.

Response: Section 1833(h)(7)(B) of the Act does not require that each measure we adopt for the ASCQR Program be endorsed by a national consensus building entity, or the NQF specifically. Under this provision, the Secretary has further authority to adopt non-endorsed measures. As stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74465 and 74505), we believe the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, broad acceptance and use of the measure, and public comments. As part of the measure development process, a national Technical Expert Panel (TEP), clinical experts, and stakeholders provided input at multiple points during development. We believe the ASC–18 measure meets these statutory requirements.

We strive to adopt NQF-endorsed measures when possible. Although ASC–18 is not currently NQF-endorsed, our research and analysis conducted during development demonstrate that the measure is accurate, valid, and actionable. We refer readers to the technical report for more information about the measure and testing results: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Urology-ASC-Procedures_Measure-Technical-Report_052017.pdf*. We will submit this measure, with complete evidence, specifications, and testing results, to NQF for endorsement when an appropriate NQF project has a call for the measure.

In addition, in December 2016, the MAP Hospital Workgroup reviewed and classified the measure as ''Refine and Resubmit Prior to Rulemaking.'' [170] We understand that the measure received this classification because: (1) The measure was still undergoing field testing at the time, and (2) the MAP also recommended that the measure be submitted to the NQF for review and endorsement. Between that initial MAP review in December 2016 and the CY 2018 OPPS/ASC proposed rule, we completed field testing and refined the measure.[171] The final methodology report, which was presented in the proposed rule, included the final results of measure testing and completed measure specifications that occurred between the MAP's review in December 2016 and CMS' proposal to adopt the measure in the ASCQR Program.[172] We also intend to update the MAP at the next appropriate opportunity. As stated above, we also intend to submit the measure to the NQF for endorsement during the next appropriate call for measures.

Comment: A commenter expressed concern about the attribution of outcomes. Specifically, the commenter flagged eight of the top reasons for hospital visits within 7 days of urologic procedures that likely reflect routine follow-up rather than quality of care as intended by the measure. Another commenter suggested that CMS develop a numerator exclusion for unrelated hospital visits.

Response: We acknowledge that the rate of hospital visits is not expected to be zero, since some patients will have visits for reasons unrelated to the procedure. In designing the measure, we narrowed the measure to include surgical procedures that: (1) Are routinely performed at ASCs; (2) involve increased risk of post-surgery hospital visits; and (3) are routinely performed by urologists. In addition, the measure is risk-adjusted for patient demographics, clinical characteristics, and surgical procedural complexity, so that facilities that experience more unrelated visits due to a generally higher-risk patient mix will not be disadvantaged. We refer readers to the methods section in the measure specifications for more information about the risk-adjustment methodology.

In addition, we only measure the rate of *unplanned* hospital admissions; ED visits and observation stays are never considered planned.[173] [174] This approach removes from the outcome admissions that are not a signal of quality of care, because they represent:

[170] Spreadsheet of MAP 2017 Final Recommendations. February 1, 2017. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452*.

[171] MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals. Final Report. February 15, 2017. Available at: *http://www.qualityforum.org/Publications/2017/02/2017_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx*.

[172] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE). Measure Technical Report: Hospital Visits after Urology Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Urology-ASC-Procedures_Measure-Technical-Report_052017.pdf*.

[173] Horwitz, Leora I., et al. ''Development and validation of an algorithm to identify planned readmissions from claims data.'' *Journal of hospital medicine* 10.10 (2015): 670–677.

[174] Ranasinghe, Isuru, et al. ''Differences in colonoscopy quality among facilities: development of a post-colonoscopy risk-standardized rate of unplanned hospital visits.'' *Gastroenterology* 150.1 (2016): 103–113.

(1) A condition or diagnosis that is considered to be always planned (such as transplants or maintenance chemotherapy); or (2) that are considered potentially planned (such as cardiovascular procedures) and are not accompanied by an acute diagnosis. The planned admission algorithm is based on CMS' widely-used Planned Readmission Algorithm v4.0.[175] We refer readers to the measure methodology report at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* for more details.

Regarding the commenter's concerns about the attribution of outcomes, and whether hospital visit within 7 days of ASC procedure is a sign of poor quality, we believe that the measure captures the full range of potentially serious adverse events related to urologic procedures performed at ASCs. We designed the outcome timeframe to encompass the first 7 days for capture of hospital visits (ED visits, observation stays, and unplanned admissions), because existing literature suggests that the vast majority of adverse events after an urology procedure occur within the first 7 days following the procedure [176] [177] and because the highest rates of hospital visits were observed in claims data within 7 days following the procedure. A 7-day timeframe helps to ensure that the measure will capture adverse events following the procedure, but will not capture events impacted by factors unrelated to the care patients received.[178] We appreciate the commenter's careful review of the top hospital visit diagnoses within seven days of urologic procedures. We welcome specific examples of potentially planned admissions following outpatient urologic procedures.

In response to a commenter's suggestion that we develop a numerator exclusion for unrelated hospital visits, this measure was intentionally designed to broadly evaluate all-cause hospital visits to capture serious adverse events experience by patients after undergoing urologic ASC procedures, rather than a narrow set of identifiable complications, for many reasons. The outcome of all-cause hospital visits is consistent with a patient-centric view of care that is designed to prompt ASC providers to minimize the risk and reduce the need for a broad range of outcomes after undergoing urologic ASC procedures, including the risk of dehydration, nausea and vomiting, dizziness, and urinary retention. Measuring only hospital visits that are overtly related to a procedure, such as visits for pain and bleeding, would limit the measure's intended broad impact on quality improvement efforts. These are common problems that may or may not be related to a recent ASC procedure. Thus, the measure is structured so that facilities that most effectively minimize patient risk of these outcomes will perform better on the measure.

Comment: A commenter suggested that CMS provide a detailed clinical review of all the measure results by several seasoned urologists to ensure the measure algorithm is appropriate.

Response: In developing the measure, we incorporated significant input from various experts and stakeholders. In addition to the MUC and MAP processes described above, a multidisciplinary team of clinicians, health services researchers, and statisticians were informed, in part, by a national TEP consisting of patients, methodologists, researchers, and providers, including urologists who conducted a detailed clinical review of all the measure results to ensure the measure algorithm is appropriate. We also held a public comment period soliciting stakeholder input on the measure methodology, including the planned admission algorithm. However, we will continue to evaluate the measure, as our goal is to ensure that the measure accurately reflects the quality of care provided in ASCs.

We appreciate the commenter's careful review of the top hospital visit diagnoses within seven days of urology procedures. We welcome specific examples of potentially planned admissions following outpatient urologic procedures.

Comment: Several commenters were concerned that ASCs may not have actionable information generated from ASC–18. Specifically, some commenters did not support adoption of the measure, because measure score calculation relies on retrospective claims data. The commenters expressed concerns that the delay in providing data to facilities would provide limited usefulness for quality improvement or for consumers in choosing an ASC facility. Regarding a similar measure, ASC–12 Facility Risk-Standardized Visit Rate after Outpatient Colonoscopy, one commenter noted that in their members' experience with the confidential feedback reports, facilities were already aware of most of the visits in the claims detail report and did not review the reports unless the facilities were categorized as underperforming. The commenter also questioned the usefulness of the measure to make distinctions among facilities and to consumers, because the performance for the overwhelming majority of the ASCs would be no different than expected.

Response: We acknowledge the commenters' concerns regarding the use of claims data for the ASC–18 measure; however, the measure would provide facilities with the most recently available, patient-level data to help guide quality improvement efforts that would also be low burden.

Further, we believe that measures of hospital events following specific types of surgical procedures fully based on Medicare FFS claims recently adopted (for example, ASC–12: Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy Measure) and including those newly finalized in this final rule that is, ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures and ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures) will better inform Medicare beneficiaries and other consumers about post-procedure complication rates. Existing ASC quality measures tend to focus on very rare, patient safety-related events. For example, ASC–3 counts cases in which a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant event occurred (76 FR 74499).[179] Measures designed to capture more common adverse outcomes that patients experience, such as urinary retention, urinary tract infection, pain, and other complications prompting acute care hospital visits or admissions

[175] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE). Measure Technical Report: Hospital Visits after Urology Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Urology-ASC-Procedures_Measure-Technical-Report_052017.pdf*.

[176] Fleisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly patients: Importance of patient and system characteristics and location of care. Archives of Surgery. 2004;139(1):67–72.

[177] Mattila K, Toivonen J, Janhunen L, Rosenberg PH, Hynynen M. Postdischarge symptoms after ambulatory surgery: First-week incidence, intensity, and risk factors. Anesthesia and Analgesia. 2005;101(6):1643–1650.

[178] Parry, Nicola. ''7-Day Readmissions: Better Indicators of Patient Care.'' *Medscape,* 2016.

[179] Centers for Medicare & Medicaid Services. Ambulatory Surgical Center Quality Reporting Specifications Manual Release Notes Version: 6.0. 2016; Available at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754*.

are lacking at this time, and this is what this measure is intended to accomplish.

While we appreciate the commenter's feedback that some ASCs were already aware of most of the visits in the claims detail report and did not review the reports unless the facilities were categorized as underperforming, that is not always the case. Providers at ASCs are more often unaware of patients' subsequent acute care visits given that separate providers (for example, emergency department physicians) tend to provide post-urological care when it is required.[180] This measure is intended to bring greater awareness to a larger number of ASCs and patients, in addition to actionable information to lower the rate of preventable adverse events and to improve the quality of care following procedures performed at an ASC.

Although the majority of ASCs would be expected to have risk-standardized rates that would be classified as ''no different than the national rate'' on *Hospital Compare,* we believe that the measure will be able to make distinction among facilities and to consumers because the variation in risk-standardized hospital visit rates across ASCs nationally suggests that there is still room for quality improvement. *Hospital Compare* will also report facilities' risk-standardized rates, and facilities will receive confidential feedback reports to support quality improvement efforts. Furthermore, feedback from national TEP members showed that the ASC–18 measure, as specified, can be used to distinguish between better and worse quality facilities.[181] This shows TEP agreement with the overall face validity of the measure.

Comment: A few commenters expressed concerns about risk adjustment. A commenter noted that the measure is not risk adjusted to account for socioeconomic status and other factors beyond a hospitals' control. Another commenter expressed concern about including condition category (CC 82), Respirator dependence/tracheostomy status, on the list of condition categories that are not risk-adjusted if the condition occurs only at the time of the procedure. The commenter noted that this type of condition is not something that develops acutely within the timeframe of an ASC procedure, but rather is reflective of a more chronic patient condition.

Response: We understand the important role that factors outside of an ASC's control, for example, socioeconomic and sociodemographic status, play in the care of patients. Although the risk-adjustment methodology does not stratify by social risk factors, it does account for risk by adjusting for risk factors associated with increased risk for hospital visits after surgery. In developing this measure, we evaluated the potential effects of risk adjusting for three socioeconomic status (SES) factors that are available in CMS claims (Medicaid dual-eligibility status, African-American race, and the AHRQ SES index). Our results show that adjusting for these three factors at the patient level do not change the measure scores. We assessed the relationship of SES to hospital visits at the patient and facility levels. Unadjusted and adjusted ASC-level risk-standardized hospital visit rates were highly correlated (Spearman correlation coefficients of nearly 1.0) when calculated with and without the addition of the three SES variables (Medicaid dual-eligibility status, African-American race, and the AHRQ SES index). This indicates that including SES variables in ASC-level risk-adjusted measure score will result in limited differences in measure results after accounting for other risk factors, such as age and comorbidities. We refer readers to the methodology in the measure specifications for more information about SES testing for this measure at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* We also refer readers to section XIV.B.2. of this final rule with comment period where we discuss social risk factors in the ASCQR Program in more detail.

Furthermore, we appreciate the commenter's concern about including condition category (CC) 82 on the list of condition categories that are not risk-adjusted for if they occur only at the time of the procedure.[182] Condition categories are used to classify diagnoses into clinically coherent groups.[183] We consolidated like risk factors into candidate variables, which were the variables that we considered for the risk-adjustment model. We agree with the commenter for noting that CC 82 is unlikely to develop acutely during the timeframe of a procedure; we will review this group of codes and will consider revising the list of CCs that are not risk-adjusted for if the condition occurs at the time of the procedure. As explained above, this measure was reviewed using a consensus-driven approach, with input from a national TEP and surgeons, including urologists, providing care in the ASC setting. Potential candidate risk factors and condition categories were identified from related quality measures and the literature; [184] [185] [186] a preliminary list of risk factors was developed and then revised based on national TEP and clinical expert review that included several urologists. These risk variables were further released and reviewed during the measure development public comment period prior to the selection of the final model.[187] This consensus-based approach was used to achieve clinical face validity prior to the model selection.

Comment: One commenter noted that low-volume situations tend to produce measure scores that lack reliability. The commenter noted that the measure is only ''fairly'' reliable and suggested the reliability for a measure intended for public reporting should be substantially reliable, or have an ICC of 0.61 to 0.80. Furthermore, the commenter noted that the measure also suffers from limited discriminatory power because the number of underperforming facilities is very small. The commenter urged CMS to ensure that the publicly reported scores are reliable.

Response: We thank the commenter for their feedback about the measure reliability. We disagree with the commenter and believe that ASC–18 is

[180] Mezei G, Chung F. Return hospital visits and hospital readmissions after ambulatory surgery. Annals of Surgery. 1999;230(5):721–727.

[181] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE). Measure Technical Report: Hospital Visits after Urology Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Urology-ASC-Procedures_Measure-Technical-Report_052017.pdf.*

[182] Ibid.

[183] HCUP CCS Fact Sheet. Healthcare Cost and Utilization Project (HCUP). January 2012. Agency for Healthcare Research and Quality, Rockville, MD. *https://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccsfactsheet.jsp.*

[184] Crew JP, Turner KJ, Millar J, Cranston DW. Is day case surgery in urology associated with high admission rates? Annals of The Royal College of Surgeons of England. 1997;79(6):416–419.

[185] Fleisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly patients: Importance of patient and system characteristics and location of care. Archives of Surgery. 2004;139(1):67–72.

[186] Paez A, Redondo E, Linares A, Rios E, Vallejo J, Sanchez-Castilla M. Adverse events and readmissions after day-case urological surgery. International Brazilian Journal of Urology. 2007;33(3):330–338.

[187] Yale New Haven Health Services Corporation. Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (Version 1.0). May 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Version-10_Hospital-Visits_Orthopedic-ASC-Procedures_Measure-Technical-Report_052017.pdf.*

sufficiently reliable to be included in the ASCQR Program. Our calculated intraclass correlation coefficient (ICC),[188] a measure of reliability or the degree to which the measure can produce accurate and consistent results across multiple measurements of the same entities in a time period, for this measure was 0.45, indicating ''moderate'' reliability.[189] The NQF considers ICC values ranging from 0.01–0.20 as ''slight'' reliability, 0.21–0.40 as ''fair'' reliability, 0.41 to 0.60 as ''moderate'' reliability, and 0.61 to 0.80 as ''strong'' reliability.[190] We disagree that the measure reliability should be ''substantially'' reliable or have an ICC of 0.61 to 0.80, and believe the publicly reported scores will be sufficiently reliable. The results of reliability testing are consistent with existing measures of patient outcomes in the ambulatory surgery setting.[191] Therefore, we believe the measure is sufficiently reliable.

Regarding the comment about lack of discriminatory power, we agree that the many small-volume ASCs will limit the ability to make distinctions in performance between facilities. ASCs with few cases in a given year limit our ability to capture variation in ASC-level measure scores because our modeling methodology is conservative and will estimate measure scores toward the national mean for facilities with small volumes. Specifically, hospitals with relatively few cases in the performance period may have a true rate that is worse/better than the national average. However, the model estimates their rate as close to the mean because their low volume does not provide enough information to accurately estimate a value near their true rate. As a result, the model may capture less variation than truly exits due to low case sizes. To improve the measure's ability to detect quality differences, we crafted our proposal to use 2 years of data for public reporting to expand the number of cases available for estimating rates across all facilities and to increase both the reliability of the measure score and the ability to discriminate performance across facilities. Furthermore, ASC facilities that have too few cases to reliably estimate a measure score (moderate reliability as discussed in the prior paragraph) would be treated in the same way as other facilities with too few cases and would not have their scores posted on *Hospital Compare;* their data would be replaced with a footnote. We discuss our *Hospital Compare* footnotes at: *https://www.medicare.gov/hospitalcompare/data/Footnotes.html*. However, these facilities will still receive confidential feedback reports/facility-specific reports providing valuable information about post-surgery events. We refer readers to section XIV.B.6.c.(7) of this final rule with comment period for more details about public reporting of this measure. We expect that smaller ASCs will still benefit from confidentially reviewing their measure results and individual patient-level outcomes in the facility-specific report, as these data are currently largely unknown to ASCs and providers.

Comment: One commenter requested that the dry run results be aggregated and made available in its entirety to the public for review and comment if the measure is finalized. The commenter also suggested that CMS conduct pilot testing for the measure with volunteer ASCs rather than conduct national dry runs. Another commenter suggested that CMS pilot test the measure prior to implementation to ensure that the measure adequately account for the nuances related to urologic surgery.

Response: We refer readers to section XIV.B.6.c.(7) of this final rule with comment period where we discuss our dry run. The intent of the dry run is to test production of the measure and for ASCs to familiarize themselves with the measure and provide feedback to CMS. The dry run will generate confidential reports for ASCs on measure performance and risk-standardized hospital visit rates, among other data. We plan to perform a dry run of the measure prior to implementation. The confidential dry run results will not be publicly reported or used for payment determination. We believe a dry run will be more beneficial than pilot testing. The dry run will include all ASCs rather than just a subset of volunteer ASCs and will enable all ASCs to gain familiarity with the measure and processes, as well as provide feedback to CMS on both the measure itself and the reports. This will also enable CMS to learn about any unanticipated nuances associated with measure implementation.

As proposed we will not publicly report data for this measure until the CY 2022 payment determination and subsequent years. We do not believe publicly reporting data from the dry run is appropriate as we might still be working out unanticipated nuances; the data is preliminary and is therefore subject to change based on feedback provided by ASCs.

Comment: One commenter noted that although CMS believes that there would not be any additional burden because ASCs are not required to submit additional data, reviewing claims detail reports and measure scores would be associated with additional burden for someone at ASCs, likely a clinician.

Response: We thank the commenter for providing this input and acknowledge that this measure will be calculated completely from data already obtained from paid Medicare FFS claims submitted by ASCs, hospitals, and physicians for billing purposes. Because claims data are used, there is no burden on the part of ASCs to submit additional data for measure calculation. We strongly suggest that facilities allocate time to review their feedback reports, because they contain actionable information to identify performance gaps and further develop quality improvement strategies. However, we note that these activities do not represent burden related to program requirements.

Comment: One commenter expressed concern over the measure specifications, including the accuracy of background data on the number of unplanned hospital visits.

Response: We interpret commenter to be referring to Table 4 in the ASC–18 Measure Technical Report published in May 2017 and located at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. In the technical report for this measure, the column labeled ''number of unplanned hospital visits'' was incorrectly labeled and should read ''number of procedure performed.'' The remainder of the table is correct. We will address this discrepancy in future technical documentation. We thank the commenter for pointing out the inconsistency.

After consideration of the public comments we received, we are finalizing the proposal to adopt the ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures measure in the ASCQR Program for the

[188] Landis J, Koch G. The measurement of observer agreement for categorical data, Biometrics 1977;33:159–174.

[189] The NQF considers ICC values ranging from 0.01–0.20 as ''slight'' reliability, 0.21–0.40 as ''fair'' reliability, 0.41 to 0.60 as ''moderate'' reliability, and 0.61 to 0.80 as ''strong'' reliability. Avalable at: *http://www.qualityforum.org/Measuring_Performance/Improving_NQF_Process/Measure_Testing_Task_Force_Final_Report.aspx*.

[190] Landis J, Koch G. The measurement of observer agreement for categorical data, Biometrics 1977;33:159–174.

[191] See the Risk-Standardized Hospital Visits within 7 Days After Hospital Outpatient Surgery Measure. For ICC score of 0.50: Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Hospital-Visits-after-Hospital-Outpatient-Surgery-Measure.pdf*.

CY 2022 payment determination and subsequent years, as proposed.

d. Summary of Previously Adopted Measures and Newly Finalized ASCQR Program Measures for the CY 2022 Payment Determination and Subsequent Years

The measure set for the ASCQR Program CY 2022 payment determination and subsequent years is listed below.

ASCQR PROGRAM MEASURE SET WITH PREVIOUSLY AND NEWLY FINALIZED MEASURES FOR THE CY 2022 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	Measure name
ASC–1	0263	Patient Burn.
ASC–2	0266	Patient Fall.
ASC–3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4	0265†	All-Cause Hospital Transfer/Admission.
ASC–8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
ASC–9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use.
ASC–11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.*
ASC–12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
ASC–13	None	Normothermia Outcome.
ASC–14	None	Unplanned Anterior Vitrectomy.
ASC–15a	None	OAS CAHPS—About Facilities and Staff.**
ASC–15b	None	OAS CAHPS—Communication About Procedure.**
ASC–15c	None	OAS CAHPS—Preparation for Discharge and Recovery.**
ASC–15d	None	OAS CAHPS—Overall Rating of Facility.**
ASC–15e	None	OAS CAHPS—Recommendation of Facility.**
ASC–17	None	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures.***
ASC–18	None	Hospital Visits after Urology Ambulatory Surgical Center Procedures.***

† We note that NQF endorsement for this measure was removed.
* Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).
** Measure finalized for delay beginning with CY 2018 reporting until further action in future rulemaking as discussed in section XIV.B.4. of this final rule with comment period.
*** New measure finalized for the CY 2022 payment determination and subsequent years.

7. ASCQR Program Measures and Topics for Future Consideration

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494), we set forth our considerations in the selection of ASCQR Program quality measures. We seek to develop a comprehensive set of quality measures to be available for widespread use for making informed decisions and quality improvement in the ASC setting (77 FR 68496). We also seek to align these quality measures with the National Quality Strategy (NQS), the CMS Strategic Plan (which includes the CMS Quality Strategy), and our other quality reporting and value-based purchasing (VBP) programs, as appropriate. Accordingly, as we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66979), in considering future ASCQR Program measures, we are focusing on the following NQS and CMS Quality Strategy measure domains: Make care safer by reducing harm caused in the delivery of care; strengthen person and family engagement as partners in their care; promote effective communication and coordination of care; promote effective prevention and treatment of chronic disease; work with communities to promote best practices of healthy living; and make care affordable.

We invited public comment on one measure developed by the CDC for potential inclusion in the ASCQR Program in future rulemaking, the Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome measure (NQF #3025). This potential measure is discussed in more detail below.

Healthcare-associated infections (HAIs) are a major cause of morbidity and mortality in healthcare settings in the United States, with the most recent prevalence surveys of HAIs estimating that approximately four percent of inpatients in acute care settings have developed at least one HAI, translating to 721,800 infections in 648,000 patients in 2011.[192] Surgical site infection (SSI) is one of the most common HAIs, comprising approximately 22 percent of all HAIs, and contribute greatly to the mortality and cost burden of HAIs.[193] Breast SSIs represent a substantial proportion of SSIs overall in inpatient settings, and have one of the highest infection risks of any procedure type in outpatient settings.[194] While SSI rates following breast procedures vary from one percent to over 30 percent depending on procedure type,[195] the

[192] Magill SS, Edwards JR, Bamberg W, Beldavs ZG, Dumyati G, Kainer MA. Multistate Point-Prevalence Survey of Health Care-Associated Infections. NEJM. 2014;370:1198–1208.

[193] Ibid.

[194] This statement is based on an analysis of data reported to the National Healthcare Safety Network (NHSN). Out of 67,150 ASC procedures report to NHSN from 2010 to 2013, 30,787 (45.9 percent) were breast procedures. Out of the 142 surgical site infections reported from ASCs during the same time period, 78 (54.9 percent) were related to breast procedures, indicating an SSI risk of 0.25 percent. This was the highest volume and SSI risk out of all outpatient ASC procedures reported in the timeframe.

[195] Vilar-Compte D, Jacquemin B, Robles-Vidal C, and Volkow P. Surgical Site Infections in Breast Surgery: Case-Control Study. World Journal of Surgery. 2004;28(3):242–246; Mannien J., Wille JC, Snoeren RL, van den Hof S. Impact of Postdischarge Surveillance on Surgical Site Infection Rates for Several Surgical Procedures: Results from the Nosocomial Surveillance Network in the Netherlands. Infection Control and Hospital Epidemiology. 2006;27:809–816; Vilar-Compte D., Rosales S., Hernandez-Mello N, Maafs E and Volkow P. Surveillance, Control, and Prevention of Surgical Site Infections in Breast Cancer Surgery: A

trend in surgery transitioning to outpatient and ambulatory surgery settings due to advances in surgical techniques and economic incentives for ambulatory surgery make these events an outcome of interest for the ASCQR Program.

Numerous individual studies and systematic reviews provide strong evidence that measurement and feedback of surgical site infections leads to lower SSI rates in the long term.[196] Although standardized metrics have been developed to measure SSI rates for inpatient surgeries in the hospital setting,[197] these have not yet been developed for outpatient surgeries in ASCs, which comprise a fast-growing proportion of all surgeries performed in the United States.[198] We believe this measure, if adopted in the future, could serve as a quantitative guide for ASCs, enabling them to benchmark SSI rates in their facilities against nationally aggregated data and set targets for improvement.

This issue is of interest to the ASCQR Program because breast procedures are becoming increasingly common at ASCs.[199] In addition, the Ambulatory Breast Procedure Surgical Site Infection Outcome measure addresses the MAP-identified measure gap area of surgical quality measures, including surgical site infection measures, for the ASCQR Program.[200]

The Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome measure was included on the 2016 MUC list [201] and reviewed by the MAP. The MAP conditionally supported the measure (MUC16–155), noting the rapid shift of care to the ambulatory surgery setting and the need to ensure transparency about the safety of ambulatory surgery centers.[202] The MAP further noted that this measure should be submitted for NQF review and endorsement.[203] A summary of the MAP recommendations can be found at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*. We note that this measure received NQF endorsement in January 2017, and therefore satisfies the MAP's condition for support.[204]

The Ambulatory Breast Procedure Surgical Site Infection Outcome measure is used to assess the risk-adjusted Standardized Infection Ratio (SIR) for all SSIs following breast procedures conducted at ASCs among adult patients and reported to the CDC's National Healthcare Safety Network. The measure compares the reported number of SSIs observed at an ASC with a predicted value based on nationally aggregated data. The numerator for this measure is all SSIs during the 30-day and 90-day postoperative periods following breast procedures in ASCs. The term SSI as used in this measure is defined in accordance with the CDC NHSN's surveillance protocol as an infection, following a breast procedure, of either the skin, subcutaneous tissue and breast parenchyma at the incision site (superficial incisional SSI), deep soft tissues of the incision site (deep incisional SSI), or any part of the body deeper than the fascial/muscle layers that is opened or manipulated during the operative procedure (organ/space SSI).[205] The denominator for this measure is all adult patients (defined as patients ages 18 to 108 years) undergoing breast procedures, as specified by the operative codes that comprise the breast procedure category of the NHSN Patient Safety Component Protocol, at an ASC. This measure cohort excludes hospital inpatient and outpatient departments, pediatric patients (patients younger than 18 years) and very elderly patients (older than 108 years), and brain-dead patients whose organs are being removed for donor purposes. The specifications for this measure for the ASC setting can be found at: *http://www.qualityforum.org/QPS/* after searching ''Ambulatory Breast Procedure Surgical Site Infection Outcome Measure.''

We invited public comment on the possible inclusion of this measure in the ASCQR Program measure set in the future.

Comment: Several commenters supported the inclusion of the Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome measure (NQF #3025) in the ASCQR Program in future rulemaking, noting that the measure is fully developed, was tested in the ASC setting, and addresses an important area of care. One commenter recommended that CMS consider refining this and other measures so that data is collected at the NPI level, rather than by CCN. One commenter agreed that breast procedure SSI outcomes are a concern, but noted that significant development and testing may be required before the Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome measure (NQF #3025) is ready for implementation due to the difficulty of capturing data on whether an SSI has occurred. One commenter expressed concern that the measure could lead to unintended consequences related to the administration of perioperative antibiotics across breast procedures.

Response: We thank commenters for their support and recommendations. We will consider the suggestions and concerns as we craft future policy. In addition, we note that our goal is to develop a parsimonious measure set made up of meaningful measures that fill important gaps with consideration of the impact on burden in the ASCQR Program.

8. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74513 through 74514), where we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures, including the subregulatory process for making updates to the adopted measures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68496 through 68497), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66981), we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy, including the processes for addressing

5-year Experience. American Journal of Infection Control. 2009;37(8):674–679.

[196] Anderson DJ, Podgorny K, Berríos-Torres S, et al. Strategies to Prevent Surgical Site Infections in Acute Care Hospitals: 2014 Update. Infection Control and Hospital Epidemiology. 2014;35:605–627; Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for Prevention of Surgical Site Infection. Hospital Infection Control Practices Advisory Committee. Infection Control and Hospital Epidemiology. 1999; 20:250–278; Gaynes R, Richards C, Edwards JR, et al. Feeding Back Surveillance Data to Prevent Hospital-Acquired Infections. Emerging Infectious Diseases. 2001;7:295–298.

[197] Mu Y, et al. Improving Risk-Adjusted Measures of Surgical Site Infection for the National Healthcare Safety Network. Infection Control and Hospital Epidemiology. 2011;32(10):970–986.

[198] Ibid.

[199] Cullen KA, Hall MJ, Golosinskiy A, Statistics NFcH. Ambulatory Surgery in the United States, 2006. National Health Statistics Report; 2009.

[200] National Quality Forum. ''MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals.'' Report. 2017. Available at: *http://www.qualityforum.org/map/* under ''Hospitals—Final Report.''

[201] Available at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*, under ''2016 Measures Under Consideration List (PDF).''

[202] National Quality Forum. 2016–2017 Spreadsheet of Final Recommendations to HHS and CMS, available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

[203] Ibid.

[204] National Quality Forum. Endorsed measure specification available at: *http://www.qualityforum.org/QPS/3025*.

[205] Centers for Disease Control and Prevention. ''Surgical Site Infection (SSI) Event. Available at: *https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf*.

nonsubstantive and substantive changes to adopted measures. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531), we provided clarification regarding our decision to not display the technical specifications for the ASCQR Program on the CMS Web site, but stated that we will continue to display the technical specifications for the ASCQR Program on the QualityNet Web site. In addition, our policies regarding the maintenance of technical specifications for the ASCQR Program are codified at 42 CFR 416.325. We did not propose any changes to our policies regarding the maintenance of technical specifications for the ASCQR Program.

9. Public Reporting of ASCQR Program Data

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS Web site after providing an ASC an opportunity to review the data to be made public. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531 through 70533), we finalized our policy to publicly display data by the National Provider Identifier (NPI) when the data are submitted by the NPI and to publicly display data by the CCN when the data are submitted by the CCN. In addition, we codified our policies regarding the public reporting of ASCQR Program data at 42 CFR 416.315 (80 FR 70533). In the CY 2017 OPPS/ASC final rule with comment period, we formalized our current public display practices regarding timing of public display and the preview period by finalizing our proposals to publicly display data on the *Hospital Compare* Web site, or other CMS Web site as soon as practicable after measure data have been submitted to CMS; to generally provide ASCs with approximately 30 days to review their data before publicly reporting the data; and to announce the timeframes for each preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs (81 FR 79819 through 79820). We did not propose any changes to these policies. However, we note that in section XIV.B.6.b. and c. of this final rule with comment period, we are finalizing two new measures: ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, and ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures, beginning with the CY 2022 payment determination, and specific public reporting policies associated with these measures.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133) for a detailed discussion of the QualityNet security administrator requirements, including setting up a QualityNet account, and the associated timelines, for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533), we codified the administrative requirements regarding maintenance of a QualityNet account and security administrator for the ASCQR Program at 42 CFR 416.310(c)(1)(i). We refer readers to section XIV.D.3.b.1. of this final rule with comment period where we are finalizing our proposals to expand submission via the CMS online tool to also allow for batch data submission and make corresponding changes to the 42 CFR 416.310(c)(1)(i).

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533 and 70534), we codified these requirements regarding participation status for the ASCQR Program at 42 CFR 416.305. We did not propose any changes to these policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(1) and (2). We did not propose any changes to these requirements.

We note that, in section XIV.B.3.b.(1) of this final rule with comment period, we are finalizing a proposal to remove one claims-based measure using QDCs, ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing, beginning with the CY 2019 payment determination. The following previously finalized claims-based measures using QDCs will be collected for the CY 2020 payment determination and subsequent years:

- ASC–1: Patient Burn;
- ASC–2: Patient Fall;
- ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- ASC–4: Hospital Transfer/ Admission.

2. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135 through 75137), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534 through 70535) as well as 42 CFR 416.310(a)(3) and 42 CFR 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. We did not propose any changes to these policies.

3. Requirements for Data Submitted via an Online Data Submission Tool

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74505 through 74509); CY 2014 OPPS/ASC final rule with comment period (78 FR 75137 through 75140); CY 2015 OPPS/ASC final rule with comment period (79 FR 66983 through 66986); CY 2016 OPPS/ASC final rule with comment period (80 FR 70535 through 70536); CY 2017 OPPS/ASC final rule with comment period (81 FR 79820 through 79822); and 42 CFR 416.310(c) for our previously finalized policies for data submitted via an online data submission tool. For more information on data submission using QualityNet, we refer readers to: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228773314768*. We note that we are finalizing proposals to remove two measures submitted via a CMS online data submission tool, ASC–6 and ASC–7, in section XIV.B.3.b.(2) and XIV.B.3.b.(3) of this final rule with comment period. We are not finalizing our proposal to adopt one measure submitted via a CMS online data submission tool, as described in section XIV.B.6.a. of this final rule with comment period.

a. Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS online data submission tool (CDC NHSN Web site). We codified our existing policies regarding the data collection time periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool at 42 CFR 416.310(c)(2). Currently, we only have one measure (ASC–8: Influenza Vaccination Coverage among Healthcare Personnel) that is submitted via a non-CMS online data submission tool.

We did not propose any changes to the reporting requirements for this measure.

b. Requirements for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75137 through 75139), CY 2016 OPPS/ASC final rule with comment period (80 FR 70535 through 70536), CY 2017 OPPS/ASC final rule with comment period (81 FR 79821 through 79822), and 42 CFR 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the QualityNet Web site as our CMS online data submission tool: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetHomepage&cid=1120143435383*. In the CY 2018 OPPS/ASC proposed rule (82 FR 33701), we made one proposal to expand the method of data submission via a CMS online data submission tool.

(1) Batch Submission

We did not propose any changes to our policies regarding data submitted via a CMS online data submission tool when data is entered for individual facilities. Currently, for individual facility data entry, users must have a QualityNet account and use one Hospital Quality Reporting (HQR) External File per facility that is uploaded into the QualityNet secure portal. However, using one HQR External File that only allows data entry for one facility can be burdensome for entities responsible for submitting such data for multiple facilities, such as multi-facility ASCs. Therefore, in an effort to streamline the process, we proposed to expand the CMS online tool to also allow for batch submission beginning with data submitted during CY 2018 for the CY 2020 payment determination and subsequent years.

Batch submission is submission of data for multiple facilities simultaneously using a single, electronic file containing data from multiple facilities submitted via one agent QualityNet account. Under the batch submission process, ASC agents (for example, a corporate representative for a corporate entity consisting of multiple ASC facilities with separate NPIs) would be assigned a vendor ID and an ASC's representative would submit the Security Administrator (SA) form with the assigned vendor ID for the agent to establish their own QualityNet account. Once approved, the agent may submit data for any ASC associated with that ID, individually or in a batch, and access data reports for the same ASCs. Agents would only have access to data reports for facilities that have authorized them to have access. For batch submission, agents would be provided the HQR external file layout with which to upload their associated ASCs' data under the agents' QualityNet account. In order to submit batch data, agents would need to meet all QualityNet account requirements, such as establishing a QualityNet account and maintaining a QualityNet security administrator. Additional details regarding logistics of batch data submission would be included in future guidance in the Specifications Manual.

In addition, we proposed to make corresponding changes to 42 CFR 416.310(c)(1)(i) to reflect this proposal and replace the term ''ASCs'' with the phrase ''ASCs, and any agents submitting data on an ASC's behalf.''

We invited public comment on our proposals, as discussed above, to: (1) Expand the CMS online tool to also allow for batch submission of measure data beginning with data submitted during CY 2018, and (2) make corresponding changes to modify 42 CFR 416.310(c)(1)(i) to reflect the aforementioned proposal.

Comment: Several commenters supported the proposal to allow batch submission, noting that it will increase submission efficiency and decrease administrative burden. One commenter requested that the process for batch submission be determined in a timely fashion to allow ASCs to use this option prior to the 2018 data submission deadline.

Response: We thank the commenters for their support and agree that batch submission will increase efficiency and decrease administrative burden. In addition, as noted above, we proposed to expand the CMS online tool to allow for batch submission beginning with data submitted during CY 2018 for the CY 2020 payment determination and subsequent years, such that the option will be available prior to the 2018 data submission deadline.

After consideration of the public comments we received, we are finalizing our proposals to: (1) Expand the CMS online tool to also allow for batch submission of measure data beginning with data submitted during CY 2018, and (2) make corresponding changes to modify 42 CFR 416.310(c)(1)(i).

(2) Measures Using the CMS Online Data Submission Tool for the CY 2020 Payment Determination and Subsequent Years

In sections XIV.B.3.b.(2) and XIV.B.3.b.(3) of this final rule with comment period, respectively, we are finalizing proposals to remove two measures collected via a CMS online data submission tool—ASC–6: Safe Survey Checklist Use and ASC–7: ASC Facility Volume Data on Selected Surgical Procedures—beginning with the CY 2019 payment determination. The following previously finalized measures will require data to be submitted via a CMS online data submission tool for the CY 2020 payment determination and subsequent years:

- *ASC–9:* Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients;
- *ASC–10:* Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and
- *ASC–11:* Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery.[206]

We are not finalizing our proposal to adopt one new measure collected via a CMS online data submission tool, ASC–16: Toxic Anterior Segment Syndrome, beginning with the CY 2021 payment determination, as described in section XIV.B.6.a. of this final rule with comment period.

4. Requirements for Non-QDC Based, Claims-Based Measure Data

We refer readers to the CY 2015 OPPS/ASC final rule with comment

[206] We note that the ASC–11 measure is voluntarily collected effective beginning with the CY 2017 payment determination, as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

period (79 FR 66985) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70536) for our previously adopted policies regarding data processing and collection periods for claims-based measures for the CY 2018 payment determination and subsequent years. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70536), we codified these policies at 42 CFR 416.310(b). We did not propose any changes to these requirements.

We note that one previously finalized measure, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, will be collected via claims for the CY 2020 payment determination and subsequent years (79 FR 66970 through 66978). In addition, in sections XIV.B.6.b. and c., respectively, of this final rule with comment period, we are finalizing our proposals to adopt two new claims-based measures—ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, and ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures—beginning with the CY 2022 payment determination.

5. Requirements for Data Submission for ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79822 through 79824) for our previously finalized policies regarding survey administration and vendor requirements for the CY 2020 payment determination and subsequent years. In addition, we codified these policies at 42 CFR 416.310(e). However, in section XIV.B.4. of this final rule with comment period, we are finalizing a proposal to delay implementation of the ASC–15a–e: OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data submission) until further action in future rulemaking and refer readers to that section for more details.

As noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79815), some commenters suggested shortening sections of the survey, such as the ''About You'' section. We continue to evaluate the utility of individual questions as we collect new data from the survey's voluntary national implementation, and will consider different options for shortening the OAS CAHPS Survey without the loss of important data in the future. Specifically, we continue to consider the removal of two demographic questions—the ''gender'' and ''age'' questions—from the OAS CAHPS Survey in a future update.

Comment: A few commenters supported removal of the gender and age questions from the survey.

Response: We thank the commenters for their suggestions. We will take these comments under consideration as we craft policies for the OAS CAHPS Survey.

6. Extraordinary Circumstances Extensions or Exemptions for the CY 2019 Payment Determination and Subsequent Years

a. Background

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75140 through 75141), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79824 through 79825), and 42 CFR 416.310(d) for the ASCQR Program's policies for extraordinary circumstance extensions or exemptions (ECE) requests.[207]

Many of our quality reporting and value-based purchasing programs share a common process for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control. We refer readers to the Hospital IQR Program (76 FR 51615 through 51652, 78 FR 50836 through 50837, 79 FR 50277, 81 FR 57181 through 57182, and 42 CFR 412.140(c)(2)), the Hospital OQR Program (77 FR 68489, 78 FR 75119 through 75120, 79 FR 66966, and 80 FR 70524), the IPFQR Program (77 FR 53659 through 53660 and 79 FR 45978), and the PCHQR Program (78 FR 50848), as well as the HAC Reduction Program (80 FR 49542 through 49543) and the Hospital Readmissions Reduction Program (80 FR 49542 through 49543), for program-specific information about extraordinary circumstances exemption requests. As noted below, some of these policies were updated in the FY 2018 IPPS/LTCH PPS final rule.

In reviewing the policies for these programs, we recognized that there are five areas in which these programs have variances regarding ECE requests. These are: (1) Allowing the facilities or hospitals to submit a form signed by the facility's or hospital's CEO versus CEO or designated personnel; (2) requiring the form be submitted within 30 days following the date that the extraordinary circumstance occurred versus within 90 days following the date the extraordinary circumstance occurred; (3) inconsistency regarding specification of a timeline for us to provide our formal response notifying the facility or hospital of our decision; (4) inconsistency regarding specification of our authority to grant ECEs due to CMS data system issues; and (5) referring to the program as ''extraordinary extensions/exemptions'' versus as ''extraordinary circumstances exceptions.'' We believe addressing these five areas, as appropriate, can improve administrative efficiencies for affected facilities or hospitals. We note that, in the FY 2018 IPPS/LTCH PPS final rule, we examined our policies in these areas for the Hospital Readmissions Reduction Program, the HAC Reduction Program, the Hospital IQR Program, the PCHQR Program and the IPFQR Program (82 FR 38240, 38277, 38410, 38425 and 38473 through 38474, respectively) and finalized proposals to address differences in these areas for those programs. In section XIII.D.8. of this final rule with comment period, we are also finalizing revisions to our ECE policies for the Hospital OQR Program.

With the exception of the terminology used to describe these processes (item 5 above), the ASCQR Program is aligned with other quality reporting programs. As a result, in the CY 2018 OPPS/ASC proposed rule (82 FR 33702), we proposed to rename the process as the extraordinary circumstances exceptions (ECE) policy and make conforming changes to 42 CFR 416.310(d). These are discussed below.

b. ECE Policy Nomenclature

We have observed that while all quality programs listed above have developed similar policies to provide exceptions from program requirements to facilities that have experienced extraordinary circumstances, such as natural disasters, these programs refer to these policies using inconsistent terminology. Some programs refer to these policies as ''extraordinary circumstances extensions/exemptions'' while others refer to the set of policies as ''extraordinary circumstances exceptions.'' Several programs (specifically, the Hospital VBP Program, the HAC Reduction Program, and the Hospital Readmissions Reduction Program) are not able to grant extensions to required data reporting timelines due to their reliance on data external to their program, and thus the term, ''extraordinary circumstances extensions/exemptions'' is not

[207] In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66987), we stated that we will refer to the process as the ''Extraordinary Circumstances Extensions or Exemptions'' process rather than the ''Extraordinary Circumstances Extensions or Waivers'' process.

applicable to all programs. However, all of the described programs are able to offer exceptions from their reporting requirements. Therefore, in an effort to align across CMS quality programs, we proposed to change the name of this policy from ''extraordinary circumstances extensions or exemption'' to ''extraordinary circumstances exceptions'' for the ASCQR Program, beginning January 1, 2018, and to revise § 416.310(d) of our regulations to reflect this change.

We invited public comment on these proposals as discussed above.

Comment: A few commenters supported the proposal to align the ECE policy with other quality reporting programs.

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing the proposals to rename the process as the extraordinary circumstances exceptions (ECE) policy and make conforming changes to 42 CFR 416.310(d).

c. Timeline for CMS Response to ECE Requests

We also note that we believe it is important for facilities to receive timely feedback regarding the status of ECE requests. We strive to complete our review of each ECE request as quickly as possible. However, we recognize that the number of requests we receive, and the complexity of the information provided impacts the actual timeframe to make ECE determinations. To improve transparency of our process, we believe it is appropriate to clarify that we will strive to complete our review of each request within 90 days of receipt.

7. ASCQR Program Reconsideration Procedures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75141), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70537), and 42 CFR 416.330 for the ASCQR Program's reconsideration policy. We did not propose any changes to this policy.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to section XVI.D.1. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system equal the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. Currently, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the multifactor productivity (MFP)-adjusted CPI–U update factor, which is the adjustment set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted CPI–U update factor is the Consumer Price Index for all urban consumers (CPI–U), which currently is the annual update for the ASC payment system, minus the MFP adjustment. As discussed in the CY 2011 MPFS final rule with comment period (75 FR 73397), if the CPI–U is a negative number, the CPI–U would be held to zero. Under the ASCQR Program in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor, we refer readers to section XII.G. of this final rule with comment period.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: A full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to the proposed rule, which are available via the Internet on the CMS Web site): ''A2'', ''G2'', ''P2'', ''R2'' and ''Z2'', as well as the service portion of device-intensive procedures identified by ''J8'' (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2'', ''G2'', ''J8'', ''P2'', ''R2'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, certain radiology services and diagnostic tests where payment is based on the MPFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the MPFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in section XII.D.2.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for the new category of covered ancillary services (that is, certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS and when they are integral to covered ASC surgical procedures) will be at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard

ASC ratesetting methodology. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: The wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015, CY 2016 and CY 2017 OPPS/ASC final rules with comment period (79 FR 66981 through 66982; 80 FR 70537 through 70538; and 81 FR 79825 through 79826, respectively), we did not make any other changes to these policies.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33702 through 33703), we did not propose any changes to these policies for CY 2018.

XV. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available only via the Internet on the CMS Web site. To view the Addenda to this final rule with comment period pertaining to CY 2018 payments under the OPPS, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; select ''1678–FC'' from the list of regulations. All OPPS Addenda to this final rule with comment period are contained in the zipped folder entitled ''2018 OPPS 1678–FC Addenda'' at the bottom of the page. To view the Addenda to this final rule with comment period pertaining to CY 2018 payments under the ASC payment system, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html*; select ''1678–FC'' from the list of regulations. All ASC Addenda to this final rule with comment period are contained in the zipped folders entitled ''Addendum AA, BB, DD1, DD2, and EE.''

XVI. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day 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. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33705 through 33710), we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

B. ICRs for the Hospital OQR Program

1. Background

The Hospital OQR Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital IQR Program (82 FR 20031 through 20075). We refer readers to the CY 2011 through CY 2017 OPPS/ASC final rules with comment periods (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through 67015; 80 FR 70580 through 70582; and 81 FR 79862 through 79863, respectively) for detailed discussions of Hospital OQR Program information collection requirements we have previously finalized. The information collection requirements associated with the Hospital OQR Program are currently approved under OMB control number 0938–1109.

In section XIII.B.4.c. of this final rule with comment period, we are finalizing the removal of six measures. Specifically, beginning with the CY 2020 payment determination, we are finalizing, as proposed, to remove: (1) OP–21: Median Time to Pain Management for Long Bone Fracture; and (2) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures. Also, while we proposed to remove: (1) OP 1: Median Time to Fibrinolysis, (2) OP–4: Aspirin at Arrival, (3) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional, and (4) OP–25: Safe Surgery Checklist beginning with the CY 2021 payment determination, we are finalizing removal of these measures with modification so that removal begins with the CY 2020 payment determination, one year earlier than proposed. To summarize, the following measures will be removed for the CY 2020 payment determination: (1) OP–1: Median Time to Fibrinolysis; (2) OP–4: Aspirin at Arrival; (3) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional; (4) OP–21: Median Time to Pain Management for Long Bone Fracture; (5) OP–25: Safe Surgery Checklist; and (6) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures. We expect these finalized proposals will reduce the burden of reporting for the Hospital OQR Program, as discussed in more detail below. We note that we discuss only the changes in burden resulting from the provisions in this final rule with comment period.

In section XIII.B.10.b. of this final rule with comment period, we are finalizing our proposal, with modification, to publicly report OP–18c using data

beginning with patient encounters during the third quarter of CY 2017. However, we do not expect our modifications to affect the burden estimates made in the CY 2018 OPPS/ASC proposed rule (82 FR 33705 through 33708), as discussed below.

In section XIII.B.5. of this final rule with comment period, we are finalizing our proposal to delay the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection period) until further notice in future rulemaking.

In addition, in this final rule with comment period, beginning with the CY 2020 payment determination, we are finalizing our proposals: (1) To codify at § 419.46(e) our previously finalized process for targeting hospitals for validation of chart-abstracted measures (section XIII.D.7.b. of this final rule with comment period); (2) to formalize the educational review process and use it to correct incorrect validation results for chart-abstracted measures (section XIII.D.7.c. of this final rule with comment period); (3) to align the first quarter for which hospitals must submit data for all hospitals that did not participate in the previous year's Hospital OQR Program, and make corresponding revisions at 42 CFR 419.46(c)(3) (section XIII.D.1. of this final rule with comment period); and (4) to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy and make conforming changes to the CFR (section XIII.D.8.a. of this final rule with comment period). We are not finalizing our proposal to change the NOP submission deadlines such that hospitals are required to submit the NOP any time prior to registering on the QualityNet Web site and to make conforming revisions at 42 CFR 419.46(a) (section XIII.C.2.b. of this final rule with comment period). We do not believe that these changes will affect our burden estimates, as further discussed below.

2. Newly Finalized Change in Hourly Labor Cost for Burden Calculation for the Hospital OQR Program

In previous rules (80 FR 70581), we estimated that a hospital pays an individual approximately $30 per hour to abstract and submit clinical data. We previously did not specify whether our wage estimate of $30 included overhead and fringe benefit costs. However, although we did not specify that this estimate included fringe benefit costs, in previous rules (80 FR 70581), we used $30 to calculate the total cost to hospitals to pay for staff that abstract and submit clinical data. In CY 2018 OPPS/ASC proposed rule (82 FR 33705), we proposed a new cost to hospitals and specified that this cost included both wage and overhead and fringe benefit costs. Specifically, we proposed to estimate that reporting data for the Hospital OQR Program can be accomplished by staff with a median hourly wage of $18.29 per hour.[208] This labor rate is based on the Bureau of Labor Statistics (BLS) median hourly wage for a medical records and health information technician. The BLS is the principal Federal agency responsible for measuring labor market activity, working conditions, and price changes in the economy.[209] Acting as an independent agency, the BLS provides objective information for not only the government, but also for the public.[210] The BLS describes medical records and health information technicians as those responsible for processing and maintaining health information data.[211] Therefore, we believe is reasonable to assume that these individuals would be tasked with abstracting clinical data for the Hospital OQR Program measures.

We also proposed to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage rate ($18.29 × 2 = $36.58) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 throughout the discussion below for the Hospital OQR Program.

We invited public comment on these proposals.

Comment: One commenter expressed concern that a medical records and health information technician with a wage of $18.29 per hour is not appropriate to complete chart-abstraction and requested that we not reduce the estimated hourly wage rate from previous years.

Response: We note that we believe the wage for a medical records and health information technician is appropriate for use in this program, because such a technician is described as an individual who compiles, processes, and maintains medical records of hospital and clinic patients in a manner consistent with medical, administrative, ethical, legal, and regulatory requirements of the health care system.[212] We previously estimated a total cost to hospitals of $30 per hour (80 FR 70581), though we have not previously specified whether that rate included overhead and fringe benefits as well as wage. We note that our current calculations result in a higher estimate of total hourly cost for hospitals, as we proposed to use a median hourly wage of $18.29 per hour and double it to account for overhead and fringe benefits ($18.29 × 2 = $36.58), resulting in a higher hourly cost to hospitals of $36.58 per hour (compared to $30 per hour) to estimate burden in the Hospital OQR Program.

After consideration of the public comment we received, we are finalizing our estimates, as presented in the proposed rule to: (1) Estimate that reporting data for the Hospital OQR Program can be accomplished by staff with a median hourly wage of $18.29 per hour, and (2) calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage. These result in a wage plus benefits estimate of $36.58 for the Hospital OQR Program.

3. Estimated Burden Due to Newly Finalized Proposal To Delay OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With the CY 2020 Payment Determination

As described in section XIII.B.5. of this final rule with comment period, we are finalizing our proposal to delay OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection period). As we stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79863), the information collection requirements associated with the five OAS CAHPS Survey-based measures (OP–37a, OP–37b, OP–37c, OP–37d, and OP–37e) are currently approved under OMB Control Number 0938–1240. For this reason, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79863), we did not provide an independent estimate of the burden associated with OAS CAHPS Survey based measures for the Hospital

[208] BLS Occupational Employment Statistics; May 2016. Available at: *https://www.bls.gov/oes/current/oes292071.htm.*

[209] *http://www.bls.gov/bls/infohome.htm.*

[210] Ibid.

[211] BLS Occupational Employment Statistics; May 2016. Available at: *https://www.bls.gov/oes/current/oes292071.htm.*

[212] Ibid.

OQR Program. Similarly, our finalized proposal to delay implementation of these measures does not affect our current burden estimates.

4. Estimated Burden Due To Proposal to Publicly Report OP–18c: Median Time From Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients

In section XIII.B.10.b. of this final rule with comment period, we are finalizing, with modifications, our proposal to publicly report 18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients beginning with patient encounters from the third quarter of 2017. As noted in that section, the data required for public reporting of OP–18c are already collected as part of the existing Hospital OQR Program requirements. Accordingly, we did not estimate changes to burden due to this proposal, and we do not expect the modifications we are finalizing to affect burden.

5. Estimated Burden Due to Newly Finalized Proposals for the CY 2020 Payment Determination and Subsequent Years

a. Burden Due to Measure Removals

In section XIII.B.4.c. of this final rule with comment period, we are finalizing the removal of six measures from the Hospital OQR Program. Specifically, beginning with the CY 2020 payment determination, we are finalizing, as proposed, to remove: (1) OP–21: Median Time to Pain Management for Long Bone Fracture; and (2) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures. Also, while we proposed to remove: (1) OP 1: Median Time to Fibrinolysis, (2) OP–4: Aspirin at Arrival, (3) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional, and (4) OP–25: Safe Surgery Checklist beginning with the CY 2021 payment determination, we are finalizing removal of these measures with modification so that removal begins with the CY 2020 payment determination, one year earlier than proposed. In summary, we are finalizing removal of six measures beginning with the CY 2020 payment determination. We note that we have modified our estimates from the proposed rule (82 FR 33673) in order to streamline our discussion in light of the modification.

Specifically, we are finalizing the removal of four chart-abstracted measures ((1) OP–1: Median Time to Fibrinolysis; (2) OP–4: Aspirin at Arrival; (3) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional; and (4) OP–21: Median Time to Pain Management for Long Bone Fracture) and two web-based measures ((1) OP–25: Safe Surgery Checklist Use; and (2) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures). In total, we expect these finalized proposals will reduce burden by 457,490 hours and $16.7 million for the CY 2020 payment determination. These estimates are described in detail below.

We calculated the burden reduction associated with the removal of chart-abstracted measures by considering the time per case to report chart-abstracted measures (submitted using a web-based tool) as well as the number of cases per hospital and the number of participating hospitals. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582), we estimated the burden to collect chart-abstracted data for a single web-based measure, including OP–21, to be 2.92 minutes. In this final rule with comment period, we estimate that 3,300 outpatient hospitals report data under the Hospital OQR Program. Based on the most recent data from CY 2015 reporting, we also estimate that 947 cases are reported per hospital for each chart-abstracted measure. We note that although OP–1: Median Time to Fibrinolysis is a chart-abstracted measure, we do not expect removing this measure will reduce burden, as the data collected for this measure is required to calculate another program measure in the AMI measure set (OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and, therefore, will continue to be collected as an underlying part of OP–2 even though we are finalizing the proposal to remove OP–1. Accordingly, there is no change in burden associated with the finalized removal of this measure included in our calculations below.

Accordingly, we estimate a total burden reduction of 138.3 hours per outpatient hospital due to the removal of chart-abstracted measures (2.92 minutes per measure/60 minutes per hour × 3 measure × 947 cases per hospital). In total, across 3,300 outpatient hospitals, we estimate a burden reduction of 456,390 hours (138.3 hours per hospital × 3,300 hospitals) and $16,694,746 (456,390 total hours × $36.58 per hour) for the CY 2020 payment determination due to the finalized removal of (1) OP–1: Median Time to Fibrinolysis; (2) OP–4: Aspirin at Arrival; (3) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional; and (4) OP–21: Median Time to Pain Management for Long Bone Fracture.

We calculated the burden reduction associated with the finalized removal of two web-based measures (OP–25: Safe Surgery Checklist Use and OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures) by considering the time per measure to report web-based measures as well as the number of participating hospitals. As we previously stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582), we estimate that hospitals spend approximately 10 minutes per measure to report web-based measures and that 3,300 outpatient hospitals report data under the Hospital OQR Program. Accordingly, for the CY 2020 payment determination, we estimate a total burden reduction of 1,100 hours across 3,300 outpatient hospitals due to the removal of two web-based measures (10 minutes per measure/60 minutes per hour × 2 measures × 3,300 hospitals). We further estimate a cost reduction of $40,238 due to this finalized proposal (1,100 total hours × $36.58 per hour).

In total, we expect these finalized proposals will reduce burden by 457,490 hours (456,390 + 1,100) and $16,734,984 ($16,694,746 + $40,238) for the CY 2020 payment determination.

b. Burden Due to Updates to Previously Finalized Chart-Abstracted Measure Validation Procedures and the Educational Review Process

We previously estimated the burden associated with validation of chart-abstracted measures in the CY 2013 and CY 2014 OPPS/ASC final rules with comment period (77 FR 68531 and 78 FR 75172, respectively). In section XIII.D.7.a. of this final rule with comment period, we are providing clarification on our procedures for validation of chart-abstracted measures to note that the 50 poorest performing outlier hospitals will be targeted for validation. We do not expect this clarification to affect burden because it does not alter the number of hospitals selected for validation or the requirements for those hospitals that are selected.

In addition, in section XIII.D.7.c. of this final rule with comment period, we are finalizing our proposal to formalize the process of allowing hospitals to use an educational review process to correct incorrect validation results for the first three quarters of validation for chart-abstracted measures. We also are finalizing our proposal to update the process to specify that if the results of an educational review indicate that we

incorrectly scored a hospital's medical records selected for validation, the corrected quarterly validation score will be used to compute the hospital's final validation score at the end of the calendar year. Under this policy, the educational review request process remains the same for the CY 2020 payment determination and subsequent years, except that revised scores identified through an educational review will be used to correct a hospital's validation score. As a result, we do not expect this policy to affect the burden experienced by hospitals, as our changes to this policy result in a change in the way we address educational review requests and not a change to the process hospitals must follow to request an education review.

As we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we believe there is a burden associated with successful participation in the Hospital OQR Program, where successful participation results in a full annual payment update (APU) for a particular payment determination. This burden includes, but is not limited to, maintaining familiarity with the Hospital OQR Program requirements, which includes checking feedback reports to indicate a facility's current status or performance (78 FR 75171). The overall administrative burden was estimated at 42 hours per hospital (78 FR 75171). As stated above, we do not believe this burden will change with the finalization of our policy to update the educational review process to include corrections because no additional activity on the part of hospitals is required.

c. Burden Due to Proposal To Update to NOP Submission Deadline

We previously estimated the burden associated with Hospital OQR Program participation and requirements in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171). In section XIII.C.2. of this final rule with comment period, we are not finalizing our proposal to revise the NOP submission deadlines such that hospitals are required to submit the NOP any time prior to registering on the QualityNet Web site. We estimated that this proposal would have a negligible effect on the time and cost of completing the participation requirements. As a result, our decision not to finalize the proposal to revise the NOP submission deadline does not impact our burden estimates.

d. Burden Due To Aligning the First Quarter for Which Hospitals Must Submit Data for All Hospitals That Did Not Participate in the Previous Year's Hospital OQR Program

In section XIII.D.1 of this final rule with comment period, we are finalizing our proposals to align the timeline specifying the initial quarter for which hospitals must submit data for all hospitals that did not participate in the previous year's Hospital OQR Program, rather than specifying different timelines for hospitals with Medicare acceptance dates before versus after January 1 of the year prior to an affected annual payment update. Although this finalized proposal alters the timeline for hospitals to begin submitting data for the Hospital OQR Program, it does not alter program requirements. As a result, we do not anticipate that this proposal will affect burden.

e. Burden Due to Updates to the Previously Finalized ECE Policy

We previously estimated the burden associated with general and administrative Hospital OQR Program requirements in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171). In section XIII.D.8. of this final rule with comment period, we discuss our finalized alignment of the naming of this exception policy and finalized proposal to update 42 CFR 419.46(d) to reflect our current ECE policies. We also are clarifying the timing of our response to ECE requests. Because we do not seek any new or additional information in our finalized ECE proposals, we believe the updates will have no effect on burden for hospitals.

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015, CY 2016, and CY 2017 OPPS/ASC final rules with comment periods (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; and 81 FR 79863 through 79865, respectively) for detailed discussions of the ASCQR Program information collection requirements we have previously finalized. The information collection requirements associated with the ASCQR Program are currently approved under OMB control number 0938–1270. Below we discuss only the changes in burden that will result from the newly finalized provisions in this final rule with comment period.

In section XIV.B.3.b. of this final rule with comment period, we are finalizing our proposals, beginning with the CY 2019 payment determination, to remove three measures (ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing, ASC–6: Safe Surgery Checklist Use, and ASC–7: Ambulatory Surgical Center Facility Volume Data on Selected Ambulatory Surgical Center Surgical Procedures) from the ASCQR Program measure set. In section XIV.B.6.a. of this final rule with comment period, we are not finalizing our proposal, beginning with the CY 2021 payment determination, to adopt one new measure, ASC–16: Toxic Anterior Segment Syndrome. In section XIV.B.6.b. and c. of this final rule with comment period, we are finalizing our proposals, beginning with the CY 2022 payment determination, to adopt two new measures collected via claims (ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures and ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures). We expect these finalized proposals will reduce the overall burden of reporting data for the ASCQR Program, as discussed below.

In this final rule with comment period, we also are finalizing our proposals: (1) To delay ASC–15a–e: OAS CAHPS survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection) (section XIV.B.4. of this final rule with comment period); (2) to expand the CMS online tool to also allow for batch submission beginning with data submitted during CY 2018 and to make corresponding revisions to the CFR (section XIV.D.3.b. of this final rule with comment period); and, (3) to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy beginning with CY 2018 and to make conforming changes to the CFR (section XIV.D.6.b. of this final rule with comment period). As discussed below, we do not expect these finalized proposals to affect our burden estimates.

2. Newly Finalized Change in Hourly Labor Cost for Burden Calculation for the ASCQR Program

To better align this program with our other quality reporting and value-based purchasing programs, we are finalizing our proposal to update our burden calculation methodology to standardize elements within our burden calculation. Specifically, we are finalizing our proposal to utilize an updated standard hourly labor cost for data reporting activities.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79863

through 79864), we finalized our proposal to use the hourly labor cost of $32.84 (hourly wage plus fringe and overhead, discussed in more detail below) in estimating the labor costs associated with abstracting clinical data. This labor rate was based on the Bureau of Labor Statistics (BLS) median hourly wage for a medical records and health information technician of $16.42 per hour.[213] The BLS is the principal Federal agency responsible for measuring labor market activity, working conditions, and price changes in the economy.[214] Acting as an independent agency, the BLS provides objective information for not only the government, but also for the public.[215] The BLS describes medical records and health information technicians as those responsible for processing and maintaining health information data.[216] Therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for ASCQR Program measures.

The BLS recently released updated wage estimates for Medical Records and Health Information Technicians. These updates increased the median hourly wage from $16.42 per hour to $18.29 per hour.[217] Applying the same 100 percent overhead cost estimate finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79863 through 79864) to estimate the elements assigned as ''indirect'' or ''overhead'' costs, we estimate an updated total hourly cost to ASCs of $36.58. Therefore, we proposed to apply an updated hourly labor cost of $36.58 ($18.29 base salary + $18.29 fringe and overhead) to our burden calculations for chart abstraction.

We invited public comment on this proposal. We did not receive any public comments and are finalizing our proposal to apply an updated hourly labor cost of $36.58 ($18.29 base salary + $18.29 fringe and overhead) to our burden calculations for chart abstraction.

3. Estimated Burden of Newly Finalized ASCQR Program Proposals Beginning With CY 2018

In section XIV.B.4. of this final rule with comment period, we are finalizing our proposal to delay ASC–15a–e: OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection) until further notice in future rulemaking. As described in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79864), the information collection requirements associated with the five OAS CAHPS Survey based measures (ASC–15a, ASC–15b, ASC–15c, ASC–15d, and ASC–15e) are currently approved under OMB Control Number 0938–1240. For this reason, we did not provide an independent estimate of the burden associated with OAS CAHPS Survey administration for the ASCQR Program in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79864). Similarly, our finalized proposal to delay reporting on these measures does not affect our current burden estimates.

In section XIV.D.3. of this final rule with comment period, we are finalizing our proposals to expand the CMS online tool to also allow for batch submission beginning with data submitted during the CY 2018 reporting period and to make corresponding revisions to the CFR. We expect this finalized proposal to increase the efficiency of data submission via the CMS online tool. However, the finalized proposal does not change our data reporting requirements, and therefore, we do not expect a change in the burden experienced by ASCs.

In section XIV.D.6. of this final rule with comment period, we are finalizing our proposals to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy beginning with CY 2018 and to make conforming changes to the CFR. We are also clarifying the timing of our response to ECE requests. Because we do not seek any new or additional information in our ECE finalized proposals, we believe the updates will have no effect on burden for hospitals.

4. Estimated Burden of Newly Finalized ASCQR Program Proposals for the CY 2019 Payment Determination

In section XIV.B.3.b. of this final rule with comment period, we are finalizing our proposals, beginning with the CY 2019 payment determination, to remove three measures from the ASCQR Program. These measures include one claims-based measure (ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing) and two collected via a CMS online data submission tool (ASC–6: Safe Surgery Checklist Use and ASC–7: Ambulatory Surgical Center Facility Volume Data on Selected Ambulatory Surgical Center Surgical Procedures).

Data for ASC–5 is submitted via CMS claims using Quality Data Codes, which impose only a nominal burden on providers because these claims are already submitted for the purposes of payment. Therefore, we estimate a nominal reduction in burden associated with our finalized proposal to remove the ASC–5 measure from the ASCQR Program measure set beginning with the CY 2019 payment determination.

We believe 3,937 ASCs will experience a reduction in burden associated with our finalized proposals to remove ASC–6 and ASC–7 from the ASCQR Program measure set. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173), we finalized our estimates that each participating ASC will spend 10 minutes per measure per year to collect and submit the required data for the ASC–6 and ASC–7 measures, making the total estimated annual burden associated with each of these measures 657 hours (3,937 ASCs × 0.167 hours per ASC) and $24,033 (657 hours × $36.58 per hour). Therefore, we estimate a total reduction in burden of 1,314 (657 hours × 2 measures) hours and $48,066 (1,314 hours × $36.58 per hour) for all ASCs as a result of our finalized proposals to remove ASC–6 and ASC–7 from the ASCQR Program measure set. The reduction in burden associated with these requirements is available for review and comment under OMB Control Number 0938–1270.

5. Estimated Burden of ASCQR Program for the CY 2021 Payment Determination

In section XIV.B.6.a. of this final rule with comment period, we are not finalizing our proposal to adopt one new measure collected via a CMS online data submission tool, ASC–16: Toxic Anterior Segment Syndrome, beginning with the CY 2021 payment determination. Therefore, the initially estimated burden from the CY 2018 OPPS/ASC proposed rule (82 FR 33709) does not apply.

6. Estimated Burden of ASCQR Program Newly Finalized Proposals for the CY 2022 Payment Determination

In section XIV.B.6.b. and c. of this final rule with comment period, we are finalizing our proposals, beginning with the CY 2022 payment determination, to adopt two measures collected via claims: (1) ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and (2) ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures. Data used to calculate scores for these measures is collected via Part A and Part B Medicare administrative claims and Medicare

[213] Available at: *http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

[214] Available at: *http://www.bls.gov/bls/infohome.htm.*

[215] Ibid.

[216] BLS Occupational Employment Statistics; May 2016. Available at: *https://www.bls.gov/oes/current/oes292071.htm.*

[217] Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

enrollment data, and therefore does not require ASCs to report any additional data. Because these measures do not require ASCs to submit any additional data, we do not believe there will be any additional burden associated with these proposals.

XVII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this final rule with comment period, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XVIII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this final rule with comment period, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). This section of this final rule with comment period contains the impact and other economic analyses for the provisions that we are making for CY 2018.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule with comment period has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Congressional Review Act. Accordingly, this final rule with comment period has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this final rule with comment period. In the CY 2018 OPPS/ASC proposed rule (82 FR 33710), we solicited public comments on the regulatory impact analysis in the proposed rule, and we are addressing any public comments we received in this final rule with comment period as appropriate.

2. Statement of Need

This final rule with comment period is necessary to make updates to the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2018. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are revising the APC relative payment weights using claims data for services furnished on and after January 1, 2016, through and including December 31, 2016, and processed through June 30, 2017, and updated cost report information.

This final rule with comment period also is necessary to make updates to the ASC payment rates for CY 2018, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2018. Because ASC payment rates are based on the OPPS relative payment weights for the majority of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC not less frequently than every 2 years.

3. Overall Impacts for the OPPS and ASC Payment Provisions

We estimate that the total increase in Federal government expenditures under the OPPS for CY 2018, compared to CY 2017, due only to the changes to OPPS finalized in this final rule with comment period, will be approximately $690 million. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2018, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2018 will be approximately $69.9 billion; approximately $5.8 billion higher than estimated OPPS expenditures in CY 2017. Because this final rule with comment period is economically significant as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 88 displays the distributional impact of the CY 2018 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through estimates, and the application of the frontier State wage adjustment for CY 2017) will increase total OPPS payments by 1.3 percent in CY 2018. The changes to the APC relative payment weights, the changes to the wage indexes, the continuation of a payment adjustment for rural SCHs, including EACHs, and the payment adjustment for cancer hospitals will not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2017 and CY 2018, considering all payments, changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, will increase total estimated OPPS payments by 1.4 percent.

We estimate the total increase (from changes to the ASC provisions in this final rule with comment period as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures under the ASC payment system for CY 2018 compared to CY 2017 to be approximately $130 million. Because the provisions for the ASC payment system are part of a final rule that is economically significant as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the changes to the ASC payment system that, to the best of our

ability, presents the costs and benefits of this portion of this final rule with comment period. Table 89 and 90 of this final rule with comment period display the redistributive impact of the CY 2018 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule with comment period, 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 rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this final rule with comment period. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this final rule with comment period. In the CY 2018 OPPS/ASC proposed rule (82 FR 33711), we welcomed any comments on the approach in estimating the number of entities that will review the proposed rule. However, we did not receive any comments on our approach.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule with comment period, and therefore for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. In the CY 2018 OPPS/ASC proposed rule, we also sought public comments on this assumption, but we did not receive any comments.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/2016/may/naics4_621100.htm*). Assuming an average reading speed, we estimate that it will take approximately 8 hours for the staff to review half of this final rule with comment period. For each facility that reviews the rule, the estimated cost is $841.28 (8 hours × $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $2,851,939 ($841.28 × 3,390 reviewers).

5. Detailed Economic Analyses

a. Estimated Effects of OPPS Changes in This Final Rule With Comment Period

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2018 policy changes on various hospital groups. We post on the CMS Web site our hospital-specific estimated payments for CY 2018 with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1678–FC'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 88 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we have not made adjustments for future changes in variables such as service volume, service-mix, or number of encounters.

In the CY 2018 OPPS/ASC proposed rule, we solicited public comment and information about the anticipated effects of the proposed changes included in the proposed rule on providers and our methodology for estimating them. Any public comments that we receive are addressed in the applicable sections of this final rule with comment period that discuss the specific policies.

(2) Estimated Effects of OPPS Changes to Part B Drug Payment on 340B Eligible Hospitals Paid Under the OPPS

In section V.B.7. of this final rule with comment period, we discuss our finalized policies to reduce the payment for nonpass-through, separately payable drugs purchased by certain 340B-participating hospitals through the 340B Program. Rural SCHs, children's hospitals, and PPS-exempt cancer hospitals are excepted from this payment policy in CY 2018. Specifically, in this final rule with comment period, for CY 2018, for hospitals paid under the OPPS (other than those that are excepted for CY 2018), we are paying for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 22.5 percent instead of ASP+6 percent. For context, based on CY 2016 claims data, the total OPPS Part B drug payment is approximately $10.2 billion.

We recognize that it may be difficult to determine precisely what the impact on Medicare spending will be because OPPS claims data do not currently indicate if the drug being provided was purchased with a 340B discount. Furthermore, a list of outpatient drugs covered under the 340B program is not publicly available. Accordingly, for purposes of estimating the impact for this final rule with comment period, as we did in the CY 2018 OPPS/ASC proposed rule, we assumed that all applicable drugs purchased by hospitals eligible to participate in the 340B Program were purchased at a discounted price under the 340B program. While we recognize that certain newly covered entities do not have access to 340B drug pricing for designated orphan drugs, we believe that our CY 2018 policy to except newly covered entity types such as rural SCHs, PPS-exempt cancer hospitals, and children's hospitals, largely mitigates the 340B drug spend attributable to orphan drugs and therefore does not dramatically affect our final estimate. In addition, for this final rule with comment period, we utilized the HRSA covered entity database to identify 340B participating hospitals and cross-checked these providers with the CY 2018 OPPS facility impact public use file to determine which 340B hospitals are paid under the OPPS. The HRSA covered entity database is available via the Internet at *https://340bopais.hrsa.gov/coveredentitysearch*. Using this database, we found 1,338 OPPS hospitals in the 340B program (compared to the 954 estimated for the proposed rule). Of these, 270 were rural SCHs, 47 were children's hospitals, and 3 were PPS-exempt cancer hospitals. We did not assume changes in the quantity of 340B purchased drugs provided by hospitals participating in the 340B program (thereby affecting unit volume) or changes in the number of hospitals

participating in the 340B program that may occur due to the payment reduction.

While we acknowledge that there are some limitations in Medicare's ability to prospectively calculate a precise estimate for purposes of this final rule with comment period, we note that each hospital has the ability to calculate how this policy will change its Medicare payments for separately payable drugs in CY 2018. Specifically, each hospital that is not participating in the 340B program or that is excepted from the policy to pay for drugs acquired under the 340B Program at ASP minus 22.5 percent in CY 2018 will know that its Medicare payments for drugs will be unaffected by this finalized policy; whereas each hospital participating in the 340B Program has access to 340B ceiling prices (and subceiling prices if it participates in the Prime Vendor Program), knows the volume of 340B drugs that it has historically billed to Medicare, and can generally project the specific covered 340B drugs (and volume thereof) for which it expects to bill Medicare in CY 2018. Accordingly, a hospital participating in the 340B Program is able to estimate the difference in payment that it will receive if Medicare pays ASP minus 22.5 percent instead of ASP+6 percent for 340B drugs.

Using the list of participating 340B providers (derived from the HRSA database) and updated CY 2016 claims data available for this final rule with comment period for the applicable separately payable drugs and biologicals, excluding those on pass-through payment status and vaccines, billed by hospitals eligible to participate in the 340B Program, except for those hospital types that are excepted from this policy in CY 2018, we estimate that OPPS payments for separately payable drugs, including beneficiary copayments, will decrease by approximately $1.6 billion under this finalized policy, which reflects an additional estimated reduction of $700 million over the proposed rule estimate of $900 million. If PPS-exempt cancer hospitals, children's hospitals, and rural SCHs had *not* been excluded from the reduced drug payment in CY 2018, drug payments to PPS-exempt cancer hospitals would have been reduced by approximately $29 million, to children's hospitals by approximately $2 million, and to rural SCHs by approximately $199 million—this would have resulted in a total savings estimate of approximately $1.8 billion. Because we are implementing this payment reduction in a budget neutral manner within the OPPS, the reduced payments for separately payable drugs purchased through the 340B Program will increase payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount.

Because data on drugs that are purchased with a 340B discount are not publicly available, we do not believe it is possible to more accurately estimate the amount of the aggregate payment reduction and the offsetting amount of the adjustment that is necessary to ensure budget neutrality through higher payment rates for other services. Furthermore, there are potential offsetting factors, including possible changes in provider behavior and overall market changes that would likely lower the impact of the payment reduction. As a result, we may need to make an adjustment in future years to revise the conversion factor once we have received more accurate data on drugs purchased with a 340B discount within the OPPS, similar to the adjustment we made for clinical diagnostic laboratory test packaging policy in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70352 through 70357).

In this final rule, we project that reducing payment for 340B drugs to ASP minus 22.5 percent will increase OPPS payment rates for non-drug items and services by approximately 3.2 percent in CY 2018. The estimated impacts of this policy are displayed in Table 88 below. We note that the payment rates included in Addendum A and Addendum B of this final rule with comment period do not reflect the reduced payments for drugs purchased under the 340B Program; however, they do include the increase to payments rates for non-drug items and services due to the corresponding increase in the conversion factor. In the proposed rule (82 FR 33712), we reminded commenters that this estimate could change in the final rule based on a number of factors, including other policies that are adopted in the final rule and the availability of updated data and/or method of assessing the impact in the final rule. We sought public comment on our estimate and stated that we were especially interested in whether commenters believe there are other publicly available data sources or proxies that can be used for determining which drugs billed by hospitals paid under the OPPS were acquired under the 340B Program.

We proposed that the reduced payments for separately payable drugs and biologicals purchased under the 340B Program would be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scalar would not be applied in determining payments for these separately paid drugs and biologicals purchased under the 340B Program.

In addition, we solicited public comment on whether we should apply all or part of the savings generated by this payment reduction to increase payments for specific services paid under the OPPS, or under Part B generally, in CY 2018, rather than simply increasing the conversion factor. In particular, we sought public comment on whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured. Finally, we sought public comment on whether the redistribution of savings associated with the proposal would result in unnecessary increases in the volume of covered services paid under the OPPS that should be adjusted in accordance with section 1833(t)(2)(F) of the Act.

Comment: Several commenters stated that if the 340B drug payment policy was finalized, the funds should be redistributed across the OPPS, as has been the case for the application of budget neutrality in the past. One commenter supported CMS' proposal to implement the savings attributed to the 340B payment reduction in a budget neutral manner within the OPPS. Commenters noted that the budget neutrality requirement upon which CMS relied in the proposed rule at section 1833(t)(9)(B) of the Act has historically been interpreted by CMS as requiring budget neutrality within the OPPS. Commenters strongly urged CMS to follow its longstanding interpretation of section 1833(t)(9)(B) of the Act and offset the full amount of the aggregate 340B payment reduction through offsetting payment increases within the OPPS.

MedPAC reiterated its March 2016 recommendation that that payments be distributed in proportion to the amount of uncompensated care that hospitals provide, ''to make sure that dollars in the uncompensated care pool actually go to the hospitals providing the most uncompensated care.'' MedPAC commented that the 340B Program is not well targeted to hospitals that provide high levels of uncompensated care and noted that 40 percent of 340B hospitals provide less than the median level of uncompensated care. MedPAC stated that it believed that legislation would be needed to direct the savings to the uncompensated care pool because current law would require that the savings be retained within the OPPS to make it budget neutral. However,

MedPAC encouraged CMS to request that Congress enact the legislation necessary to allow CMS to implement its recommendation. MedPAC further noted that legislation would also allow CMS to apply the policy to all separately payable drugs, including those that are separately payable as a result of their pass-through status.

Response: We thank the commenters for their feedback. After consideration of the public comments we received, we are finalizing our proposal to fully redistribute the savings associated with adoption of the alternative payment methodology for drugs acquired under the 340B Program within the OPPS to non-drug items and services. That is, we will redistribute $1.6 billion dollars in estimated lower payment for OPPS drugs by increasing the conversion factor for all OPPS non-drug items and services by 3.2 percent. We may revisit how the funds should be targeted in the future.

Comment: Some commenters challenged the accuracy of the $900 million estimate CMS calculated in the proposed rule. According to these commenters, their analysis of the proposal would have an estimated impact in the range of $1.2 billion to $1.65 billion. As a result, these commenters asserted that if the proposed payment reductions are applied in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor, their analysis showed that payments for non-drug APCs would increase across hospitals by about 3.7 percent (in contrast to CMS's estimate of 1.4 percent) based on the proposed rule data. Moreover, based on their analysis, the commenters believed the redistribution of the savings would result in a net decrease in payments to 340B hospitals of approximately 2.6 percent, or approximately $800 million—funding that they stated was intended to support the congressionally-mandated mission of 340B hospitals—not be redistributed to other hospitals that do not participate in the 340B Program.

Response: We stated in the proposed rule that the estimate of the 340B payment reductions would likely change in the final rule based on updated data, revised assumptions, and final policies. For this final rule with comment period, as discussed in detail earlier, we used updated CY 2016 claims data and an updated list of 340B eligible providers to calculate an estimated impact of $1.6 billion based on the final policy. As shown in Table 88 below this reflects a reduction of about $1.5 billion to urban hospitals and $86 million to rural hospitals. We are redistributing the savings from this payment reduction in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor. This increase to the conversion factor increases all OPPS non-drug payment rates to all providers under the OPPS by 3.2 percent. With respect to comments on the redistribution of the 340B savings to non-340B participating hospitals, we note that 340B hospitals will also receive the conversion factor increase.

Comment: In response to the comment solicitation on whether the savings generated by the reduced payment on 340B drugs should be used to increase payments for specific services paid under the OPPS or under Part B generally in CY 2018, commenters generally objected to the notion that CMS has authority to redistribute savings outside of OPPS. One commenter stated that CMS did not provide any analysis or justification to support a reading that section 1833(t)(9)(B) of the Act establishes a budget neutrality concept for the Medicare Part B Trust Fund. Another commenter stated that CMS should not redistribute the savings gained by the 340B proposal based on Medicare DSH metrics (that is, insured low-income days) because such metrics are not well correlated with uncompensated care costs. This commenter also expressed concern regarding the suitability of using uncompensated care as a metric ''to identify hospitals that provide the most help to needy patients because it includes bad debt as well as charity care.'' The commenter stated that bad debt is the amount that hospitals billed but did not collect, and therefore is not a measure of hospital assistance to the poor. Several commenters challenged the logic of reducing 340B payments to participating 340B hospitals, only to return the savings to the very same hospitals.

Response: We appreciate the feedback. Because the OPPS is a budget neutral payment system, historically CMS has maintained budget neutrality through offsetting estimated payment decreases/increases within the OPPS, such as by increasing/decreasing the conversion factor by an equal offsetting amount. We have articulated the policy justification for reducing drug payment to ASP minus 22.5 percent for 340B-acquired drugs in section V.B.7. of this final rule with comment period and are redistributing the resulting dollars within the OPPS to maintain budget neutrality for CY 2018. Therefore, we are finalizing our proposal to redistribute the estimated reduction in payment for 340B-acquired drugs and biologicals by increasing the conversion factor, and we are not targeting the savings to specific services paid under the OPPS or under Part B generally. We continue to be interested in exploring ways that funds from a subsequent proposal could be targeted in future years to hospitals that serve a high share of low-income or uninsured patients.

Comment: Many commenters noted that CMS' proposal to redistribute the savings that result from the 340B reduction in a budget neutral manner within the OPPS would increase beneficiary copayments on non-drug services. Accordingly, the commenters stated that most patients would not directly receive the benefit of the 340B copayment reduction even if reduced payments for 340B drugs lower coinsurance amounts for these drugs. The commenters stated the proposal will likely increase costs for uninsured patients because 340B hospitals provide a disproportionate amount of care to that population and participating 340B hospitals may no longer be able to provide ''discounts to low-income patients'' or other uncompensated care. One commenter suggested that CMS, with stakeholder input, develop an outpatient hospital charity care metric that could be used to redistribute the 340B savings based on the level of outpatient charity care provided by the hospital.

Response: We appreciate the stakeholders' concerns. We believe that reducing payments on 340B purchased drugs to better align with hospital acquisition costs directly lowers drug costs for those beneficiaries who receive a covered outpatient drug from a 340B participating hospital. Further, to the extent that studies have found that 340B participating hospitals tend to use more high costs drugs, we believe that this 340B payment policy helps address drug pricing in the hospital outpatient setting by lessening the incentive for unnecessary utilization of costly drugs. In addition, even though many beneficiaries have supplemental coverage, those plans make coinsurance payments on behalf of beneficiaries. Thus, to the extent this policy lessens the coinsurance amount such supplemental plans would have to make, we would expect the price of such plans could decrease or otherwise reflect these lower costs in the future.

In summary, to maintain budget neutrality within the OPPS, the estimated $1.6 billion in reduced drug payments from adoption of this final 340B payment methodology will be redistributed in an equal offsetting amount to all hospitals paid under the

OPPS through increasing the payment rates by 3.2 percent for nondrug items and services furnished by all hospitals paid under the OPPS for CY 2018.

(3) Estimated Effects of OPPS Changes on Hospitals

Table 88 below shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 88, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2018, we are paying CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs), and we are paying hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in section II.B. of this final rule with comment period. Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The IPPS market basket percentage increase for FY 2018 is 2.7 percent (82 FR 38177). Section 1833(t)(3)(F)(i) of the Act reduces that 2.7 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.6 percentage point for FY 2018 (which is also the MFP adjustment for FY 2018 in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38177 through 38178)), and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act further reduce the market basket percentage increase by 0.75 percentage point, resulting in the OPD fee schedule increase factor of 1.35 percent. We are using the OPD fee schedule increase factor of 1.35 percent in the calculation of the CY 2018 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2018 estimates in Table 88.

To illustrate the impact of the CY 2018 changes, our analysis begins with a baseline simulation model that uses the CY 2017 relative payment weights, the FY 2017 final IPPS wage indexes that include reclassifications, and the final CY 2017 conversion factor. Table 88 shows the estimated redistribution of the increase or decrease in payments for CY 2018 over CY 2017 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2017 and CY 2018 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 1.35 percent OPD fee schedule increase factor update to the conversion factor; and the estimated impact taking into account all payments for CY 2018 relative to all payments for CY 2017, including the impact of changes in estimated outlier payments, the frontier State wage adjustment, and changes to the pass-through payment estimate (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2018. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2018 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2017 and CY 2018 by various groups of hospitals, which CMS cannot forecast.

In CY 2016, we excluded all molecular pathology laboratory tests from our packaging policy, and in CY 2017, we expanded the laboratory packaging exception to apply to all advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act. For CY 2018, we sought public comments on whether laboratories (instead of hospitals) should be permitted to bill Medicare directly for molecular pathology tests and ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act (and are granted ADLT status by CMS), that are ordered less than 14 days following the date of a hospital outpatient's discharge from the hospital outpatient department.

The laboratory date of service (DOS) issue is discussed in section X.F. of this final rule with comment period. Because there are currently no laboratory tests designated as ADLTs and because the payment rate for laboratory tests excluded from our packaging policy billed by a hospital would have been the applicable rate for the laboratory test under the CLFS, any aspect of this discussion that is finalized in this final rule with comment period will not result in a net costs or savings to the program. Accordingly, section X.F. of this final rule with comment period is not included in the impact table in the regulatory impact analysis.

Overall, we estimate that the rates for CY 2018 will increase Medicare OPPS payments by an estimated 1.4 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 1.5 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 88 shows the total number of facilities (3,878), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2016 hospital outpatient and CMHC claims data to model CY 2017 and CY 2018 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2017 or CY 2018 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State

of Maryland. This process is discussed in greater detail in section II.A. of this final rule with comment period. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,765), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 49 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience an increase of 0.1 percent, with the impact ranging from an increase of 0.1 percent to no change, depending on the number of beds. Rural hospitals will experience a decrease of 0.3 percent, with the impact ranging from a decrease of 0.2 percent to a decrease of 0.5 percent, depending on the number of beds. Major teaching hospitals will experience an increase of 0.1 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the FY 2018 IPPS post-reclassification wage indexes; the rural adjustment; and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2017 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the frontier State wage index adjustment, which is not budget neutral and is included in Column 6. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2018, as described in section II.E. of this final rule with comment period.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2018 scaled weights and a CY 2017 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2017 and CY 2018. The FY 2018 wage policy results in modest redistributions.

There is a slight increase of less than 0.1 in Column 3 for the CY 2018 cancer hospital payment adjustment budget neutrality calculation because we are using a payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2018 of 0.88, compared to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79869) payment-to-cost ratio target of 0.91. We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.89, not the 0.88 target payment-to-cost ratio we are applying in section II.F. of this final rule with comment period.

Column 4: Effect of the Reduced Payment for 340B Drugs

Column 4 demonstrates the total payment effect of the finalized reduction in payment for drugs purchased under the 340B Program from ASP+6 percent to ASP minus 22.5 percent. This column includes both the reduced payment for 340B acquired drugs and the increase to the conversion factor for budget neutrality purposes, which increases payment for all non-drug services. For rural sole community hospitals, this column shows a 2.6 percent increase, reflecting a 0.0 percent increase for drugs (because these providers are exempt from these reductions) and a 3.2 percent increase for non-drug services.

Column 5: All Budget Neutrality Changes Combined With the Market Basket Update

Column 5 demonstrates the combined impact of all of the changes previously described and the update to the conversion factor of 1.35 percent. Overall, these changes will increase payments to urban hospitals by 1.2 percent and to rural hospitals by 2.5 percent. Urban hospitals will receive an increase in line with the 1.3 percent overall increase for all facilities after the update is applied to the proposed budget neutrality adjustments. The increase for classes of rural hospitals is more variable with sole community hospitals receiving a 3.9 percent increase and other rural hospitals receiving an increase of 0.8 percent.

Column 6: All Changes for CY 2018

Column 6 depicts the full impact of the CY 2018 policies on each hospital group by including the effect of all of the changes for CY 2018 and comparing them to all estimated payments in CY 2017. Column 6 shows the combined budget neutral effects of Columns 2 through 4; the OPD fee schedule increase; the impact of the frontier State wage index adjustment; the impact of estimated OPPS outlier payments as discussed in section II.G. of this final rule with comment period; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIII. of this final rule with comment period); and the difference in total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2017 update (and assumed, for modeling purposes, to be the same number for CY 2018), we included 33 hospitals in our model because they had both CY 2016 claims data and recent cost report data. We estimate that the cumulative effect of all of the changes for CY 2018 will increase payments to all facilities by 1.4 percent for CY 2018. We modeled the independent effect of all of the changes in Column 6 using the final relative payment weights for CY 2017 and the final relative payment weights for CY 2018. We used the final conversion factor for CY 2017 of $75.001 and the final CY 2018 conversion factor of $78.636 discussed in section II.B. of this final rule with comment period.

Column 6 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the

FY 2018 IPPS/LTCH PPS final rule (82 FR 38527) of 4.6 percent (1.04574) to increase individual costs on the CY 2016 claims, and we used the most recent overall CCR in the July 2017 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2017. Using the CY 2016 claims and a 4.6 percent charge inflation factor, we currently estimate that outlier payments for CY 2017, using a multiple threshold of 1.75 and a fixed-dollar threshold of $3,825 will be approximately 1.11 percent of total payments. The estimated current outlier payments of 1.11 percent are incorporated in the comparison in Column 6. We used the same set of claims and a charge inflation factor of 9.4 percent (1.09357) and the CCRs in the July 2017 OPSF, with an adjustment of 0.985569, to reflect relative changes in cost and charge inflation between CY 2016 and CY 2018, to model the CY 2018 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $4,150. The charge inflation and CCR inflation factors are discussed in detail in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527).

Overall, we estimate that facilities will experience an increase of 1.4 percent under this final rule with comment period in CY 2018 relative to total spending in CY 2017. This projected increase (shown in Column 6) of Table 88 reflects the 1.35 percent OPD fee schedule increase factor, plus 0.2 percent for the change in the pass-through estimate between CY 2017 and CY 2018, minus a decrease of 0.11 percent for the difference in estimated outlier payments between CY 2017 (1.11 percent) and CY 2018 (1.0 percent). We estimate that the combined effect of all of the changes for CY 2018 will increase payments to urban hospitals by 1.3 percent. Overall, we estimate that rural hospitals will experience a 2.7 percent increase as a result of the combined effects of all of the changes for CY 2018.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include a decrease of 0.9 percent for major teaching hospitals and an increase of 2.9 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 1.7 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 1.3 percent, proprietary hospitals will experience an increase of 4.5 percent, and governmental hospitals will experience no change.

TABLE 88—ESTIMATED IMPACT OF THE CY 2018 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	APC recalibration (all changes)	New wage index and provider adjustments	340B adjustment	All budget neutral changes (combined cols 2–4) with market basket update	All changes
	(1)	(2)	(3)	(4)	(5)	(6)
ALL FACILITIES *	3,878	0.0	0.0	0.0	1.3	1.4
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,765	0.0	0.1	−0.1	1.4	1.5
URBAN HOSPITALS:	2,951	0.1	0.1	−0.3	1.2	1.3
LARGE URBAN (GT 1 MILL.)	1,589	0.1	0.0	−0.2	1.2	1.3
OTHER URBAN (LE 1 MILL.)	1,362	0.0	0.2	−0.3	1.3	1.4
RURAL HOSPITALS:	814	−0.3	0.0	1.4	2.5	2.7
SOLE COMMUNITY	372	−0.2	0.1	2.6	3.9	4.1
OTHER RURAL	442	−0.4	−0.2	0.0	0.8	0.9
BEDS (URBAN):						
0–99 BEDS	1,021	0.0	0.0	1.9	3.3	3.4
100–199 BEDS	850	0.0	0.2	1.2	2.8	2.9
200–299 BEDS	468	0.1	0.1	0.5	2.0	2.1
300–499 BEDS	399	0.1	0.0	−0.4	1.1	1.2
500 + BEDS	213	0.0	0.1	−2.2	−0.7	−0.6
BEDS (RURAL):						
0–49 BEDS	333	−0.5	−0.2	2.1	2.7	2.9
50–100 BEDS	297	−0.2	−0.2	1.9	2.8	3.0
101–149 BEDS	97	−0.3	0.1	1.1	2.3	2.5
150–199 BEDS	49	−0.2	0.1	0.7	1.9	2.1
200 + BEDS	38	−0.3	0.4	0.8	2.4	2.5
REGION (URBAN):						
NEW ENGLAND	144	0.2	0.4	−0.3	1.7	1.7
MIDDLE ATLANTIC	348	0.1	−0.2	−0.1	1.2	1.3
SOUTH ATLANTIC	463	0.0	0.3	−0.4	1.3	1.4
EAST NORTH CENT	471	0.0	0.1	−0.2	1.3	1.4
EAST SOUTH CENT	178	−0.1	−0.1	−1.6	−0.4	−0.3
WEST NORTH CENT	191	0.0	0.5	−0.6	1.3	1.4
WEST SOUTH CENT	513	0.0	0.3	0.9	2.5	2.6
MOUNTAIN	211	0.3	−0.9	−0.2	0.5	0.8
PACIFIC	383	0.1	0.0	−0.6	0.8	0.9
PUERTO RICO	49	−0.2	0.2	2.9	4.3	4.4
REGION (RURAL):						
NEW ENGLAND	21	0.1	1.5	1.2	4.2	4.2

TABLE 88—ESTIMATED IMPACT OF THE CY 2018 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	APC recalibration (all changes)	New wage index and provider adjustments	340B adjustment	All budget neutral changes (combined cols 2–4) with market basket update	All changes
	(1)	(2)	(3)	(4)	(5)	(6)
MIDDLE ATLANTIC	53	0.0	−0.5	1.8	2.6	2.7
SOUTH ATLANTIC	124	−0.4	−0.6	0.7	1.1	1.2
EAST NORTH CENT	122	−0.2	0.0	1.5	2.7	2.8
EAST SOUTH CENT	155	−0.6	−0.1	0.0	0.7	0.8
WEST NORTH CENT	98	−0.1	0.2	2.4	3.9	4.1
WEST SOUTH CENT	161	−0.6	0.3	2.6	3.6	3.7
MOUNTAIN	56	0.0	−0.3	1.9	3.0	3.3
PACIFIC	24	−0.1	0.1	1.7	3.0	3.1
TEACHING STATUS:						
NON-TEACHING	2,655	0.0	0.1	1.3	2.8	2.9
MINOR	761	0.1	0.1	0.1	1.6	1.7
MAJOR	349	0.1	0.0	−2.4	−1.0	−0.9
DSH PATIENT PERCENT:						
0	10	0.0	0.2	3.2	4.8	4.9
GT 0–0.10	272	0.2	−0.1	2.8	4.4	4.5
0.10–0.16	263	0.1	0.0	2.7	4.3	4.4
0.16–0.23	572	0.1	0.3	2.6	4.4	4.5
0.23–0.35	1,132	0.0	0.1	−0.4	1.0	1.2
GE 0.35	935	0.0	0.0	−2.2	−0.9	−0.8
DSH NOT AVAILABLE**	581	−2.0	0.1	2.0	1.4	1.5
URBAN TEACHING/DSH:						
TEACHING & DSH	1,002	0.1	0.0	−1.1	0.3	0.4
NO TEACHING/DSH	1,386	0.1	0.2	1.3	3.0	3.1
NO TEACHING/NO DSH	10	0.0	0.2	3.2	4.8	4.9
DSH NOT AVAILABLE**	553	−2.0	0.1	1.9	1.4	1.5
TYPE OF OWNERSHIP:						
VOLUNTARY	1,979	0.0	0.0	−0.3	1.2	1.3
PROPRIETARY	1,293	0.1	0.1	2.7	4.4	4.5
GOVERNMENT	493	−0.1	0.2	−1.6	−0.1	0.0
CMHCs	49	12.5	0.2	3.2	17.8	17.2

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all CY 2018 OPPS policies and compares those to the CY 2017 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2018 hospital inpatient wage index, including all hold harmless policies and transitional wages. The rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.0008 because the target payment-to-cost ratio changes from 0.91 in CY 2017 to 0.89 in CY 2018 and is further reduced by 1 percentage point to 0.88 in accordance with the 21st Century Cures Act. However, this reduction does not affect the budget neutrality adjustment consistent with statute.

Column (4) shows the impact of the 340B drug payment reductions and the corresponding increase in non-drug payments.

Column (5) shows the impact of all budget neutrality adjustments and the addition of the 1.35 percent OPD fee schedule update factor (2.7 percent reduced by 0.6 percentage points for the productivity adjustment and further reduced by 0.75 percentage point as required by law).

Column (6) shows the additional adjustments to the conversion factor resulting from the frontier adjustment, a change in the pass-through estimate, and adding estimated outlier payments.

*These 3,878 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

**Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

(4) Estimated Effects of OPPS Changes on CMHCs

The last line of Table 88 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2017, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming that CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2016 claims data used for this final rule with comment period. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs will experience an overall 17.2 percent increase in payments from CY 2017 (shown in Column 6). We note that this includes the trimming methodology described in section VIII.B. of this final rule with comment period.

Column 3 shows that the estimated impact of adopting the FY 2018 wage index values will result in a small increase of 0.2 percent to CMHCs. Column 5 shows that combining this OPD fee schedule increase factor, along with changes in APC policy for CY 2018 and the FY 2018 wage index updates, will result in an estimated increase of 17.8 percent. Column 6 shows that adding the changes in outlier and pass-though payments will result in a total 17.2 percent increase in payment for CMHCs. This reflects all changes to CMHCs for CY 2018.

(5) Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment will increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this final rule with comment period. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage will be 18.5 percent for all services paid under the OPPS in CY 2018. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the CY 2018 comprehensive APC payment policy discussed in section II.A.2.e. of this final rule with comment period.

(6) Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs as discussed in section XII. of this final rule with comment period. No types of providers or suppliers other than hospitals, CMHCs, and ASCs will be affected by the changes in this final rule with comment period.

(7) Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $690 million in program payments for OPPS services furnished in CY 2018. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We refer readers to our discussion of the impact on beneficiaries in section XVIII.A.4.a.(4) of this final rule with comment period.

(8) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are making and the reasons for our selected alternatives are discussed throughout this final rule with comment period.

• Alternatives considered for the enforcement instruction for the supervision of outpatient therapeutic services in critical access hospitals (CAHs) and certain small rural hospitals

We considered whether to address enforcement of the direct supervision requirement for outpatient therapeutic services in CAHs and small, rural hospitals with fewer than 100 beds by extending the notice of nonenforcement while we further develop our policies. There are grounds for applying the same supervision requirements to CAHs as to all other hospitals. One of these grounds is that hospital outpatient services are furnished ''incident to'' physicians' services, and we believe that the incident to rules apply equally to critical access and other types of hospitals. We also believe that Medicare should purchase the same basic level of quality and safe outpatient care for all beneficiaries, whether from a CAH, a small rural hospital, or other hospitals. At the same time, we acknowledge that in order to ensure the same level of outpatient care is furnished in CAHs and small rural hospitals as other hospitals, we need to continue the national discussion about what constitutes the appropriate supervision for a given service. We also need to acknowledge the challenges CAHs and small, rural hospitals have in recruiting and retaining physicians and qualified non-physician practitioners.

Therefore, we are extending the notice of nonenforcement for CAHs and small rural hospitals with fewer than 100 beds for CY 2018 and CY 2019, to give all parties time to submit specific services to be considered for a reduced minimum supervision standard. We believe that the policies in this final rule with comment period will address industry concerns while maintaining an adequate level of safety and quality of care in the hospital outpatient services that Medicare purchases.

• Alternatives Considered for the Methodology for Assigning Skin Substitutes to High or Low Cost Groups

We refer readers to section V.B.1.d. of this final rule with comment period for a discussion of our proposal to assign any skin substitute product that was assigned to the high cost group in CY 2017 to the high cost group in CY 2018, regardless of whether the product's mean unit cost (MUC) or the product's per day cost (PDC) exceeds or falls below the overall CY 2018 MUC or PDC threshold. We will continue to assign products that exceed either the overall CY 2018 MUC or PDC threshold to the high cost group. We also considered, but did not propose or finalize, retaining our methodology from CY 2017 and assigning skin substitutes to the high cost group based on whether an individual product's MUC or PDC exceeded the overall CY 2018 MUC or PDC threshold based on calculations done for either the proposed rule or this final rule with comment period.

b. Estimated Effects of CY 2018 ASC Payment System Policies

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XII. of this final rule with comment period, we are setting the CY 2018 ASC relative payment weights by scaling the CY 2018 OPPS relative payment weights by the ASC scalar of 0.8990. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 89 and 90 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which currently is the CPI–U) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2018 payment determinations will be based on the application of a 2.0 percentage points reduction to the annual update factor, which currently is the CPI–U. We calculated the CY 2018 ASC conversion factor by adjusting the CY 2017 ASC conversion factor by 1.0007 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2017 and CY 2018 and by applying the CY 2018 MFP-adjusted CPI–U update factor of 1.2 percent (projected CPI–U update of 1.7 percent minus a projected productivity adjustment of 0.5 percentage point). The CY 2018 ASC conversion factor is $45.575.

(1) Limitations of Our Analysis

Presented here are the projected effects of the changes for CY 2018 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2016 and CY 2018 with precision. We believe that the net effect

on Medicare expenditures resulting from the CY 2018 changes will be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs will experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the update to the CY 2018 payments will depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the CY 2018 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2016 claims data. Table 89 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2017 payments to estimated CY 2018 payments, and Table 90 shows a comparison of estimated CY 2017 payments to estimated CY 2018 payments for procedures that we estimate will receive the most Medicare payment in CY 2017.

Table 89 shows the estimated effects on aggregate Medicare payments under the ASC payment system by surgical specialty or ancillary items and services group. We have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 89.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—Estimated CY 2017 ASC Payments were calculated using CY 2016 ASC utilization (the most recent full year of ASC utilization) and CY 2017 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2017 ASC payments.
- Column 3—Estimated CY 2018 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that are attributable to updates to ASC payment rates for CY 2018 compared to CY 2017.

As seen in Table 89, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the update to ASC payment rates for CY 2017 will result in a 1-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 2-percent increase in aggregate payment amounts for digestive system procedures, 1-percent increase in aggregate payment amounts for nervous system procedures, a 3-percent increase in aggregate payment amounts for musculoskeletal system procedures, a 1-percent increase in aggregate payment amounts for genitourinary system procedures, and a 5-percent increase in aggregate payment amounts for integumentary system procedures.

Also displayed in Table 89 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. We estimate that aggregate payments for these items and services will decrease by 44 percent for CY 2018.

TABLE 89—ESTIMATED IMPACT OF THE CY 2018 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2018 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group	Estimated CY 2017 ASC payments (in millions)	Estimated CY 2018 percent change
(1)	(2)	(3)
Total	$4,460	1
Eye and ocular adnexa	1,688	1
Digestive system	852	2
Nervous system	849	1
Musculoskeletal system	530	3
Genitourinary system	186	1
Integumentary system	141	5
Ancillary items and services	55	−44

Table 90 below shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2018. The table displays 30 of the procedures receiving the greatest estimated CY 2017 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2017 program payment.

- Column 1—CPT/HCPCS code.

• Column 2—Short Descriptor of the HCPCS code.

• Column 3—Estimated CY 2017 ASC Payments were calculated using CY 2016 ASC utilization (the most recent full year of ASC utilization) and the CY 2017 ASC payment rates. The estimated CY 2017 payments are expressed in millions of dollars.

• Column 4—Estimated CY 2018 Percent Change reflects the percent differences between the estimated ASC payment for CY 2017 and the estimated payment for CY 2018 based on the update.

TABLE 90—ESTIMATED IMPACT OF THE CY 2018 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code	Short descriptor	Estimated CY 2017 ASC payment (in millions)	Estimated CY 2018 percent change
(1)	(2)	(3)	(4)
66984	Cataract surg w/iol 1 stage	$1,172	1
45380	Colonoscopy and biopsy	216	3
43239	Egd biopsy single/multiple	178	2
63685	Insrt/redo spine n generator	151	−1
45385	Colonoscopy w/lesion removal	146	3
63650	Implant neuroelectrodes	118	4
64483	Inj foramen epidural l/s	99	1
66982	Cataract surgery complex	94	1
0191T	Insert ant segment drain int	86	1
66821	After cataract laser surgery	69	0
64635	Destroy lumb/sac facet jnt	68	0
29827	Arthroscop rotator cuff repr	61	3
64493	Inj paravert f jnt l/s 1 lev	60	1
64590	Insrt/redo pn/gastr stimul	50	2
G0105	Colorectal scrn; hi risk ind	45	3
62323	Njx interlaminar lmbr/sac	45	3
45378	Diagnostic colonoscopy	44	3
G0121	Colon ca scrn not hi rsk ind	42	3
64721	Carpal tunnel surgery	34	−1
15823	Revision of upper eyelid	32	6
29881	Knee arthroscopy/surgery	30	5
29880	Knee arthroscopy/surgery	26	5
67042	Vit for macular hole	25	1
28285	Repair of hammertoe	24	5
52000	Cystoscopy	23	−1
26055	Incise finger tendon sheath	23	6
43235	Egd diagnostic brush wash	23	2
64561	Implant neuroelectrodes	22	6
50590	Fragmenting of kidney stone	21	1
67904	Repair eyelid defect	20	2

(3) Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2018 update to the ASC payment system will be generally positive for beneficiaries with respect to the new procedures that we are adding to the ASC list of covered surgical procedures and for those that we are designating as office-based for CY 2018. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services). Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. However, for those additional procedures that we are designating as office-based in CY 2018, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the MPFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

(4) Alternative ASC Payment Policies Considered

Alternatives to the ASC changes we are making and the reasons for our selected alternatives are discussed throughout this final rule with comment period.

c. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget Web site at: *https://www.whitehouse.gov/omb/circulars_a004_a-4#a*), we have prepared two accounting statements to illustrate the

impacts of this final rule with comment period. The first accounting statement, Table 91 below, illustrates the classification of expenditures for the CY 2018 estimated hospital OPPS incurred benefit impacts associated with the CY 2018 OPD fee schedule increase. The second accounting statement, Table 92 below, illustrates the classification of expenditures associated with the 1.2 percent CY 2018 update to the ASC payment system, based on the provisions of this final rule with comment period and the baseline spending estimates for ASCs. Lastly, the tables classify most estimated impacts as transfers.

TABLE 91—ACCOUNTING STATEMENT: CY 2018 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2017 TO CY 2018 ASSOCIATED WITH THE CY 2018 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$690 million.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS.
Total	$690 million.

TABLE 92—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2017 TO CY 2018 AS A RESULT OF THE CY 2018 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$40 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Total	$40 million.

d. Effects of Requirements for the Hospital OQR Program

(1) Background

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79874), for the previously estimated effects of changes to the Hospital OQR Program for the CY 2018, CY 2019, and CY 2020 payment determinations. Of the 3,228 hospitals that met eligibility requirements for the CY 2017 payment determination, we determined that 87 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. Most of these hospitals (66 of the 87), chose not to participate in the Hospital OQR Program for the CY 2017 payment determination. We estimate that approximately 100 hospitals will not receive the full OPD fee schedule increase factor for the CY 2018 payment determination and subsequent years.

In section XIII.B.4.c. of this final rule with comment period, we are finalizing the removal of six measures. Specifically, beginning with the CY 2020 payment determination, we are finalizing, as proposed, to remove: (1) OP–21: Median Time to Pain Management for Long Bone Fracture; and (2) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures. Also, while we proposed to remove: (1) OP 1: Median Time to Fibrinolysis, (2) OP–4: Aspirin at Arrival, (3) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional, and (4) OP–25: Safe Surgery Checklist beginning with the CY 2021 payment determination, we are finalizing removal of these measures with modification so that removal begins with the CY 2020 payment determination, one year earlier than proposed. To summarize, the following measures will be removed for the CY 2020 payment determination: (1) OP–1: Median Time to Fibrinolysis; (2) OP–4: Aspirin at Arrival; (3) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional; (4) OP–21: Median Time to Pain Management for Long Bone Fracture; (5) OP–25: Safe Surgery Checklist; and (6) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures. We expect these finalized proposals will reduce the burden of reporting for the Hospital OQR Program, as discussed in more detail below.

In section XIII.B.10.b. of this final rule with comment period, we are finalizing, with modifications, our proposal to publicly report OP–18c using data beginning with patient encounters during the third quarter of 2017. However, we do not expect our modifications to affect the burden estimates made in the CY 2018 OPPS/ASC proposed rule (82 FR 33705 through 33708), as discussed below.

In section XIII.B.5. of this final rule with comment period, we are finalizing our proposal to delay the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection period) until further notice in future rulemaking.

In addition, in this final rule with comment period, beginning with the CY 2020 payment determination, we are finalizing our proposals: (1) To codify at § 419.46(e) our previously finalized process for targeting hospitals for validation of chart-abstracted measures (section XIII.D.7.b. of this final rule with comment period); (2) to formalize the educational review process and use it to correct incorrect validation results for chart-abstracted measures (section XIII.D.7.c. of this final rule with comment period); (3) to align the first quarter for which hospitals must submit data for all hospitals that did not participate in the previous year's Hospital OQR Program, and make corresponding revisions at 42 CFR 419.46(c)(3) (section XIII.D.1. of this final rule with comment period); and (4) to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy and make conforming changes to the CFR (section XIII.D.8.a. of this final rule with comment period). We are not finalizing our proposals to change the NOP submission deadlines such that hospitals are required to submit the NOP any time prior to registering on the QualityNet Web site and to make conforming revisions at 42 CFR 419.46(a) (section XIII.C.2.b. of this final rule with comment period). We do not believe that these changes will affect our burden estimates, as further discussed below.

(2) Estimated Impact of Newly Finalized Proposal To Delay OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With the CY 2020 Payment Determination

As described in section XIII.B.5. of this final rule with comment period, we are finalizing our proposal to delay OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection period). As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79863), the information collection requirements associated with the five OAS CAHPS Survey-based measures (OP–37a, OP–37b, OP–37c, OP–37d, and OP–37e) are currently approved under OMB Control Number 0938–1240. For this reason, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79863), we did not provide an independent estimate of the burden associated with OAS CAHPS Survey based measures for the Hospital OQR Program. Similarly, our finalized proposal to delay implementation of these measures does not affect our current burden estimates.

(3) Estimated Impact of Proposal To Publicly Report OP–18c: Median Time From Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients

In section XIII.B.10.b. of this final rule with comment period, we are finalizing, with modifications, our proposal to publicly report 18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients beginning with patient encounters from the third quarter of 2017. As noted in that section, the data required for public reporting of OP–18c is already collected as part of the existing Hospital OQR Program requirements. Accordingly, we did not estimate changes to burden due to this proposal and we do not expect the modifications we are finalizing to affect burden.

(4) Estimated Impact of Newly Finalized Proposals for the CY 2020 Payment Determination and Subsequent Years

(a) Impact of Measure Removals

In section XIII.B.4.c. of this final rule with comment period, we are finalizing our proposals to remove six measures from the Hospital OQR Program. Specifically, beginning with the CY 2020 payment determination, we are finalizing, as proposed, to remove: (1) OP–21: Median Time to Pain Management for Long Bone Fracture; and (2) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures. Also, while we proposed to remove: (1) OP 1: Median Time to Fibrinolysis, (2) OP–4: Aspirin at Arrival, (3) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional, and (4) OP–25: Safe Surgery Checklist beginning with the CY 2021 payment determination, we are finalizing removal of these measures with modification so that removal begins with the CY 2020 payment determination, one year earlier than proposed. In summary, we are finalizing removal of six measures beginning with the CY 2020 payment determination. We note that we have modified our estimates from the proposed rule (82 FR 33673) in order to streamline our discussion in light of the modification.

Specifically, we are finalizing the removal of four chart-abstracted measures ((1) OP–1: Median Time to Fibrinolysis; (2) OP–4: Aspirin at Arrival; (3) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional; and (4) OP–21: Median Time to Pain Management for Long Bone Fracture) and two Web-based measures ((1) OP–25: Safe Surgery Checklist Use; and (2) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures). As described in section XVI.B. of this final rule with comment period, we expect these measure removals to reduce burden by 457,490 hours and $16.7 million for the CY 2020 payment determination.

(b) Impact of Updates to Previously Finalized Chart-Abstracted Measure Validation Procedures and the Educational Review Process

In section XIII.D.7.a. of this final rule with comment period, we provide clarification on our procedures for validation of chart-abstracted measures to note that the 50 poorest performing outlier hospitals will be targeted for validation. We do not expect this clarification to affect burden because it does not alter the number of hospitals selected for validation or the requirements for those hospitals that are selected.

In addition, in section XIII.D.7.c. of this final rule with comment period, we are finalizing our proposal to formalize the process of allowing hospitals to use an educational review process to correct incorrect validation results for the first three quarters of validation for chart-abstracted measures. We are also finalizing our proposal to update the process to specify that if the results of an educational review indicate that we incorrectly scored a hospital's medical records selected for validation, the corrected quarterly validation score will be used to compute the hospital's final validation score at the end of the calendar year. Under this finalized policy, the educational review request process remains the same for the CY 2020 payment determination and subsequent years, except that revised scores identified through an educational review will be used to correct a hospital's validation score. As a result, we do not expect this policy to affect the burden experienced by hospitals, as our changes to this policy result in a change in the way we address educational review requests and not a change to the process hospitals must follow to request an education review. As we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171), we believe there is a burden associated with successful participation in the Hospital OQR Program, where successful participation results in a full annual payment update (APU) for a particular payment determination. This burden includes, but is not limited to, maintaining familiarity with the Hospital OQR Program requirements, which includes checking feedback reports to indicate a facility's current status or performance (78 FR 75171). The overall administrative burden was estimated at 42 hours per hospital (78 FR 75171). As stated above, we do not believe this burden will change with the finalization of our policy to update the educational review process to include corrections.

(c) Impact of Proposed Update to NOP Submission Deadline

In section XIII.C.2. of this final rule with comment period, we are not finalizing our proposal to revise the NOP submission deadlines such that hospitals are required to submit the NOP any time prior to registering on the QualityNet Web site. We estimated that this proposal would have a negligible effect on the time and cost of completing the participation requirements. As a result, our decision not to finalize the proposal to revise the NOP submission deadline does not affect our burden estimates.

(d) Impact of Aligning the First Quarter for Which Hospitals Must Submit Data for All Hospitals That Did Not Participate in the Previous Year's Hospital OQR Program

In section XIII.D.1 of this final rule with comment period, we are finalizing our proposal to align the timeline specifying the initial quarter for which hospitals must submit data for all hospitals that did not participate in the previous year's Hospital OQR Program, rather than specifying different timelines for hospitals with Medicare acceptance dates before versus after January 1 of the year prior to an affected annual payment update. Although this finalized proposal alters the timeline for hospitals to begin submitting data for the Hospital OQR Program, it does not alter program requirements. As a result, we do not anticipate that this policy will affect burden.

(e) Impact of Updates to the Previously Finalized ECE Policy

We previously estimated the burden associated with general and administrative Hospital OQR Program requirements in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171). In section XIII.D.8. of this final rule with comment period, we discuss our finalized alignment of the naming of this exception policy and finalized proposal to update 42 CFR 419.46(d) to reflect our current ECE policies. We are also clarifying the timing of our response to ECE requests. Because we do not seek any new or additional information in our finalized ECE proposals, we believe the updates will have no effect on burden for hospitals.

We refer readers to section XVI.B. of this final rule with comment period (information collection requirements) for a detailed discussion of the burden of the requirements for submitting data to the Hospital OQR Program.

e. Effects of Proposed Requirements for the ASCQR Program

1. Background

In section XIV. of this final rule with comment period, we discuss our proposals to adopt policies affecting the ASCQR Program. For the CY 2017 payment determination, of the 3,937 ASCs that met eligibility requirements for the ASCQR Program, 209 ASCs did not meet the requirements to receive the full annual payment update. We note that, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79874), we used the CY 2016 payment determination numbers as a baseline, and estimated that approximately 200 ASCs will not receive the full annual payment update in CY 2018 due to failure to meet the ASCQR Program requirements (CY 2017 and CY 2018 payment determination information were not yet available).

In section XIV.B.3.b. of this final rule with comment period, we are finalizing our proposals, beginning with the CY 2019 payment determination, to remove three measures (ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing, ASC–6: Safe Surgery Checklist Use, and ASC–7: Ambulatory Surgical Center Facility Volume Data on Selected Ambulatory Surgical Center Surgical Procedures) from the ASCQR Program measure set. In section XIV.B.6.a. of this final rule with comment period, we are not finalizing our proposal, beginning with the CY 2021 payment determination, to adopt one new measure, ASC–16: Toxic Anterior Segment Syndrome. In section XIV.B.6.b. and c. of this final rule with comment period, we are finalizing our proposals, beginning with the CY 2022 payment determination, to adopt two new measures collected via claims (ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures and ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures). We expect these finalized proposals will reduce the overall burden of reporting data for the ASCQR Program, as discussed below.

In this final rule with comment period, we are also finalizing our proposals: (1) To delay ASC–15a–e: OAS CAHPS survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection) (section XIV.B.4. of this final rule with comment period); (2) to expand the CMS online tool to also allow for batch submission beginning with data submitted during CY 2018 and to make corresponding revisions to the CFR (section XIV.D.3.b. of this final rule with comment period); and, (3) to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy beginning with CY 2018 and to make conforming changes to the CFR (section XIV.D.6.b. of this final rule with comment period). As discussed below, we do not expect these finalized proposals to affect our burden estimates.

2. Estimated Burden of Newly Finalized ASCQR Program Proposals Beginning With CY 2018

In section XIV.B.4. of this final rule with comment period, we are finalizing our proposal to delay ASC–15a–e: OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection) until further notice in future rulemaking. As described in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79864), the information collection requirements associated with the five OAS CAHPS Survey based measures (ASC–15a, ASC–15b, ASC–15c, ASC–15d, and ASC–15e) are currently approved under OMB Control Number 0938–1240. For this reason, we did not provide an independent estimate of the burden associated with OAS CAHPS Survey administration for the ASCQR Program in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79864). Similarly, our finalized proposal to delay reporting on these measures does not affect our current burden estimates.

For CY 2018, we are finalizing two additional policies. First, in section XIV.D.3.b. of this final rule with comment period, we are finalizing our proposal to expand the CMS online tool to also allow for batch submission beginning with data submitted during CY 2018 and to make corresponding revisions to the CFR. Second, in section XIV.D.6. of this final rule with comment period, we discuss our intent to align the naming of this exception policy and update 42 CFR 416.310(d) to reflect our current ECE policies. We are also clarifying the timing of CMS' response to ECE requests. Because none of these policies change the reporting requirements of the ASCQR Program or require ASCs to submit any new or additional information, we believe the updates will have no effect on burden for ASCs.

3. Estimated Burden of Newly Finalized ASCQR Program Proposals for the CY 2019 Payment Determination

In section XIV.B.3.b. of this final rule with comment period, we are finalizing our proposals to remove one claims-based measure (ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing [218]) and two measures collected via a CMS online data submission tool (ASC–6: Safe Surgery Checklist Use and ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures) from the ASCQR Program measure set beginning with the CY 2019 payment determination. As discussed in section XVI.C.4. of this final rule with comment period, data for ASC–5 is submitted via

[218] As discussed in section XVI.C.4. of this final rule with comment period, data for ASC–5 is submitted via CMS claims using Quality Data Codes, which impose only a nominal burden on providers because these claims are already submitted for the purposes of payment. We therefore estimate a nominal reduction in burden associated with our finalized proposal to remove the ASC–5 measure from the ASCQR Program measure set beginning with the CY 2019 payment determination.

CMS claims using Quality Data Codes, which impose only a nominal burden on providers because these claims are already submitted for the purposes of payment. Therefore, we estimate a nominal reduction in burden associated with our finalized proposal to remove the ASC–5 measure from the ASCQR Program measure set beginning with the CY 2019 payment determination. As also discussed in section XVI.C.4. of this final rule with comment period, we estimate the proposals to remove ASC–6 and ASC–7 from the ASCQR Program measure set will reduce ASCs' data collection and submission burden by approximately 657 hours (3,937 ASCs × 0.167 hours per ASC) and $24,033 (657 hours × $36.58 per hour) per measure, or a total burden reduction of 1,314 (657 hours × 2 measures) and $48,066 (1,314 hours × $36.58 per hour) across all ASCs.

We did not propose to add any quality measures to the ASCQR measure set for the CY 2020 payment determination, and we do not believe that the other measures we previously adopted will cause any additional ASCs to fail to meet the ASCQR Program requirements. (We refer readers to section XIV.B.5. of this final rule with comment period for a list of these measures.) Therefore, we do not believe that these policies will increase the number of ASCs that do not receive a full annual payment update for the CY 2020 payment determination.

4. Estimated Burden of ASCQR Program for the CY 2021 Payment Determination

In section XIV.B.6.a. of this final rule with comment period, we are not finalizing our proposal to adopt one new measure collected via a CMS online data submission tool, ASC–16: Toxic Anterior Segment Syndrome. Therefore, the initially estimated burden from the CY 2018 OPPS/ASC proposed rule (82 FR 33721) does not apply.

5. Estimated Burden of ASCQR Program Newly Finalized Proposals for the CY 2022 Payment Determination

In sections XIV.B.6.b. and c. of this final rule with comment period, we are finalizing our proposals, beginning with the CY 2022 payment determination, to adopt two measures collected via claims: (1) ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and (2) ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures. Data used to calculate scores for these measures is collected via Part A and Part B Medicare administrative claims and Medicare enrollment data, and therefore does not require ASCs to report any additional data. Because these measures do not require ASCs to submit any additional data, we do not believe there will be any additional burden associated with these proposals.

We refer readers to the information collection requirements in section XVI.C. of this final rule with comment period for a detailed discussion of the financial and hourly burden of the ASCQR Program's current and proposed requirements.

B. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $38.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $15 million or less in any single year. For details, see the Small Business Administration's ''Table of Small Business Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards.*

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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 100 or fewer beds. We estimate that this final rule with comment period will increase payments to small rural hospitals by less than 3 percent; therefore, it should not have a significant impact on approximately 626 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

C. Unfunded Mandates Reform Act Analysis

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. That threshold level is currently approximately $148 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise promulgates, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. OMB's guidance, issued on April 5, 2017, explains that ''In general, Federal spending regulatory actions that cause only income transfers between taxpayers and program beneficiaries (*e.g.,* regulations associated with . . . Medicare spending) are considered 'transfer rules' and are not covered by EO 13771. However, in some cases, such regulatory actions may impose requirements apart from transfers, or transfers may distort markets causing inefficiencies. In those cases, the actions would need to be offset to the extent they impose more than de minimis costs.'' As shown in the previous discussion of Regulatory Review Costs under section XVIII.A.4. of this final rule with comment period, we estimate that total regulatory review costs on the affected entities will be approximately $2.8 million. As discussed in section XVI. of this final rule with comment period, we estimate that this rule leads to paperwork cost savings of approximately $16.8 million per year on an ongoing basis. It has been determined that this final rule with comment period is a deregulatory action for the purposes of Executive Order 13771.

E. Conclusion

The changes we are making in this final rule with comment period will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2018. Table 88 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements

that will result in a 1.4 percent increase in payments for all services paid under the OPPS in CY 2018, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, estimated payment for outliers, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS will experience more significant gains or losses in OPPS payments in CY 2018.

The updates to the ASC payment system for CY 2018 will affect each of the approximately 5,500 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 89 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted CPI–U update factor of 1.2 percent for CY 2018.

XIX. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this final rule with comment period in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 88 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will experience no change under this final rule with comment period. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this final rule with comment period, in conjunction with the remainder of this document, demonstrate that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This final rule with comment period will affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney disease, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is amending 42 CFR chapter IV as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1).

■ 2. Section 414.510 is amended by adding paragraph (b)(5) to read as follows:

§ 414.510 Laboratory date of service for clinical laboratory and pathology specimens.

* * * * *

(b) * * *

(5) In the case of a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test in § 414.502, the date of service of the test must be the date the test was performed only if—

(i) The test was performed following a hospital outpatient's discharge from the hospital outpatient department;

(ii) The specimen was collected from a hospital outpatient during an encounter (as both are defined in § 410.2 of this chapter);

(iii) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;

(iv) The results of the test do not guide treatment provided during the hospital outpatient encounter; and

(v) The test was reasonable and medically necessary for the treatment of an illness.

PART 416—AMBULATORY SURGICAL SERVICES

■ 3. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 4. Section 416.310 is amended by revising paragraphs (c)(1)(i) and (d) to read as follows:

§ 416.310. Data collection and submission requirements under the ASCQR Program.

* * * * *

(c) * * *

(1) * * *

(i) *QualityNet account for web-based measures.* ASCs, and any agents submitting data on an ASC's behalf, must maintain a QualityNet account in order to submit quality measure data to the QualityNet Web site for all web-based measures submitted via a CMS online data submission tool. A QualityNet security administrator is necessary to set up such an account for the purpose of submitting this information.

* * * * *

(d) *Extraordinary circumstances exceptions.* CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or if CMS determines that a systemic problem with one of its data collection systems directly affected the ability of the hospitals to submit data. CMS may grant an exception as follows:

(1) *Upon request of the ASC.* Specific requirements for submission of a request for an exception are available on the QualityNet Web site; or

(2) *At the discretion of CMS.* CMS may grant exceptions to ASCs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 5. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

■ 6. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*9*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*9*) For calendar year 2018, a multiproductivity adjustment (as determined by CMS) and 0.75 percentage point.

* * * * *

■ 7. Section 419.46 is amended—

■ a. In paragraph (a)(1) by removing the phrase ''Web site'' and adding in its place the term ''Web site''.

■ b. In paragraphs (b) and (c)(2) by removing the phrase ''Web site'' and adding in its place the term ''Web site''.

■ c. By revising paragraphs (c)(3)(i) and (ii) and (d).

■ d. By adding paragraph (e)(3).

■ e. In paragraphs (f)(1) and (g)(2) by removing the phrase ''Web site'' and adding in its place the term ''Web site'' wherever it appears.

The revisions and additions read as follow:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(c) * * *

(3) * * *

(i) Hospitals that did not participate in the previous year's Hospital OQR Program must initially submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update.

(ii) Hospitals that did not participate in the previous year's Hospital OQR Program must follow data submission deadlines as specified in paragraph (c)(2) of this section.

* * * * *

(d) *Exception.* CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) *Upon request by the hospital.* Specific requirements for submission of a request for an exception are available on the QualityNet Web site.

(2) *At the discretion of CMS.* CMS may grant exceptions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

(e) * * *

(3) CMS will select a random sample of 450 hospitals for validation purposes, and will select an additional 50 hospitals for validation purposes based on the following criteria:

(i) The hospital fails the validation requirement that applies to the previous year's payment determination; or

(ii) The hospital has an outlier value for a measure based on the data it submits. An ''outlier value'' is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score.

* * * * *

■ 8. Section 419.71 is added to read as follows:

§ 419.71 Payment reduction for certain X-ray imaging services.

(a) *Definition.* For purposes of this section, the term ''computed radiography technology'' means cassette-based imaging which utilizes an imaging plate to create the image involved.

(b) *Payment reduction for film X-ray imaging services.* For an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) is reduced by 20 percent.

(c) *Payment reduction for computed radiography imaging services.* The payment amount for an imaging service that is an X-ray taken using computed radiography technology (including the X-ray component of a packaged service) is reduced by—

(1) 7 percent, for such services furnished in CY 2018, 2019, 2020, 2021, or 2022.

(2) 10 percent, for such services furnished in CY 2023 or a subsequent calendar year.

(d) *Application without regard to budget neutrality.* The reductions taken under this section are not considered adjustments under section 1833(t)(2)(E) of the Act and are not implemented in a budget neutral manner.

Dated: October 26, 2017.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: October 30, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017–23932 Filed 11–1–17; 4:15 pm]

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FEDERAL REGISTER

Vol. 82 Monday,
No. 217 November 13, 2017

Part III

The President

Proclamation 9672—Veterans Day, 2017

Federal Register
Vol. 82, No. 217
Monday, November 13, 2017

Presidential Documents

Title 3—

The President

Proclamation 9672 of November 7, 2017

Veterans Day, 2017

By the President of the United States of America

A Proclamation

Our veterans represent the very best of America. They have bravely answered the call to serve in the finest military force in the world, and they have earned the dignity that comes with wearing the uniform and defending our great flag. On Veterans Day, we honor all Americans who have served in the Army, Navy, Air Force, Marines, and Coast Guard, both in times of war and peace. For nearly 100 years, since the end of World War I, Veterans Day has given us a time to pay due respect to our veterans, who have passed the torch of liberty from one generation to the next.

Part of paying our respect means recommitting to our Nation's sacred obligation to care for those who have protected the freedom we often take for granted. I have pledged to provide our service members with the best equipment, resources, and support in the world—support that must continue after they return to civilian life as veterans. This is why veterans' healthcare is a top priority for my Administration. I have signed legislation that improves accountability at the Department of Veterans Affairs (VA) and provides additional funding for the Veterans Choice Program, which ensures veterans continue to receive care in their communities from providers they trust. I have also signed legislation to give veterans GI Bill education benefits for their lifetime, and legislation to fix the VA appeals process, to ensure veterans can access the resources they are rightly due.

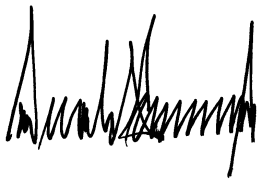
Additionally, this Veterans Day, more than 50 years from the beginning of the Vietnam War, I will be in Da Nang, Vietnam, with leaders of the Asia-Pacific Economic Cooperation forum. As we discuss ways to improve economic relationships between the United States and Asia in a country where Americans and Vietnamese once fought a war, we are compelled to recall and recognize the sacrifices of the more than 8 million Vietnam veterans who served here, beginning with those who arrived in the first American troop deployment in 1965 and ending with those who fought through the cease-fire of 1973. These men and women dedicated themselves, during one of the most challenging periods in our history, to promoting freedom across the globe. Many spent years away from their loved ones as they endured the burdens of battle and some experienced profound pain and anguish as their fellow warriors, more than 50,000 of them, lost their lives. Some of these heroes have yet to return home, as 1,253 of America's sons and daughters still remain missing. Along with our Vietnamese partners, however, we continue to work to account for them and to bring them home to American soil. We will not rest until that work is done.

With respect for, and in recognition of, the contributions our service members have made to the cause of peace and freedom around the world, the Congress has provided (5 U.S.C. 6103(a)) that November 11 of each year shall be set aside as a legal public holiday to honor our Nation's veterans. As Commander in Chief of our heroic Armed Forces, I humbly thank our veterans and their families as we remember and honor their service and their sacrifice.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, do hereby proclaim November 11, 2017, as Veterans Day. I encourage all Americans to recognize the fortitude and sacrifice of our

veterans through public ceremonies and private thoughts and prayers. I call upon Federal, State, and local officials to display the flag of the United States and to participate in patriotic activities in their communities. I call on all Americans, including civic and fraternal organizations, places of worship, schools, and communities to support this day with commemorative expressions and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this seventh day of November, in the year of our Lord two thousand seventeen, and of the Independence of the United States of America the two hundred and forty-second.



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Federal Register

Vol. 82, No. 217

Monday, November 13, 2017

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FEDERAL REGISTER PAGES AND DATE, NOVEMBER

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

Proposed Rules:
11 52036
73 52037
101 52036
573 50598
880 51585

23 CFR

Proposed Rules:
Ch. I 51178
490 51786
Ch. II 51178
Ch. III 51178

25 CFR

Ch. I 50532
Ch. II 50532
Ch. III 50532
Ch. V 50532
Ch. VI 50532
Ch. VII 50532
Proposed Rules:
514 52253

29 CFR

1926 51986

30 CFR

Ch. II 50532
Ch. IV 50532
Ch. V 50532
Ch. VII 50532
Ch. XII 50532

31 CFR

515 51998
543 52209
1010 51758

33 CFR

100 ..... 50575, 51765
117 ..... 50577, 51158, 51766, 52004, 52005, 52210
165 ..... 50578, 51347, 51767, 52005, 52007, 52210, 52212

36 CFR

Ch. I 50532
Ch. II 50580

37 CFR

42 51570
201 ..... 52213, 52221
202 52224
Proposed Rules:
201 ..... 51369, 52258
202 ..... 51369, 52258
381 51589

38 CFR

4 50802
17 51770
61 51158
62 51158

40 CFR

Ch. I 51160
52 ..... 50580, 50807, 50811, 50814, 51349, 51575
62 51350
97 50580
180 ..... 51351, 51355
Proposed Rules:
52 ..... 50851, 50853, 51178, 51594, 52259
60 ..... 51787, 51788, 51794
62 51380
63 51380

41 CFR

Ch. 109 50491

42 CFR

413 50738
414 ..... 50738, 52356
416 52356
419 52356
484 51676

43 CFR

Subtitle A 50532
Subtitle B 50532

45 CFR

Proposed Rules:
147 51052
153 51052
154 51052
155 51052
156 51052
157 51052
158 51052

46 CFR

Proposed Rules:
Ch. II 51178

47 CFR

2 50820
15 50820
18 50820
73 ..... 50820, 51178
74 50820
78 50820
80 50820
87 50820
90 50820
101 50820
Proposed Rules:
1 50598
54 51180

48 CFR

Ch. 1 51526
1 ..... 51527, 51773
4 ..... 51527, 51773
9 ..... 51527, 51773
17 ..... 51527, 51773
22 ..... 51358, 51527, 51773
42 ..... 51526, 51773
52 ..... 51358, 51527, 51773
Ch. 9 50491
Proposed Rules:
Ch. 12 51178

49 CFR

40 52229
Proposed Rules:
Ch. I 51178
Ch. II 51178
Ch. III 51178
Ch. V 51178
Ch. VI 51178
Ch. VII 51178
Ch. VIII 51178
Ch. X 51178
Ch. XI 51178

50 CFR

Ch. I 50532
20 51538
32 ..... 51940, 52009
36 52009
Ch. IV 50532
622 ..... 50839, 51577, 51777, 52248
648 ..... 51578, 51778, 52249
660 51166
679 ..... 51168, 52011
680 52011
Proposed Rules:
Ch. I 51382
17 ..... 50606, 52262
224 51186
226 51186
648 ..... 51492, 51594
660 51381

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List November 6, 2017

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