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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2017-0701; Directorate Identifier 2016-SW-063-AD; Amendment 39-18962; AD 2017-15-02]

RIN 2120-AA64

Airworthiness Directives; Bell Helicopter Textron, Inc. (Bell) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for Bell Model 212 and Model 412 helicopters. This AD requires replacing certain oil and fuel check valves and prohibits installing them on any helicopter. This AD is prompted by a report of cracked or leaking check valves. These actions are intended to address an unsafe condition on these helicopters.

DATES: This AD becomes effective August 4, 2017.

We must receive comments on this AD by September 18, 2017.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to <http://www.regulations.gov>. Follow the online instructions for sending your comments electronically.
- *Fax:* 202-493-2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.
- *Hand Delivery:* Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0701; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this final rule, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (817) 280-3391; fax (817) 280-6466; or at <http://www.bellcustomer.com/files/>. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Jurgen E. Priester, Aviation Safety Engineer, Delegation Systems Certification Office, ASW-130, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5159; email jurgen.e.priester@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments prior to it becoming effective. However, we invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that resulted from adopting this AD. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit them only one time. We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this

rulemaking during the comment period. We will consider all the comments we receive and may conduct additional rulemaking based on those comments.

Discussion

We are adopting a new AD for Bell Model 212 and Model 412 helicopters. This AD is prompted by a report that certain part numbered 209-062-520-001 check valves manufactured by Circo Aerospace as replacement parts have been found cracked or leaking on several Bell Model 427 and Model 429 helicopters. These check valves may be installed as engine oil check valves on Bell Model 212 helicopters. Similar check valves, part number 209-062-607-001, may be installed as fuel check valves on Bell Model 212 or 412 helicopters. These check valves may have a condition induced during assembly that can cause the valve body to crack, resulting in oil or fuel leakage. These suspect check valves are marked "Circle Seal" and were manufactured between October 2011 and March 2015. If not corrected, this condition could result in a crack, fuel or oil leakage, and subsequent failure of the engine or a fire and loss of control of the helicopter.

FAA's Determination

We are issuing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other helicopters of these same type designs.

Related Service Information

We reviewed Bell Alert Service Bulletin (ASB) 212-15-153, dated September 4, 2015 (212-15-153), and Bell ASB 212-15-155, dated September 15, 2015 (212-15-155), for Model 212 helicopters and Bell ASB 412-15-168, dated September 15, 2015 (412-15-168), for Model 412 helicopters. ASB 212-15-153 describes procedures for inspecting and replacing engine oil check valve part number (P/N) 209-062-520-001 installed on certain serial-numbered Model 212 helicopters. ASB 212-15-155 and ASB 412-15-168 describe procedures for inspecting and replacing fuel check valve P/N 209-062-607-001 installed on certain serial-numbered Model 212 and Model 412 helicopters.

AD Requirements

This AD requires, within 25 hours time-in-service (TIS), replacing the engine oil and fuel check valves.

This AD also prohibits installing a check valve P/N 209-062-520-001 or P/N 209-062-607-001 that was manufactured by Circor Aerospace, marked "Circle Seal," and marked with a manufacturing date code of "10/11" (October 2011) through "03/15" (March 2015) on any helicopter.

Differences Between This AD and the Service Information

The manufacturer's service information describes procedures for an inspection of the check valves within 25 hours TIS for a crack and allows 300 hours TIS to determine if the valve is affected and to replace any affected check valve. This AD requires replacing all affected check valves within 25 hours TIS.

Costs of Compliance

We estimate that this AD affects 161 (59 Model 212 and 102 Model 412) helicopters of U.S. Registry.

We estimate that operators may incur the following costs in order to comply with this AD. At an average labor rate of \$85, replacing each check valve (engine oil or fuel) will require about 1 work-hour, and required parts will cost \$85. For the Model 212, we estimate a total cost of \$340 per helicopter and \$20,060 for the U.S. fleet. For the Model 412, we estimate a total cost of \$170 per helicopter and \$17,340 for the U.S. fleet.

According to Bell's service information some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage by Bell. Accordingly, we have included all costs in our cost estimate.

FAA's Justification and Determination of the Effective Date

Providing an opportunity for public comments prior to adopting these AD requirements would delay implementing the safety actions needed to correct this known unsafe condition. Therefore, we find that the risk to the flying public justifies waiving notice and comment prior to the adoption of this rule because the actions required by this AD must be accomplished within 25 hours TIS, a very short interval for helicopters used in firefighting and logging operations.

Since an unsafe condition exists that requires the immediate adoption of this AD, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this

amendment effective in less than 30 days.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have 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.

For the reasons discussed, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by Reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2017-15-02 Bell Helicopter Textron, Inc. (Bell): Amendment 39-18962; Docket No. FAA-2017-0701; Directorate Identifier 2016-SW-063-AD.

(a) Applicability

This AD applies to Bell Model 212 and 412 helicopters, certificated in any category, with an engine oil check valve part number (P/N) 209-062-520-001 or fuel check valve P/N 209-062-607-001 manufactured by Circor Aerospace, marked "Circle Seal" and with a manufacturing date code of "10/11" (October 2011) through "03/15" (March 2015), installed.

(b) Unsafe Condition

This AD defines the unsafe condition as a cracked or leaking check valve, which could result in loss of lubrication or fuel to the engine, failure of the engine or a fire, and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective August 4, 2017.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

- (1) Within 25 hours time-in-service:
 - (i) Replace each fuel check valve.
 - (ii) For Model 212 helicopters, replace each engine oil check valve.
- (2) After the effective date of this AD, do not install any check valve P/N 209-062-520-001 or P/N 209-062-607-001 manufactured by Circor Aerospace, marked "Circle Seal" and with a manufacturing date code of "10/11" (October 2011) through "03/15" (March 2015), on any helicopter.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Delegation Systems Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Jurgen E. Priester, Aviation Safety Engineer, Delegation Systems Certification Office, ASW-130, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5159; email jurgen.e.priester@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

Bell Alert Service Bulletin (ASB) 212–15–153, dated September 4, 2015; Bell ASB 212–15–155, dated September 15, 2015; and Bell ASB 412–15–168, dated September 15, 2015, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (817) 280–3391; fax (817) 280–6466; or at <http://www.bellcustomer.com/files/>. You may review this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(h) Subject

Joint Aircraft Service Component (JASC) Codes: 7900 Engine Oil System and 2800 Aircraft Fuel System.

Issued in Fort Worth, Texas, on July 7, 2017.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2017–15031 Filed 7–19–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Parts 1 and 31**

[TD 9821]

RIN 1545–BN13

Return Due Date and Extended Due Date Changes

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations that update the due dates and extensions of time to file certain tax returns and information returns. The dates are updated to reflect the new statutory requirements set by section 2006 of the Surface Transportation and Veterans Health Care Choice Improvement Act of 2015 and section 201 of the Protecting Americans from Tax Hikes Act of 2015. These regulations affect taxpayers who file Form W–2 (series, except Form W–2G), Form W–3, Form 990 (series), Form 1099–MISC, Form 1041, Form 1041–A, Form 1065, Form 1120 (series), Form 4720, Form 5227, Form 6069, Form 8804, or Form 8870.

DATES: *Effective Date:* These regulations are effective July 20, 2017.

Applicability Date: For dates of applicability, see §§ 1.1446–3T(g)–(h),

1.6012–6T(c)–(d), 1.6031(a)–1T(f)–(g), 1.6032–1T(b)–(c), 1.6033–2T(k)–(l), 1.6041–2T(d)–(e), 1.6041–6T(c)–(d), 1.6072–2T(g)–(h), 1.6081–1T(c)–(d), 1.6081–2T(h)–(i), 1.6081–3T(g)–(h), 1.6081–5T(f)–(g), 1.6081–6T(g)–(h), 1.6081–9T(f)–(g), and 31.6071(a)–1T(g)–(h). For additional information, see the dates of applicability section of this preamble.

FOR FURTHER INFORMATION CONTACT:

Concerning these temporary regulations, Jonathan R. Black, (202) 317–6845; concerning submissions of comments and/or requests for a hearing, Regina Johnson (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:**Background**

These updates to the regulations reflect changes in tax return due dates enacted by section 2006 of the Surface Transportation and Veterans Health Care Choice Improvement Act of 2015 (the Surface Transportation Act), Public Law 114–41, 129 Stat. 443 (2015), as well as changes to information return due dates enacted by section 201 of the Protecting Americans from Tax Hikes Act of 2015 (PATH Act), Public Law 114–113, Div. Q, 129 Stat. 2242 (2015).

Prior to amendment by the Surface Transportation Act, section 6072(a) provided that the income tax returns of partnerships (generally Form 1065, “U.S. Return of Partnership Income”), trusts and estates (generally Form 1041, “U.S. Income Tax Return for Estates and Trusts”), and individuals (generally Form 1040, “U.S. Individual Income Tax Return”) were due on the fifteenth day of the fourth month following the close of the taxable year (April 15 for calendar-year taxpayers). Section 6072(b) generally provided that the income tax returns of corporations (most forms in the Form 1120 series) were due on the fifteenth day of the third month following the close of the taxable year (March 15 for calendar-year taxpayers).

Under section 6081(a), the Secretary generally has authority to grant a reasonable extension of time of up to six months for filing any return, statement, or other document (longer in the case of taxpayers who are abroad). Additionally, prior to amendment by the Surface Transportation Act, section 6081(b) provided for a three-month automatic extension of time to file for all corporations.

Immediately prior to the enactment of the Surface Transportation Act, § 1.6081–2 provided an automatic five-month extension of time to file Form 1065 and Form 8804, “Annual Return for Partnership Withholding Tax

(Section 1446),” § 1.6081–3 provided a six-month automatic extension of time to file the income tax return of all corporations (three months longer than the minimum three-month automatic extension), and § 1.6081–6 provided an automatic five-month extension of time to file Form 1041, such that the extended due date of these returns was the fifteenth day of the ninth month after the close of the taxable year (September 15 for calendar-year taxpayers). Section 1.6081–4 provided an automatic six-month extension of time to file individual income tax returns, such that the extended due date of an individual’s return was the fifteenth day of the tenth month after the close of the taxable year (October 15 for calendar-year taxpayers).

The amendments to section 6072(b) of the Internal Revenue Code made by section 2006(a) of the Surface Transportation Act change the due date for filing an income tax return by a C corporation from the fifteenth day of the third month following the close of the taxable year (March 15 for calendar-year taxpayers) to the fifteenth day of the fourth month following the close of the taxable year (April 15 for calendar-year taxpayers). The amendments also change the due date for filing an income tax return by a partnership from the fifteenth day of the fourth month following the close of the taxable year (April 15 for calendar-year taxpayers) to the fifteenth day of the third month following the close of the taxable year (March 15 for calendar-year taxpayers). Generally these amendments apply to returns for taxable years beginning after December 31, 2015. However, for any C corporation with a taxable year ending on June 30, these amendments apply to returns for taxable years beginning after December 31, 2025.

Section 2006(b) of the Surface Transportation Act provides that for taxable years beginning after December 31, 2015, the Secretary of the Treasury, or the Secretary’s designee, shall modify appropriate regulations regarding the due dates of certain returns and the maximum extensions of time to file certain returns, as specified in that section.

Section 2006(c) of the Surface Transportation Act generally changes the automatic extension of time to file the tax return of a C corporation provided by section 6081(b) from three months to six months. However, there are exceptions for C corporations with taxable years that begin before January 1, 2026. These statutory exceptions are (1) if a C corporation files for a calendar year, the automatic extension is five months; and (2) if the C corporation files

for a taxable year that ends on June 30, the automatic extension is seven months. These amendments apply to income tax returns for taxable years beginning after December 31, 2015.

Prior to enactment of the PATH Act, the due dates for filing forms in the Form W-2 series, Form W-3, and Form 1099-MISC on paper were either February 28 or the last day of February of the calendar year following the calendar year for which the information was being reported. See § 1.6041-2(a)(3)(ii) (Form W-2 not subject to FICA); § 31.6071(a)-1(a)(3)(i) (Form W-2 subject to FICA); and § 1.6041-6 (Form 1099-MISC). The due date for filing these information returns electronically was March 31 of the calendar year following the calendar year for which the information was being reported. See section 6071(b) prior to amendment by the PATH Act.

Section 201(a) and (c) of the PATH Act amended section 6071(b) and added new section 6071(c) to change the due date for information returns in the Form W-2 series, Form W-3, and “any returns or statements required by the Secretary to report nonemployee compensation.” Nonemployee compensation is currently reportable in box 7 of Form 1099-MISC. The amendments are effective for information returns for calendar years beginning after 2015. Under new section 6071(c), the new due date for returns in the Form W-2 series, Form W-3, and Forms 1099-MISC that report nonemployee compensation is January 31 of the calendar year following the calendar year for which the information is being reported, regardless of whether the returns are filed on paper or electronically. The due date for information returns on Forms 1099-MISC that do not report nonemployee compensation remains unchanged.

Explanation of Provisions

I. Section 2006 of the Surface Transportation Act

A. Partnership and Corporate Tax Returns

These temporary regulations amend § 1.6072-2 to account for the due dates for the income tax returns of C corporations specified by section 2006(a) of the Surface Transportation Act. Under § 1.6072-2T, except in the case of a C corporation that has a taxable year that ends on June 30, the last date for filing the income tax return of a C corporation is the fifteenth day of the fourth month following the close of the taxable year.

Additionally, § 1.6081-3T conforms to amended section 6081(b) by

providing a seven-month automatic extension of time to file the income tax return of any C corporation with a taxable year that ends on June 30 and before January 1, 2026. Prior to the Surface Transportation Act and these temporary regulations, § 1.6081-3 relied on the Secretary’s authority under section 6081(a) to provide for a six-month automatic extension of time to file for all corporations, despite section 6081(b) only requiring an automatic three-month extension. Similarly, these temporary regulations provide a six-month automatic extension of time to file a return for all corporations, except for C corporations that have a tax year that ends on June 30 and before January 1, 2026.

As a matter of administrative necessity, the return for a short period (within the meaning of section 443) that ends on any day in June is treated as if it is the return for a taxable year ending on June 30 for purposes of the last date for filing the income tax return of a C corporation under § 1.6072-2 and the duration of the extension of time to file the income tax return of a C corporation under § 1.6081-3.

Section 2006(b)(1) of the Surface Transportation Act specifies a maximum extension of time to file of six months for partnerships filing Form 1065. Accordingly, § 1.6081-2T provides that partnerships may obtain an automatic six-month extension of time to file Forms 1065 and 8804 if the partnership files an application in accordance with § 1.6081-2(b).

B. Form 1041, “U.S. Income Tax Return for Estates and Trusts”

Section 2006(b)(2) of the Surface Transportation Act requires the Secretary to amend appropriate regulations to provide that the maximum extension of time for the returns of trusts filing Form 1041 is five and one-half months (ending on September 30 in the case of calendar-year filers). Section 1.6081-6(a)(1) provides an automatic five-month extension of time for a non-bankruptcy estate or a trust to file this return, provided that the estate or trust files an application in accordance with § 1.6081-6(b). To implement section 2006(b)(2) of the Surface Transportation Act and provide consistency for automatic extensions for non-bankruptcy estates and trusts filing Form 1041, § 1.6081-6T(a)(1) provides both non-bankruptcy estates and trusts an automatic five and one-half month extension of time to file a Form 1041, provided that the estate or trust files an application in accordance with § 1.6081-6(b). These regulations do not

amend § 1.6081-6(a)(2), which addresses bankruptcy estates filing Form 1041.

C. Exempt Organizations

Section 2006(b)(4) through (b)(8) of the Surface Transportation Act requires the Secretary to modify appropriate regulations to provide a maximum six-month automatic extension of time to file returns of tax exempt organizations that were eligible for an automatic extension under § 1.6081-9 (except Form 1041-A, “U.S. Information Return-Trust Accumulation of Charitable Amounts,” which section 2006 of the Surface Transportation Act does not address). These returns are those in the Form 990 series (Form 990, “Return of Organization Exempt From Income Tax,” Form 990-BL, “Information and Initial Excise Tax Return for Black Lung Benefit Trusts and Certain Related Persons,” Form 990-EZ, “Short Form Return of Organization Exempt From Income Tax,” Form 990-PF, “Return of Private Foundation,” and Form 990-T, “Exempt Organization Business Tax Return”), Form 4720, “Return of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code,” Form 5227, “Split-Interest Trust Information Return,” Form 6069, “Return of Excise Tax on Excess Contributions to Black Lung Benefit Trust Under Section 4953 and Computation of Section 192 Deduction,” and Form 8870, “Information Return for Transfers Associated With Certain Personal Benefit Contracts.”

Section 1.6081-9 provided a six-month automatic extension of time to file the Form 990-T, but provided only a three-month automatic extension of time to file the other forms (including the Form 1041-A). To implement the Surface Transportation Act and for consistency, § 1.6081-9T provides an automatic six-month extension of time to file all of these forms if the exempt organization files an application in accordance with § 1.6081-9(b).

Also, for administrative convenience and to provide filers of Form 1120-POL, “U.S. Tax Return for Certain Political Organizations,” with an automatic extension of time to file that is consistent with the automatic extension of time to file applicable to other exempt organization returns identified above, the automatic extension of time to file Form 1120-POL is removed from the forms eligible for an extension of time to file under § 1.6081-3 and added to the forms eligible for a six-month extension of time to file under § 1.6081-9T.

D. Surface Transportation Act Provisions Not Addressed by These Regulations

Section 2006(b)(3) of the Surface Transportation Act requires the Secretary to amend appropriate regulations to provide that the maximum extension for returns of employee benefit plans filing Form 5500, "Annual Return/Report of Employee Benefit Plan," is an automatic three and one-half-month period (ending on November 15 in the case of calendar-year plans). Section 32104 of the FAST Act, Public Law 114-94, 129 Stat. 1312 (2015), repealed section 2006(b)(3) of the Surface Transportation Act effective for returns for taxable years beginning after December 31, 2015, such that the provision never took effect. Currently, § 1.6081-11 provides a two and one-half month extension of time to file Form 5500 if the administrator or sponsor files an application in accordance with § 1.6081-11(b), and these regulations do not amend that provision.

Section 2006(b)(9) of the Surface Transportation Act requires the Secretary to provide that the due date for Form 3520-A, "Annual Information Return of Foreign Trust with a US Owner," shall be the fifteenth day of the third month after the close of the trust's taxable year with a maximum extension of time to file of six months. Although § 404.6048-1(c)(1) provides that the due date of this return is the fifteenth day of the fourth month following the close of the taxable year, the form's instructions currently provide that the due date of this return is the fifteenth day of the third month following the close of the taxable year. Additionally, § 301.6081-2 provides for a six-month extension of time to file this return if the trust files an application in accordance with § 301.6081-2(b).

Section 2006(b)(10) of the Surface Transportation Act requires the Secretary to provide that the due date for Form 3520, "Annual Return to Report Transactions with Foreign Trusts and Receipt of Foreign Gifts," for calendar year filers shall be April 15 with a maximum extension of time to file of six months ending on October 15. The form's instructions currently provide that the due date of this return is the due date of the taxpayer's income tax return (in the case of a decedent, the decedent's estate and gift tax return), including any extension of time to file, and there are no regulations under section 6081 providing a separate extension of time to file this return. The due dates for the Forms 3520-A and 3520 and the extension of time to file

the Form 3520 will be addressed in a separate regulations project. Therefore, these regulations do not affect Forms 3520-A and 3520.

Section 2006(b)(11) of the Surface Transportation Act requires that the Secretary provide a due date of April 15 with a maximum extension of time to file of six months, ending on October 15, and a provision for extension rules similar to those in § 1.6081-5 (extension of time to file and pay until June 15 if taxpayer is out of the country), for FinCEN Report 114, "Report of Foreign Bank and Financial Accounts." Further, for any taxpayer required to file this return for the first time, section 2006(b)(11) of the Surface Transportation Act provides that the Secretary may waive any penalty for failure to timely request an extension.

On March 10, 2016, FinCEN published a notice of proposed rulemaking to address the extension of time to file FinCEN Report 114 (81 FR 12613). Therefore, these regulations do not address FinCEN Report 114.

The filing date changes enacted by the Surface Transportation Act also indirectly affect various due dates and extended due dates that, although determined by section 6072, are often specified throughout Title 26 of the Code of Federal Regulations by cross-reference to, or by restating the dates in, section 6072 prior to amendment by the Surface Transportation Act. Examples of such regulations include §§ 1.170A-11, 1.316-1, 1.338-10, 1.367(a)-7, 1.381(c)(14)-1, 1.468A-4, 1.468B-2, 1.547-4, 1.563-1, 1.563-2, 1.921-2, 1.923-1T, 1.925(a)-1T, 1.927(b)-1T, 1.936-1, 1.1248(f)-3, 1.1446-6, 1.6425-1, 1.6655-1, and 1.6655-7. Because the Treasury Department must prioritize limited resources, these regulations generally do not make amendments to update, conform, or clarify the due dates and extended due dates referenced in such sections. To the extent that any existing regulations (including examples) are not consistent with the due dates specified by section 6072 (as amended by the Surface Transportation Act), the statutory due dates control. If resources permit, the Treasury Department and the IRS will update outdated examples and regulatory text through future guidance projects. In the meantime, taxpayers should refer to the relevant form instructions for guidance.

E. Miscellaneous Clarifications, Corrections, and Updates

These regulations also include some changes that correct minor typographical errors or make clarifications or updates. The period of underpayment of estimated tax by a

corporation under section 6655 for the section 1446 withholding tax described in § 1.1446-3(b)(2)(v)(C) is administratively tied to the due date of Form 8804. These regulations therefore revise § 1.1446-3(b)(2)(v)(C) to update the period of underpayment for the section 1446 withholding tax. Additionally, the due date for returns of banks with respect to common trust funds, commonly filed on Form 1065, is administratively tied to the due date of Form 1065, so these regulations update § 1.6032-1 to clarify that the due date for these returns has changed. Similarly, the annual return filed by a religious or apostolic association or corporation on Form 1065 is to be filed on the due date of a partnership return under section 6072(b), so these regulations update § 1.6033-2(e) to clarify that the due date for these returns has changed.

II. PATH Act

These regulations also contain conforming amendments to reflect that the due date for forms in the Form W-2 series, Form W-3, and Forms 1099-MISC that report nonemployee compensation is January 31 of the calendar year following the calendar year for which the information is being reported, as enacted by section 201 of the PATH Act.

Dates of Applicability

These regulations are generally applicable for returns filed on or after the date of publication of this Treasury Decision. Many of the amendments in these regulations, however, reflect statutory changes that were effective for taxable years beginning after December 31, 2015, and those statutory changes, described in the background section of this preamble, supersede regulations that are amended by this Treasury Decision. Additionally, taxpayers may elect to apply these regulations to returns filed for periods beginning after December 31, 2015. The election is made by filing a return by the due date or extended due date specified in these regulations if that due date is later than the due date specified by regulations in effect at the time the return is filed.

Special Analyses

Certain IRS regulations, including these regulations, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory assessment is not required. For applicability of the Regulatory Flexibility Act, please refer to the cross-reference notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. Pursuant to section

7805(f) of the Internal Revenue Code, these temporary regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact on small businesses.

Drafting Information

The principal author of these regulations is Jonathan R. Black of the Office of the Associate Chief Counsel (Procedure and Administration).

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 31

Employment taxes, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social security, Unemployment compensation.

Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 31 are amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Revise paragraph (b)(2)(v)(C) and add paragraph (g) to § 1.1446-3 to read as follows:

§ 1.1446-3 Time and manner of calculating and paying over the 1446 tax.

* * * * *

(b) * * *
(2) * * *
(v) * * *

(C) [Reserved]. For further guidance, see § 1.1446-3T(b)(2)(v)(C).

* * * * *

(g) [Reserved]. For further guidance, see § 1.1446-3T(g).

■ **Par. 3.** Add § 1.1446-3T to read as follows:

§ 1.1446-3T Time and manner of calculating and paying over the 1446 tax (temporary).

(a) [Reserved]. For further guidance, see § 1.1446-3(a).

(b)(1) [Reserved]. For further guidance, see § 1.1446-3(b)(1).

(2)(i) through (iv) [Reserved]. For further guidance, see § 1.1446-3(b)(2)(i) through (iv).

(v)(A) through (B) [Reserved]. For further guidance, see § 1.1446-3(b)(2)(v)(A) and (B).

(C) *Period of underpayment.* The period of the underpayment set forth in section 6655(b)(2) shall end on the

earlier of the date the partnership is required to file Form 8804 (as provided in paragraph (d)(1)(iii) of this section and without regard to extensions), or with respect to any portion of the underpayment, the date on which such portion is paid.

(c) through (f) [Reserved]. For further guidance, see § 1.1446-3(c) through (f).

(g) *Applicability date.* This section applies to returns filed on or after July 20, 2017. Sections 1.1446-3 and 1.1446-7 (as contained in 26 CFR part 1, revised April 2017) apply to returns filed before July 20, 2017.

(h) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

■ **Par. 4.** Revise paragraph (a)(1) of § 1.6012-6 to read as follows:

§ 1.6012-6 Returns by political organizations.

(a) * * * (1) [Reserved]. For further guidance, see § 1.6012-6T(a)(1).

* * * * *

■ **Par. 5.** Add § 1.6012-6T to read as follows:

§ 1.6012-6T Returns by political organizations (temporary).

(a) *Requirement of return—(1) In general.* For taxable years beginning after December 31, 1974, every political organization described in section 527(e)(1), and every fund described in section 527(f)(3) or section 527(g), and every organization described in section 501(c) and exempt from taxation under section 501(a) shall, if a tax is imposed on such an organization or fund by section 527(b), make a return of income on or before the fifteenth day of the fourth month following the close of the taxable year.

(2) [Reserved]. For further guidance, see § 1.6012-6(a)(2).

(b) [Reserved]. For further guidance, see § 1.6012-6(b).

(c) *Applicability date.* This section applies to returns filed after July 20, 2017. Section 1.6012-6 (as contained in 26 CFR part 1, revised April 2017) applies to returns filed before July 20, 2017.

(d) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

■ **Par. 6.** Revise paragraph (e)(2) of § 1.6031(a)-1 to read as follows:

§ 1.6031(a)-1 Return of partnership income.

* * * * *

(e) * * *

(2) [Reserved]. For further guidance, see § 1.6031(a)-1T(e)(2).

* * * * *

■ **Par. 7.** Add § 1.6031(a)-1T to read as follows:

§ 1.6031(a)-1T Return of partnership income (temporary).

(a) through (d) [Reserved]. For further guidance, see § 1.6031(a)-1(a) through (d).

(e)(1) [Reserved]. For further guidance, see § 1.6031(a)-1(e)(1).

(2) *Time for filing.* The return of a partnership must be filed on or before the date prescribed by section 6072(b).

(f) *Applicability date.* This section applies to returns filed on or after July 20, 2017. Section 1.6031(a)-1 (as contained in 26 CFR part 1, revised April 2017) applies to returns filed before July 20, 2017.

(g) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

■ **Par. 8.** Revise § 1.6032-1 to read as follows:

§ 1.6032-1 Returns of banks with respect to common trust funds.

[Reserved]. For further guidance, see § 1.6032-1T.

■ **Par. 9.** Add § 1.6032-1T to read as follows:

§ 1.6032-1T Returns of banks with respect to common trust funds.

(a) Every bank (as defined in section 581) maintaining a common trust fund shall make a return of income of the common trust fund, regardless of the amount of its taxable income. Member banks of an affiliated group that serve as co-trustees with respect to a common trust fund must act jointly in making a return for the fund. If a bank maintains more than one common trust fund, a separate return shall be made for each. No particular form is prescribed for making the return under this section, but Form 1065 may be used if it is designated by the bank as the return of a common trust fund. The return shall be made for the taxable year of the common trust fund and shall be filed on or before the date prescribed by section 6072(b) with the service center prescribed in the relevant IRS revenue procedure, publication, form, or instructions to the form (see § 601.601(d)(2) of this chapter). Such return shall state specifically with respect to the fund the items of gross income and the deductions allowed by subtitle A of the Code, shall include each participant's name and address, the participant's proportionate share of taxable income or net loss (exclusive of gains and losses from sales or exchanges of capital assets), the participant's proportionate share of gains and losses from sales or exchanges of capital assets,

and the participant's share of items which enter into the determination of the tax imposed by section 56. See §§ 1.584-2 and 1.58-5. If the common trust fund is maintained by two or more banks that are members of the same affiliated group, the return must also identify the member bank in the group that has contributed each participant's property or money to the fund. A copy of the plan of the common trust fund must be filed with the return. If, however, a copy of such plan has once been filed with a return, it need not again be filed if the return contains a statement showing when and where it was filed. If the plan is amended in any way after such copy has been filed, a copy of the amendment must be filed with the return for the taxable year in which the amendment was made. For the signing of a return of a bank with respect to common trust funds, see § 1.6062-1, relating to the manner prescribed for the signing of a return of a corporation.

(b) This section applies to returns filed on or after July 20, 2017. Section 1.6032-1 (as contained in 26 CFR part 1, revised April 2017) applies to taxable years beginning before July 20, 2017.

(c) The applicability of this section will expire on or before July 17, 2020.

■ **Par. 10.** Revise paragraph (e) of § 1.6033-2 to read as follows:

§ 1.6033-2 Returns by exempt organizations (taxable years beginning after December 31, 1969) and returns by certain nonexempt organizations (taxable years beginning after December 31, 1980).

* * * * *

(e) [Reserved]. For further guidance, see § 1.6033-2T(e).

* * * * *

■ **Par. 11.** Add § 1.6033-2T to read as follows:

§ 1.6033-2T Returns by exempt organizations (taxable years beginning after December 31, 1969) and returns by certain nonexempt organizations (taxable years beginning after December 31, 1980) (temporary).

(a) through (d) [Reserved]. For further guidance, see § 1.6033-2(a) through (d).

(e) *Time and place for filing.* The annual return required by this section shall be filed on or before the 15th day of the fifth calendar month following the close of the period for which the return is required to be filed. The annual return on Form 1065 required to be filed by a religious or apostolic association or corporation shall be filed on or before the date prescribed by section 6072(b). Each such return shall be filed in accordance with the instructions applicable thereto.

(f) through (j) [Reserved]. For further guidance, see § 1.6033-2(f) through (j).

(k) *Applicability date.* This section applies to returns filed on or after July 20, 2017. Section 1.6033-2 (as contained in 26 CFR part 1, revised April 2017) applies to returns filed before July 20, 2017.

(l) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

■ **Par. 12.** Revise paragraph (a)(3)(ii) of § 1.6041-2 to read as follows:

§ 1.6041-2 Return of information as to payments to employees.

(a) * * *

(3) * * *

(ii) [Reserved]. For further guidance, see § 1.6041-2T(a)(3)(ii).

* * * * *

■ **Par. 13.** Add § 1.6041-2T to read as follows:

§ 1.6041-2T Return of information as to payments to employees (temporary).

(a)(1) through (2) [Reserved]. For further guidance, see § 1.6041-2(a)(1) and (2).

(3)(i) [Reserved]. For further guidance, see § 1.6041-2(a)(3)(i).

(ii) *Exception.* In a case where an employer is not required to file Forms W-3 and W-2 under § 31.6011(a)-4 or § 31.6011(a)-5 of this chapter, returns on Forms W-3 and W-2 required under this paragraph (a) for any calendar year shall be filed on or before January 31 of the following year.

(b) through (c) [Reserved]. For further guidance, see § 1.6041-2(b) through (c).

(d) *Applicability date.* This section applies to returns filed on or after July 20, 2017. Section 1.6041-2 (as contained in 26 CFR part 1, revised April 2017) applies to returns filed before July 20, 2017.

(e) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

■ **Par. 14.** Revise § 1.6041-6 to read as follows:

§ 1.6041-6 Returns made on Forms 1096 and 1099 under section 6041; contents and time and place for filing.

[Reserved]. For further guidance, see § 1.6041-6T.

■ **Par. 15.** Add § 1.6041-6T to read as follows:

§ 1.6041-6T Returns made on Forms 1096 and 1099 under section 6041; contents and time and place for filing (temporary).

(a) *In general.* Except as provided in paragraph (b) of this section, returns made under section 6041 on Forms 1096 and 1099 for any calendar year shall be filed on or before February 28 (March 31

if filed electronically) of the following year with any of the Internal Revenue Service Centers, the addresses of which are listed in the instructions for such forms. The name and address of the person making the payment and the name and address of the recipient of the payment shall be stated on Form 1099. If the present address of the recipient is not available, the last known post office address must be given. See section 6109 and the regulations thereunder for rules requiring the inclusion of identifying numbers in Form 1099.

(b) *Exception.* Returns made on Form 1099 reporting nonemployee compensation shall be filed on or before January 31 of the year following the calendar year to which such returns relate.

(c) *Applicability date.* This section applies to returns filed on or after July 20, 2017. Section 1.6041-6 (as contained in 26 CFR part 1, revised April 2017) applies to returns filed before July 20, 2017.

(d) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

■ **Par. 16.** Revise paragraphs (a) and (d)(1) and (2) of § 1.6072-2 to read as follows:

§ 1.6072-2 Time for filing returns of corporations.

(a) [Reserved]. For further guidance, see § 1.6072-2T(a).

* * * * *

(d) * * *

(1) [Reserved]. For further guidance, see § 1.6072-2T(d)(1); and

(2) [Reserved]. For further guidance, see § 1.6072-2T(d)(2).

* * * * *

■ **Par. 17.** Add § 1.6072-2T to read as follows:

§ 1.6072-2T Time for filing returns of corporations (temporary).

(a) *Domestic and certain foreign corporations—(1) In general—(i) C corporations.* Except as provided in paragraph (a)(2) of this section, the income tax return required under section 6012 of a domestic C corporation (as defined in section 1361(a)(2)) or of a foreign C corporation having an office or place of business in the United States shall be filed on or before the fifteenth day of the fourth month following the close of the taxable year.

(ii) *S corporations.* The income tax return required under section 6012 and 6037 of an S corporation (as defined in section 1361(a)(1)) shall be filed on or before the fifteenth day of the third month following the close of the taxable year.

(2) *Exception.* For taxable years beginning before January 1, 2026, the income tax return of a C corporation described in paragraph (a)(1)(i) of this section that has a taxable year that ends on June 30 shall be filed on or before the fifteenth day of the third month following the close of the taxable year. For purposes of this paragraph (a)(2), the return for a short period (within the meaning of section 443) that ends on any day in June shall be treated as the return for a taxable year that ends on June 30.

(b) through (c) [Reserved]. For further guidance, see § 1.6072-2(b) and (c).

(d) introductory text [Reserved]. For further guidance, see § 1.6072-2(d) introductory text.

(1) *Section 521 associations.* A farmers', fruit growers', or like association, organized and operated in compliance with the requirements of section 521 and § 1.521-1; and

(2) *Section 1381 corporations.* For a taxable year beginning after December 31, 1962, a corporation described in section 1381(a)(2), which is under a valid enforceable written obligation to pay patronage dividends (as defined in section 1388(a) and paragraph (a) of § 1.1388-1) in an amount equal to at least 50 percent of its net earnings from business done with or for its patrons, or which paid patronage dividends in such an amount out of the net earnings from business done with or for patrons during the most recent taxable year for which it had such net earnings. Net earnings for this purpose shall not be reduced by any taxes imposed by Subtitle A of the Code and shall not be reduced by dividends paid on capital stock or other proprietary interest.

(e) through (f) [Reserved]. For further guidance, see § 1.6072-2(e) and (f).

(g) *Applicability date.* This section applies to returns filed on or after July 20, 2017. Section 1.6072-2 (as contained in 26 CFR part 1, revised April 2017) applies to returns before July 20, 2017.

(h) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

■ **Par. 18.** Revise paragraph (a) of § 1.6081-1 to read as follows:

§ 1.6081-1 Extension of time for filing returns.

(a) [Reserved]. For further guidance, see § 1.6081-1T(a).

* * * * *

■ **Par. 19.** Add § 1.6081-1T to read as follows:

§ 1.6081-1T Extension of time for filing returns (temporary).

(a) *In general.* The Commissioner is authorized to grant a reasonable extension of time for filing any return, declaration, statement, or other document that relates to any tax imposed by subtitle A of the Code and that is required under the provisions of subtitle A or F of the Code or the regulations thereunder. However, other than in the case of taxpayers who are abroad or as specified in section 6081(b), such extensions of time shall not be granted for more than six months, and the extension of time for filing the return of a DISC (as defined in section 992(a)), as specified in section 6072(b), shall not be granted. Except in the case of an extension of time pursuant to § 1.6081-5, an extension of time for filing an income tax return shall not operate to extend the time for the payment of the tax unless specified to the contrary in the extension. For rules relating to extensions of time for paying tax, see § 1.6161-1.

(b) [Reserved]. For further guidance, see § 1.6081-1(b).

(c) *Applicability date.* This section applies to requests for extension of time to file returns on or after July 20, 2017. Section 1.6081-1 (as contained in 26 CFR part 1, revised April 2017) applies to requests for extension of time to file returns before July 20, 2017.

(d) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

■ **Par. 20.** Revise paragraph (a)(1) of § 1.6081-2 to read as follows:

§ 1.6081-2 Automatic extension of time to file certain returns filed by partnerships.

(a) * * * (1) [Reserved]. For further guidance, see § 1.6081-2T(a)(1).

* * * * *

■ **Par. 21.** Add § 1.6081-2T to read as follows:

§ 1.6081-2T Automatic extension of time to file certain returns filed by partnerships (temporary).

(a) *In general.* (1) A partnership required to file Form 1065, "U.S. Partnership Return of Income," or Form 8804, "Annual Return for Partnership Withholding Tax," for any taxable year will be allowed an automatic six-month extension of time to file the return after the date prescribed for filing the return if the partnership files an application under this section in accordance with paragraph (b) of this section. No additional extension will be allowed pursuant to § 1.6081-1(b) beyond the automatic six-month extension provided by this section. In the case of a partnership described in § 1.6081-

5(a)(1), the automatic extension of time to file allowed under this section runs concurrently with an extension of time to file granted pursuant to § 1.6081-5.

(2) [Reserved]. For further guidance, see § 1.6081-2(a)(2).

(b) through (g) [Reserved]. For further guidance, see § 1.6081-2(b) through (g).

(h) *Applicability date.* This section applies to applications for an automatic extension of time to file the partnership returns listed in paragraph (a) of this section on or after July 20, 2017. Section 1.6081-2 (as contained in 26 CFR part 1, revised April 2017) applies to applications for an automatic extension of time to file before July 20, 2017.

(i) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

■ **Par. 22.** Revise the introductory text of paragraph (a), redesignate paragraph (e) as paragraph (g), revise the heading of newly redesignated paragraph (g), and add paragraphs (e) and (f) to § 1.6081-3 to read as follows:

§ 1.6081-3 Automatic extension of time for filing corporation income tax returns.

(a) introductory text [Reserved]. For further guidance, see § 1.6081-3T(a) introductory text.

* * * * *

(e) [Reserved]. For further guidance, see § 1.6081-3T(e).

(f) [Reserved]. For further guidance, see § 1.6081-3T(f).

(g) *Applicability dates.* * * *

■ **Par. 23.** Add § 1.6081-3T to read as follows:

§ 1.6081-3T Automatic extension of time for filing corporation income tax returns (temporary).

(a) *In general.* Except as provided in paragraphs (e) and (f) of this section, a corporation or an affiliated group of corporations filing a consolidated return will be allowed an automatic 6-month extension of time to file its income tax return after the date prescribed for filing the return if the following requirements are met.

(1) through (4) [Reserved]. For further guidance, see § 1.6081-3(a)(1) through (4).

(b) through (d) [Reserved]. For further guidance, see § 1.6081-3(b) through (d).

(e) *Exception.* In the case of any return for a taxable year of a C corporation that ends on June 30 and begins before January 1, 2026, the first sentence of paragraph (a) of this section shall be applied by substituting "7-month" for "6-month." For purposes of this paragraph (e), the return for a short period (within the meaning of section 443) that ends on any day in June shall

be treated as the return for a taxable year that ends on June 30.

(f) *Cross reference.* For provisions relating to extensions of time to file Form 1120-POL, "U.S. Income Tax Return for Certain Political Organizations," see § 1.6081-9.

(g) *Applicability date.* This section applies to requests for extension of time to file corporation income tax returns on or after July 20, 2017. Section 1.6081-3 (as contained in 26 CFR part 1, revised April 2017) applies to applications for an automatic extension of time to file before July 20, 2017.

(h) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

■ **Par. 24.** Revise paragraph (a)(1) of § 1.6081-5 to read as follows:

§ 1.6081-5 Extensions of time in the case of certain partnerships, corporations and U.S. citizens and residents.

(a) * * *

(1) [Reserved]. For further guidance, see § 1.6081-5T(a)(1);

* * * * *

■ **Par. 25.** Add § 1.6081-5T to read as follows:

§ 1.6081-5T Extensions of time in the case of certain partnerships, corporations and U.S. citizens and residents (temporary).

(a) introductory text [Reserved]. For further guidance, see § 1.6081-5(a) introductory text.

(1) Partnerships, which are required under section 6072(b) to file returns on the fifteenth day of the third month following the close of the taxable year of the partnership, that keep their records and books of account outside the United States and Puerto Rico;

(2) through (6) [Reserved]. For further guidance, see § 1.6081-5(a)(2) through (6).

(b) through (e) [Reserved]. For further guidance, see § 1.6081-5(b) through (e).

(f) This section applies to returns filed on or after July 20, 2017. Section 1.6081-5 (as contained in 26 CFR part 1, revised April 2017) applies to applications for an automatic extension of time to file returns before July 20, 2017.

(g) The applicability of this section will expire on or before July 17, 2020.

■ **Par. 26.** Revise paragraph (a)(1) of § 1.6081-6 to read as follows:

§ 1.6081-6 Automatic extension of time to file estate or trust income tax return.

(a) * * * (1) [Reserved]. For further guidance, see § 1.6081-6T(a)(1).

* * * * *

■ **Par. 27.** Add § 1.6081-6T to read as follows:

§ 1.6081-6T Automatic extension of time to file estate or trust income tax return (temporary).

(a) *In general.* (1) Except as provided in paragraph (a)(2) of this section, any estate, including but not limited to an estate defined in section 2031, or trust required to file an income tax return on Form 1041, "U.S. Income Tax Return for Estates and Trusts," will be allowed an automatic five and one-half month extension of time to file the return after the date prescribed for filing the return if the estate or trust files an application under this section in accordance with paragraph (b) of this section. No additional extension will be allowed pursuant to § 1.6081-1(b) beyond the automatic five and one-half month extension provided by this section.

(2) [Reserved]. For further guidance, see § 1.6081-6(a)(2).

(b) through (f) [Reserved]. For further guidance, see § 1.6081-6(b) through (f).

(g) *Applicability date.* This section applies to applications for an automatic extension of time to file an estate or trust income tax return on or after July 20, 2017. Section 1.6081-6 (as contained in 26 CFR part 1, revised April 2017) applies to applications for an automatic extension of time to file a return before July 20, 2017.

(h) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

■ **Par. 28.** Revise paragraphs (a), (b)(1) and (3), (c), (d), and (e), of § 1.6081-9 to read as follows:

§ 1.6081-9 Automatic extension of time to file exempt or political organization returns.

(a) [Reserved]. For further guidance, see § 1.6081-9T(a).

(b) * * *

(1) [Reserved]. For further guidance, see § 1.6081-9T(b)(1);

* * * * *

(3) [Reserved]. For further guidance, see § 1.6081-9T(b)(3); and

* * * * *

(c) [Reserved]. For further guidance, see § 1.6081-9T(c).

(d) [Reserved]. For further guidance, see § 1.6081-9T(d).

(e) [Reserved]. For further guidance, see § 1.6081-9T(e).

* * * * *

■ **Par. 29.** Add § 1.6081-9T to read as follows:

§ 1.6081-9T Automatic extension of time to file exempt or political organization returns (temporary).

(a) *In general.* An entity required to file a return on a form in the Form 990 series (Form 990, "Return of Organization Exempt From Income

Tax," Form 990-BL, "Information and Initial Excise Tax Return for Black Lung Benefit Trusts and Certain Related Persons," Form 990-EZ, "Short Form Return of Organization Exempt From Income Tax," Form 990-PF, "Return of Private Foundation," and Form 990-T, "Exempt Organization Business Tax Return"), Form 1041-A, "U.S.

Information Return-Trust Accumulation of Charitable Amounts," Form 1120-POL, "U.S. Income Tax Return for Certain Political Organizations," Form 4720, "Return of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code," Form 5227, "Split-Interest Trust Information Return," Form 6069, "Return of Excise Tax on Excess Contributions to Black Lung Benefit Trust Under Section 4953 and Computation of Section 192 Deduction," and Form 8870, "Information Return for Transfers Associated With Certain Personal Benefit Contracts," will be allowed an automatic six-month extension of time to file the return after the date prescribed for filing if the entity files an application in accordance with paragraph (b) of this section.

(b) introductory text [Reserved]. For further guidance, see § 1.6081-9(b) introductory text.

(1) Be submitted on Form 7004, "Application for Automatic Extension of Time to File Certain Business Income Tax, Information, and Other Returns" (in the case of an extension of time to file Form 1120-POL), Form 8868, "Application for Automatic Extension of Time to File an Exempt Organization Return" (in the case of an extension of time to file any other return listed in paragraph (a) of this section), or in any other manner as may be prescribed by the Commissioner;

(2) [Reserved]. For further guidance, see § 1.6081-9(b)(2);

(3) Show the full amount properly estimated as tentative tax for the entity for the taxable year; and

(4) [Reserved]. For further guidance, see § 1.6081-9(b)(4).

(c) *Termination of automatic extension.* The Commissioner may terminate an automatic extension at any time by mailing to the entity a notice of termination. The notice must be mailed at least 10 days prior to the termination date designated in such notice. The notice of termination must be mailed to the address shown on the application for extension or to the entity's last known address. For further guidance regarding the definition of last known address, see § 301.6212-2 of this chapter.

(d) *Penalties.* See sections 6651 and 6652(c) for failure to file a return or

failure to pay the amount shown as tax on the return.

(e) *Coordination with § 1.6081-1.* No extension of time will be granted under § 1.6081-1 for filing a return listed in paragraph (a) of this section until an automatic extension has been allowed pursuant to this section.

(f) *Applicability date.* This section applies to requests for extensions of time to file returns listed in paragraph (a) of this section on or after July 20, 2017. Sections 1.6081-3 and 1.6081-9 (as contained in 26 CFR part 1, revised April 2017) apply to requests for extensions before July 20, 2017.

(g) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT THE SOURCE

■ **Par. 30.** The authority citation for part 31 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 31.** Revise paragraph (a)(3) of § 31.6071(a)-1 to read as follows:

§ 31.6071(a)-1 Time for filing returns and other documents.

(a) * * *

(3) [Reserved]. For further guidance, see § 31.6071(a)-1T(a)(3).

* * * * *

■ **Par. 32.** Add § 31.6071(a)-1T to read as follows:

§ 31.6071(a)-1T Time for filing returns and other documents (temporary).

(a) *Federal Insurance Contributions Act and income tax withheld from wages and from nonpayroll payments.* (1) through (2) [Reserved]. For further guidance, see § 31.6071(a)-1(a)(1) and (2).

(3) *Information returns—(i) General rule.* Each information return in respect of wages as defined in Federal Insurance Contributions Act or of income tax withheld from wages as required under § 31.6051-2 must be filed on or before January 31 of the year following the calendar year for which it is made, except that, if a tax return under § 31.6011(a)-5(a) is filed as a final return for a period ending prior to December 31, the information return must be filed on or before the last day of the first calendar month following the period for which the tax return is filed.

(ii) *Expedited filing.* If an employer who is required to make a return pursuant to § 31.6011(a)-1 or § 31.6011(a)-4 is required to make a final return on Form 941, or a variation thereof, under § 31.6011(a)-6(a)(1) (relating to the final return for Federal

Insurance Contributions Act taxes and income tax withholding from wages), the return which is required to be made under § 31.6051-2 must be filed on or before the last day of the first calendar month following the period for which the final return is filed. The requirements set forth in this paragraph (a)(3)(ii) do not apply to employers with respect to employees whose wages are for domestic service in the private home of the employer. See § 31.6011(a)-1(a)(3).

(b) through (f) [Reserved]. For further guidance, see § 31.6071(a)-1(b) through (f).

(g) *Applicability date.* This section applies to returns filed after July 20, 2017. Section 31.6071(a)-1 (as contained in 26 CFR part 31, revised April 2017) applies to returns filed before July 20, 2017.

(h) *Expiration date.* The applicability of this section will expire on or before July 17, 2020.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: July 7, 2017.

Tom West,

Tax Legislative Counsel.

[FR Doc. 2017-15209 Filed 7-18-17; 4:15 pm]

BILLING CODE 4830-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2017-0695]

Drawbridge Operation Regulation; Chambers Creek, Steilacoom, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Chambers Creek Burlington Northern Santa Fe (BNSF) railroad vertical lift railroad bridge across Chambers Creek, mile 0.01, near Steilacoom in Pierce County, WA. This deviation will test a change to the drawbridge operation schedule, for the second time within the past year, to determine whether a permanent change to the schedule is appropriate.

DATES: This deviation is effective from 6 a.m. on July 22, 2017 to 6 a.m. on January 16, 2018.

Comments and related material must reach the Coast Guard on or before January 16, 2018.

ADDRESSES: You may submit comments identified by docket number USCG-2017-0695 using Federal eRulemaking Portal at <http://www.regulations.gov>.

See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Danny McReynolds, Bridge Management Specialist, Thirteenth Coast Guard District; telephone 206-220-7234, email d13-pf-d13bridges@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Background, Purpose and Legal Basis

Burlington Northern Santa Fe Railroad, the bridge owner, is requesting to test a deviation to the schedule of the Chambers Creek BNSF railroad vertical lift railroad bridge across Chambers Creek, mile 0.01, near Steilacoom in Pierce County, WA. Due to minimal usage of the drawbridge between 10 p.m. and 6 a.m., the bridge owner has requested to test this schedule to see if it better balances the needs of marine and rail traffic. The bridge has a vertical clearance of 10ft in the closed-to-navigation position and 50ft of vertical clearance in the open-to-navigation position (reference plane is MHW elevation of 12.2 feet). The bridge currently operates under 33 CFR 117.5; which requires the bridge to open anytime when a request or signal to open is given.

The following facts support BNSF’s proposal: (1) The previous test deviation from December 12, 2016 to Jun 23, 2017 had only one lift opening request (2) over the last 6 years only 2% of the subject bridge lifts have occurred between the hours of 10 p.m. and 6 a.m., which equates to approximately 5 openings a year, (3) from February 2009 to June 2015 there were 1932 total openings of which only 40 occurred between the hours of 10 p.m. and 6 a.m., and (4) the navigation traffic consists primarily of the tenants of Chambers Bay marina (recreational users) that are members of the Chambers Bay Boating Association.

The Coast Guard is publishing this temporary deviation, for a second time within a year, to test the proposed schedule change to determine whether a permanent change to the schedule is appropriate to better balance the needs of marine and rail traffic.

Under this temporary deviation, in effect from 6 a.m. on July 22, 2017 to 6 a.m. on January 15, 2018, the subject bridge shall open on signal, except from

10 p.m. to 6 a.m. the draw shall open on signal if at least 4 hours notice is given. The bridge will be required to open as soon as possible, no later than 1 hour after notification, for vessels engaged in emergency response.

The Coast Guard will inform the users of the waterways of this temporary deviation through our Local and Broadcast Notices to Mariners and through direct outreach with the Chambers Creek Boating Association so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation. Vessels able to pass underneath the bridge in the closed-to-navigation position may do so at anytime.

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

II. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

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.

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).

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 or a final rule is published.

Dated: July 13, 2017.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2017-15230 Filed 7-19-17; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2017-0670]

RIN 1625-AA87

Security Zone; Atlantic Ocean, Ft. Lauderdale, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone on the waters of the Atlantic Ocean for a United States Navy exercise. There will be a zone approximately 4 nautical miles wide extending from .75 nautical miles off the beach to 4 nautical miles offshore. The zone will begin approximately .4 nautical miles south of Port Everglades Inlet. The security zone is needed to protect personnel, vessels, and the surrounding waterway from terrorist acts, sabotage or other subversive acts, accidents, or other causes of a similar nature. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Miami.

DATES: This rule is effective without actual notice from 5 a.m. to 8 p.m. daily from July 20, 2017 through July 21, 2017. For the purposes of enforcement, actual notice will be used from 5 a.m. to 8 p.m. daily from July 8, 2017 through July 20, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Mara Brown, U.S. Coast Guard; telephone 305-535-4317, email Mara.J.Brown@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 Coast Guard did not receive notice of this event until two days prior to the exercise and there is an immediate need to protect the security of the naval vessels, the public, and the surrounding waterway from terrorist acts, sabotage or other subversive acts, accidents, or other causes of similar nature. It is impracticable to publish an NPRM because the zone must be established by July 8, 2017.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential security risks associated with naval exercises.

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 Miami (COTP) has determined the potential security concerns associated with naval exercises starting July 8, 2017. This rule is needed to protect naval vessels, the public, and the surrounding waterway from terrorist acts, sabotage or other subversive acts, accidents, or other causes of a similar nature while the exercise is occurring.

IV. Discussion of the Rule

This rule establishes a security zone from 5 a.m. until 8 p.m. daily from July 8, 2017 through July 21, 2017, while the Navy is performing the exercise. The security zone will cover all navigable waters approximately in an area 4 nautical miles wide extending from .75 nautical miles off the beach to 4 nautical miles offshore. The zone will begin approximately .4 nautical miles south of Port Everglades Inlet. No vessel or person will be permitted to enter the security zone without obtaining

permission from the COTP or a designated representative.

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 (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

The Coast Guard has made a determination this rule is not a significant regulatory action. This regulatory action determination is based on the size, durations and location of the security zone. The zone is only 4 nautical miles wide extending from .75 nautical miles off the beach to 4 nautical miles offshore. Vessel traffic will be able to safely transit around the security zone without significant diversion.

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 security 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 an 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 M16475.1D, 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 involves a security zone that will prohibit entry within certain waters of the Atlantic Ocean in Ft. Lauderdale, Florida, in order to protect the safety of life and property on the waters while the exercise is occurring. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

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 a temporary § 165.T07–0670 to read as follows:

§ 165.T07–0670 Security Zone; United States Navy Exercise, Ft. Lauderdale, FL.

(a) *Regulated area.* The following regulated area is established as a security zone: All waters starting at point 1 in position 26°05'03" N. 80°05'42" W.; thence east to point 2 in position 26°05'03" N. 80°02'04" W.; thence south to point 3 in position 26°00'57" N. 80°02'25" W.; thence west to point 4 in position 26°00'57" N. 80°06'04" W.; thence north back to origin.

(b) *Definition.* The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard Coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Miami in the enforcement of the regulated area.

(c) *Regulations.* All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the security zone without authorization from the Captain of the Port Miami or a designated representative.

(d) *Effective and enforcement dates.* This rule is effective daily from 5 a.m. until 8 p.m. on July 8, 2017 through July 21, 2017, unless cancelled sooner by the Captain of the Port. This rule will be enforced with actual notice by the U.S. Coast Guard representative on scene while operations associated with the naval exercise are in progress.

Dated: July 7, 2017.

M.M. Dean,

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

[FR Doc. 2017–15265 Filed 7–19–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2017–0688]

RIN 1625–AA00

Safety Zone; Marine City Maritime Festival Water Ski Show, St. Clair River, Marine City, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 2000-foot

portion of the St. Clair River in the vicinity of Marine City, MI. This zone is necessary to protect vessels from potential hazards associated with the Marine City Maritime Festival Water Ski Show.

DATES: This temporary final rule is effective from 10 a.m. through 5 p.m. on August 5, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2017–0688 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 temporary rule, call or email Tracy Girard, Prevention Department, Sector Detroit, U.S. Coast Guard; telephone 313–568–9564, or email Tracy.M.Girard@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 doing so would be impracticable. The Coast Guard did not receive the final details of this project until there was insufficient time remaining before the event to publish an NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be impracticable because it would inhibit the Coast Guard’s ability to protect participants, mariners and vessels from the hazards associated with this event.

We are issuing this rule under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after

publication in the **Federal Register** for the same reason noted above.

III. Legal Authority and Need for Rule

The legal basis for the rule is the Coast Guard’s authority to establish safety zones: 33 U.S.C. 1231; 33 CFR 1.05–1, 160.5; Department of Homeland Security Delegation No. 0170.1.

On August 5, 2017, a Maritime Festival Water Ski Show will take place on the St. Clair River in Marine City, MI. The Captain of the Port Detroit (COTP) has determined that a potential hazard associated with this water ski show will be a safety concern to anyone within 2000-feet of the water ski area. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the show is being conducted.

IV. Discussion of the Rule

This rule establishes a safety zone from 10 a.m. through 5 p.m. on August 5, 2017. A safety zone is established to include all U.S. navigable waters of the St. Clair River, Marine City, MI, bound by: 200 feet seaward of latitude position 42°43.382' N., and to the south by 2,000 feet to 200 feet seaward of latitude position 42°42.983' N. This regulated area will be enforced during three 30 minute time periods between 10 a.m. through 5 p.m. on August 5, 2017. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The Captain of the Port Detroit or a designated on-scene representative may be contacted via VHF Channel 16 or via telephone at 313–568–9464. The Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone and the rule allows vessels to seek permission to enter the zone.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 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 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771

(“Reducing Regulation and Controlling Regulatory Costs”), directs agencies to reduce regulation and control regulatory costs and provides that “for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.” This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

As this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. See OMB’s Memorandum titled “Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 titled ‘Reducing Regulation and Controlling Regulatory Costs’” (February 2, 2017).

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. This regulatory action determination is based on the size, location, duration, and time-of-year of the safety zone. Recreational and commercial vessel traffic will be able to safely transit around this safety zone. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zone and the rule allows vessels to seek permission to enter the zone.

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 *Regulatory Planning and Review* section 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 an 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.ID, 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 involves a safety zone lasting 7 hours that will prohibit entry within 2000–feet of the water ski show. It is categorically excluded under section 2.B.2, figure 2–1, paragraph 34(g) of the Instruction. A Record of Environmental Consideration (REC) supporting this determination is available in the docket where indicated in the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

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.T09–0688 to read as follows:

§ 165.T09–0688 Safety Zone; Marine City Maritime Festival Water Ski Show, St. Clair River, Marine City, MI.

(a) *Location.* A safety zone is established to include all U.S. navigable waters of the St. Clair River, Marine City, MI, bound by: 200 feet seaward of latitude position 42°43.382' N., and to the south by 2,000 feet to 200 feet seaward of latitude position 42°42.983' N. This regulated area will be enforced during three 30 minute periods of time between 10 a.m. through 5 p.m. on August 5, 2017.

(b) *Enforcement period.* The regulated area described in paragraph (a) will be enforced from 10 a.m. thru 10:30 a.m., 1 p.m. through 1:30 p.m., and 4 p.m. through 4:30 p.m. on August 5, 2017.

(c) *Regulations.* (1) No recreational vessel or person may enter, transit through, or anchor within the safety zone unless authorized by the Captain of the Port Detroit, or his on-scene representative.

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

(3) The “on-scene representative” of the Captain of the Port Detroit is any Coast Guard commissioned, warrant or petty officer or a Federal, State, or local law enforcement officer designated by or assisting the Captain of the Port Detroit to act on his behalf.

(4) Vessel operators shall contact the Captain of the Port Detroit or his on-scene representative to obtain permission to enter or operate within the safety zone. The Captain of the Port Detroit or his on-scene representative may be contacted via VHF Channel 16 or at 313–568–9464. Vessel operators given permission to enter or operate in the regulated area must comply with all directions given to them by the Captain of the Port Detroit or his on-scene representative.

Dated: July 13, 2017.

Jeffrey W. Novak,

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

[FR Doc. 2017–15270 Filed 7–19–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2017–0002; Internal Agency Docket No. FEMA–8489]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA’s Community Status Book (CSB). The CSB is available at <https://www.fema.gov/national-flood-insurance-program-community-status-book>.

DATES: The effective date of each community’s scheduled suspension is the third date (“Susp.”) listed in the third column of the table in the amendment.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Patricia Suber, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW., Washington, DC 20472, (202) 646–4149. **SUPPLEMENTARY INFORMATION:** The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood

insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59.

Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA’s initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National

Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.
Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.
 Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

- 1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

- 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region V				
Indiana				
Delaware County, Unincorporated Areas.	180051	June 13, 1975, Emerg; March 16, 1981, Reg; August 2, 2017, Susp.	August 2, 2017.	August 2, 2017.
Muncie, City of, Delaware County	180053	April 4, 1975, Emerg; January 16, 1981, Reg; August 2, 2017, Susp.do*	do.
Yorktown, Town of, Delaware County ...	180361	March 18, 1976, Emerg; March 16, 1981, Reg; August 2, 2017, Susp.do	do.
Region IX				
California				
Crescent City, City of, Del Norte County	060039	April 2, 1975, Emerg; November 23, 1982, Reg; August 2, 2017, Susp.do	do.

*do = Ditto.
 Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: July 7, 2017.

Michael M. Grimm,
*Assistant Administrator for Mitigation,
 Federal Insurance and Mitigation
 Administration, Department of Homeland
 Security, Federal Emergency Management
 Agency.*

[FR Doc. 2017–15241 Filed 7–19–17; 8:45 am]

BILLING CODE 9110–12–P

Proposed Rules

Federal Register

Vol. 82, No. 138

Thursday, July 20, 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.

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1003

[Docket No. CFPB–2017–0021]

RIN 3170–AA76

Home Mortgage Disclosure (Regulation C) Temporary Increase in Institutional and Transactional Coverage Thresholds for Open-End Lines of Credit

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Proposed rule with request for public comment.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau or CFPB) proposes amendments to Regulation C that would, for a period of two years, increase the threshold for collecting and reporting data with respect to open-end lines of credit so that financial institutions originating fewer than 500 open-end lines of credit in either of the preceding two years would not be required to begin collecting such data until January 1, 2020.

DATES: Comments must be received on or before July 31, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CFPB–2017–0021 or RIN 3170–AA76, by any of the following methods:

- **Email:** FederalRegisterComments@cfpb.gov. Include Docket No. CFPB–2017–0021 or RIN 3170–AA76 in the subject line of the email.

- **Electronic:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

- **Mail:** Monica Jackson, Office of the Executive Secretary, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20552.

- **Hand Delivery/Courier:** Monica Jackson, Office of the Executive Secretary, Consumer Financial Protection Bureau, 1275 First Street NE., Washington, DC 20002.

Instructions: All submissions should include the agency name and docket

number or Regulatory Information Number (RIN) for this rulemaking. 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 1275 First Street NE., Washington, DC 20002, on official business days between the hours of 10 a.m. and 5:30 p.m. Eastern Time. You can make an appointment to inspect the documents by telephoning 202–435–7275.

All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Alexandra W. Reimelt, Counsel, Office of Regulations, Consumer Financial Protection Bureau, at 202–435–7700 or cfpb_reginquiries@cfpb.gov.

SUPPLEMENTARY INFORMATION:

I. Summary of the Proposed Rule

Regulation C implements the Home Mortgage Disclosure Act (HMDA). For over four decades, HMDA has provided the public and public officials with information about mortgage lending activity within communities by requiring financial institutions to collect, report, and disclose certain data about their mortgage activities. The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) amended HMDA and, among other things, expanded the scope of information that must be collected, reported, and disclosed under HMDA and transferred rule writing authority from the Board of Governors of the Federal Reserve System (Board) to the Bureau.¹

In October 2015, the Bureau published a final rule implementing the Dodd-Frank Act amendments to HMDA (2015 HMDA Final Rule).² In that rule,

¹ Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, section 1094, 124 Stat. 1376, 2009–101 (2010).

² Home Mortgage Disclosure (Regulation C); Final Rule, 80 FR 66128 (Oct. 28, 2015). In this notice,

the Bureau adopted significant changes to Regulation C, most of which will be effective on January 1, 2018. Among other changes, the 2015 HMDA Final Rule required collection and reporting of data with regard to open-end, dwelling-secured lines of credit.³ However, the 2015 HMDA Final Rule contained an exclusion with respect to an open-end line of credit if a financial institution originated fewer than 100 such lines of credit in each of the two preceding calendar years (open-end transactional coverage threshold).⁴ The 2015 HMDA Final Rule contained parallel provisions as part of the definition of “financial institution,” which limit Regulation C’s institutional coverage to include only institutions that, in addition to meeting the other applicable coverage criteria, originated at least 25 closed-end mortgage loans or 100 open-end lines of credit in each of the two preceding calendar years (institutional coverage threshold).⁵

The Bureau has heard concerns that, in setting the open-end transactional coverage threshold at 100 transactions, the Bureau set it too low. The Bureau is now proposing to increase that threshold to 500 or more open-end lines of credit for two years (calendar years 2018 and 2019). During that period, the Bureau will reconsider the open-end transactional coverage threshold: This temporary increase would allow the Bureau to do so without requiring financial institutions originating fewer than 500 open-end lines of credit per year to collect and report data with respect to open-end lending in the meanwhile.

citations to Regulation C as amended by the 2015 HMDA Final Rule are to the applicable sections of title 12 of the Code of Federal Regulations as they will read following their effective date. See generally 12 CFR 1003.

³ 12 CFR 1003.2(e). Prior to this amendment, reporting with respect to open-end lines of credit was voluntary. See *infra* note 10.

⁴ 12 CFR 1003.3(c)(12). As adopted by the 2015 HMDA Final Rule, this provision states the test as “fewer than 100 open-end lines of credit in each of the two preceding calendar years,” but this was a drafting error; the intent was to require that a financial institution have exceeded the threshold in both of the preceding calendar years to be subject to open-end line of credit reporting, thus the exclusion should require that a financial institution originate fewer than 100 such lines of credit in either of the two preceding calendar years. As discussed below, the Bureau has since proposed to correct this error. See 82 FR 19142, 19148–49 (Apr. 25, 2017).

⁵ 12 CFR 1003.2(g)(1)(v) and (g)(2)(ii).

This proposal seeks comment on whether the Bureau should temporarily increase the threshold in this manner.

II. Background

A. Collecting and Reporting Data Concerning Open-End Lines of Credit Under the 2015 HMDA Final Rule

HMDA and its implementing regulation, Regulation C, require certain banks, savings associations, credit unions, and for-profit nondepository institutions to collect, report, and disclose data about originations and purchases of mortgage loans, as well as mortgage loan applications that do not result in originations (for example, applications that are denied or withdrawn). In 2010, Congress enacted the Dodd-Frank Act, which amended HMDA and also transferred HMDA rulemaking authority and other functions from the Board to the Bureau.⁶ Among other changes, the Dodd-Frank Act expanded the scope of information relating to mortgage applications and loans that must be collected, reported, and disclosed under HMDA. The Dodd-Frank Act also provides the Bureau with the authority to require “such other information as the Bureau may require.”⁷

In October 2015, the Bureau issued the 2015 HMDA Final Rule, which implemented the Dodd-Frank Act amendments to HMDA.⁸ That final rule modified the types of institutions and transactions subject to Regulation C, the types of data that institutions are required to collect, and the processes for reporting and disclosing the required data.

Home-equity lines of credit were uncommon in the 1970s and early 1980s when Regulation C was first implemented. In 1988, the Board amended Regulation C to permit, but not require, financial institutions to report home-equity lines of credit that were for the purpose of home improvement or home purchase.⁹ In

practice, few financial institutions elected to do so and the Bureau estimated that only about 1 percent of open-end lines of credit secured by dwellings were reported under HMDA.¹⁰

In 2000, in response to the increasing importance of open-end lending in the housing market, the Board proposed to revise Regulation C to require mandatory reporting of all home-equity lines of credit.¹¹ However, the Board’s 2002 final rule left open-end reporting voluntary, as the Board determined at that time that the benefits of mandatory reporting relative to other then-proposed changes (such as collecting information about higher-priced loans) did not justify the increased burden.¹²

As discussed in the 2015 HMDA Final Rule, open-end mortgage lending continued to increase in the years following the Board’s 2002 final rule, particularly in areas with high home-price appreciation. Further, research indicates that speculative real estate investors used open-end, home-secured lines of credit to purchase non-owner occupied properties, which correlated with higher first-mortgage defaults and home-price depression during the financial crisis.¹³ Furthermore, in the years leading up to the crisis such home-equity lines of credit often were made and fully drawn more or less simultaneously with first-lien home purchase loans, essentially creating high loan-to-value home purchase transactions that were not visible in the HMDA dataset.¹⁴ Thus, as the Bureau noted in the 2015 HMDA Final Rule, overleverage due to open-end mortgage lending and defaults on dwelling-secured open-end lines of credit contributed to the foreclosure crises that many communities experienced in the late 2000s.¹⁵

More generally, as the 2015 HMDA Final Rule also noted, dwelling-secured open-end lines of credit liquefy equity that borrowers have built up in their homes, which often are their most important assets, and increase their risk of losing their homes to foreclosure when property values decline.¹⁶ At the same time, home-equity lines of credit have become increasingly important to the housing market, and including data on such lines within the HMDA dataset would help to understand how financial

institutions are meeting the housing needs of communities.¹⁷ For these and other reasons articulated in the 2015 HMDA Final Rule,¹⁸ the Bureau determined that it is important to improve visibility into this key segment of the mortgage market by requiring reporting of open-end lines of credit.¹⁹ As noted in the 2015 HMDA Final Rule, the Bureau believes that including dwelling-secured lines of credit within the scope of Regulation C is a reasonable interpretation of HMDA section 303(2), which defines “mortgage loan” as a loan secured by residential real property or a home improvement loan. In the 2015 HMDA Final Rule, the Bureau interpreted “mortgage loan” to include dwelling-secured lines of credit, as they are secured by residential real property and they may be used for home improvement purposes.²⁰ As further noted in the 2015 HMDA Final Rule, pursuant to section 305(a) of HMDA, the Bureau believes that requiring reporting of all dwelling-secured, consumer purpose open-end lines of credit is necessary and proper to effectuate the purposes of HMDA and prevent evasions thereof.²¹

To effectuate this decision, the 2015 HMDA Final Rule defined two new terms: “covered loan,” which is defined to mean “a closed-end mortgage loan or an open-end line of credit that is not an excluded transaction,”²² and “open-end line of credit,” which is defined to mean an extension of credit that is secured by a lien on a “dwelling” (as that term is defined in the rule) and that is an open-end credit plan as defined in Regulation Z (without regard to certain limitations relevant for Regulation Z, but not Regulation C, purposes).²³

In expanding coverage to include open-end lines of credit, the Bureau recognized that doing so would impose one-time and ongoing operational costs on reporting institutions; that the one-time costs of modifying processes and systems and training staff to begin open-end line of credit reporting likely would impose significant costs on some institutions; and that institutions’ ongoing reporting costs would increase as a function of their open-end lending volume.²⁴

⁶ Public Law 111–203, 124 Stat. 1376, 1980, 2035–38, 2097–101 (2010).

⁷ *Id.*

⁸ 2015 HMDA Final Rule, 80 FR 66128 (Oct. 28, 2015).

⁹ 53 FR 31683, 31685 (Aug. 19, 1988). Under this provision, data with respect to “home equity lines of credit made in whole or in part for home purchase or home improvement” is “optional data” which a financial institution may report. 12 CFR 1003.4(c)(3). A “home-equity line of credit” is defined in current Regulation C as an “open-end credit plan secured by a dwelling as defined in Regulation Z (Truth in Lending), 12 CFR part 1026.” 12 CFR 1003.2. The definition of “open-end line of credit” in the 2015 HMDA Final Rule, effective January 1, 2018, paralleled this definition, but applies without regard to whether the credit is consumer credit, as defined in 12 CFR 1026.2(a)(12), is extended by a creditor, as defined

in 12 CFR 1026.2(a)(17), or is extended to a consumer, as defined in 12 CFR 1026.2(a)(11).

¹⁰ 2015 HMDA Final Rule, *supra* note 8, at 66282.

¹¹ 65 FR 78656, 78659–60 (Dec. 15, 2000).

¹² 67 FR 7222, 7225 (Feb. 15, 2002).

¹³ 2015 HMDA Final Rule, *supra* note 8, at 66160.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ 2015 HMDA Final Rule, *supra* note 8, at 66157.

¹⁸ *See id.* at 66149, 66160–61.

¹⁹ *Id.* at 66149.

²⁰ *Id.* at 66160.

²¹ *Id.*

²² 12 CFR 1003.2(e).

²³ *Id.* at § 1003.2(o).

²⁴ 2015 HMDA Final Rule, *supra* note 8, at 66161. The definition of “open-end line of credit” replaced the definition of a “home-equity line of credit. *See supra* note 9.

The Bureau sought to avoid imposing these costs on small institutions with limited open-end lending, where the benefits of reporting the data do not justify the costs of reporting.²⁵ In seeking to draw such a line, the Bureau acknowledged that it was handicapped by the lack of available data concerning open-end lending.²⁶ This created challenges both in estimating the distribution of open-end origination

volume across financial institutions and estimating the one-time and ongoing costs that would be incurred by institutions of various sizes in collecting and reporting data on open-end lending.

With respect to open-end origination volume, the Bureau used multiple data sources, including credit union Call Reports, Call Reports for banks and thrifts, and data from the Bureau's Consumer Credit Panel to develop

estimates for different potential thresholds.²⁷ The Bureau assumed that all of the depository institutions that were exempted from HMDA reporting under Regulation C because of their location or asset size would continue to be exempt.²⁸ With respect to the remaining depositories, the Bureau developed the following estimates:²⁹

Table 8. Estimates of Depository Institution Coverage by Open-End Line of Credit Thresholds

Potential Open-End Line-of-Credit Threshold	Number of Reporting Financial Institutions	Number of Open-End Lines of Credit (rounded to nearest ten thousand)	Percentage of Market Covered	Number of Reporting Financial Institutions that also Report Closed-End Mortgage Loans	
				Not a Closed-End Reporter	Closed-End Reporter
Proposed	4,146	910,000	94%	0	4,146
25	1,770	900,000	93	103	1,667
50	1,155	870,000	91	55	1,100
100	749	850,000	88	24	725
500	231	730,000	76	3	228
1000	123	650,000	68	0	123
5000	25	440,000	46	0	25

The Bureau noted that expansions or contractions in the number of financial institutions, or changes in product offerings and demands during implementation could alter the estimated impacts.³⁰

To estimate the one-time and ongoing costs of collecting and reporting data under HMDA, the Bureau identified seven "dimensions" of compliance operations and used those to define three broadly representative financial institutions according to the overall level of complexity of their compliance operations: "tier 1" (high-complexity); "tier 2" (moderate-complexity); and "tier 3" (low-complexity).³¹ In estimating costs specific to collecting and reporting data for open-end lines of credit, the Bureau assumed that tier 1 institutions originate more than 7,000 such lines of credit, that tier 2 institutions originate between 200 and 7,000 such lines of credit, and that tier

3 institutions originate fewer than 200 such lines of credit.³² The Bureau then sought to estimate one-time and ongoing costs for the average-size institution in each tier.³³

With respect to one-time costs, the Bureau recognized that the one-time cost of reporting open-end lines of credit could be substantial because most financial institutions do not currently report open-end lines of credit and thus would have to develop completely new reporting infrastructures to begin reporting these data. As a result, there would be one-time costs to create processes and systems for open-end lines of credit in addition to the one-time costs to modify processes and systems for other mortgage products.³⁴ However, for tier 3, low-complexity institutions, the Bureau stated that it believed that the additional one-time costs of open-end reporting would be relatively low because the Bureau

believed that these institutions are less reliant on information technology systems for HMDA reporting and that they may process open-end lines of credit on the same system and in the same business unit as closed-end mortgage loans, so that their one-time costs would be derived mostly from new training and procedures adopted for the overall changes in the final rule.³⁵

With respect to ongoing costs, the Bureau acknowledged that costs for open-end reporting vary by institutions due to many factors, such as size, operational structure, and product complexity, and that this variance exists on a continuum that was impossible to fully represent.³⁶ At the same time, the Bureau stated it believed that the HMDA reporting process and ongoing operational cost structure for open-end reporters would be fundamentally similar to closed-end reporting.³⁷ Thus, using the ongoing cost estimates

²⁵ 2015 HMDA Final Rule, *supra* note 8, at 66149.

²⁶ *Id.*

²⁷ *Id.* at 66261, 66275 n.477. As the Bureau explained, credit union Call Reports provide the number of originations of open-end lines of credit secured by real estate but exclude lines of credit with first-lien status and may include business loans that are excluded from reporting under the 2015 HMDA Final Rule. *Id.* at 66281 n.489.

²⁸ *Id.* at 66281 n.489. The Bureau limited its estimate to depositories because it believes that most nondepositories do not originate open-end lines of credit. *Id.* at 66281.

²⁹ The first row in the chart, labeled "Proposed" assumed that financial institutions would be

required to report on their open-end lines of credit regardless of the number originated so long as the institution originated at least 25 closed-end mortgages during each of the prior two calendar years. This row reflects the impact of the rule that the Bureau had proposed. The remaining rows assume that reporting of open-end lines of credit would be required without regard to the number of closed-end loans originated but only if the financial institution originated the number of open-end lines of credit shown in the various rows. *Id.* at 66281.

³⁰ *Id.* at 66275 n.477.

³¹ *Id.* at 66261. The seven factors were: The reporting system used; the degree of system integration; the degree of system automation; the

compliance program; and the tools for geocoding, performing completeness checks, and editing. *Id.* at 66269.

³² *Id.* at 66285.

³³ For purposes of calculating aggregate costs, the Bureau assumed that the average tier 1 institution received 30,000 applications for open-end lines of credit; the average tier 2 institution received 1,000 such applications; and the average tier 3 institution received 150 such applications. *Id.* at 66286.

³⁴ *Id.* at 66264; see also *id.* at 66284–85.

³⁵ *Id.* at 66265; see also *id.* at 66284.

³⁶ *Id.* at 66285.

³⁷ *Id.*

developed for closed-end reporting, the Bureau estimated that for the average tier 1 institutions the ongoing operational costs would be \$273,000 per year; for the average tier 2 institution \$43,400 per year; and for the average tier 3 institution \$8,600 per year.³⁸ These translated into average costs per HMDA record of \$9, \$43, and \$57 respectively.³⁹ Importantly, the Bureau acknowledged that, precisely because no good source of publicly available data exists concerning dwelling-secured open-end lines of credit, it was difficult to predict the accuracy of the Bureau's cost estimates, but also stated its belief that they were reasonably reliable.⁴⁰

Drawing on all of these estimates, the Bureau decided to establish an open-end transactional coverage threshold that would require institutions that originate 100 or more open-end lines of credit to collect and report data. The Bureau estimated that this threshold would avoid imposing the burden of establishing open-end reporting on approximately 3,000 predominantly smaller-sized institutions with low open-end lending⁴¹ and would require reporting by only 749 financial institutions, all but 24 of which would also report data on their closed-end mortgage lending.⁴² The Bureau explained that it believed this threshold appropriately balanced the benefits and burdens of covering institutions based on their open-end mortgage lending.⁴³

To effectuate this decision, the 2015 HMDA Final Rule amended Regulation C to define two discrete thresholds that were intended to work in tandem. First, the rule established an institutional coverage threshold that limits the definition of "depository financial institution" and "nondepository financial institution" to include only those institutions that either originated at least 25 covered closed-end mortgages in each of the preceding years or that originated at least covered 100 open-end lines of credit in each of the two preceding years.⁴⁴ Second, the rule

separately established a transactional coverage threshold for open-end lines of credit by providing that an open-end line of credit is an excluded transaction if the financial institution originated fewer than 100 open-end lines of credit in each of the two preceding calendar years.⁴⁵

B. Proposed Technical Corrections and Clarifying Amendments to the 2015 HMDA Final Rule

On April 13, 2017, the Bureau issued a Notice of Proposed Rulemaking (2017 HMDA Proposal) containing a set of proposed technical corrections and clarifying amendments to the Regulation C as amended by the 2015 HMDA Final Rule.⁴⁶ Among the corrections included in that proposal is an amendment to the open-end transactional coverage threshold. Under the 2017 HMDA Proposal, an open-end line of credit would be an excluded transaction if the institution originated fewer than 100 open-end lines of credit in either of the two preceding calendar years.⁴⁷ This would change the provision as adopted by the 2015 HMDA Final Rule to correct a drafting error.

The 2017 HMDA Proposal noted that, under the institutional coverage threshold in the 2015 HMDA Final Rule, the definition of financial institution included only institutions that originate either 25 or more closed-end mortgage loans or 100 or more open-end lines of credit in each of the two preceding calendar years. That threshold and the transaction coverage threshold were intended to be complementary exclusions.⁴⁸ But, if the transactional coverage threshold is to mirror the loan volume threshold for financial institutions, as the 2017 HMDA Proposal noted, the transactional coverage threshold should provide that an open-end line of credit is an excluded transaction if a financial institution originated fewer than 100

definition of covered loans and those excluded transactions do not count towards the institutional transaction threshold.

⁴⁵ 12 CFR 1003.3(c)(12). As noted above and discussed again below, the exclusion as adopted in the 2015 HMDA Final Rule was intended to apply if the financial institution originated fewer than 100 open-end lines of credit in either of the two preceding calendar years; the current text of the rule was a drafting error that the Bureau has now proposed to correct. The final rule created a separate transactional coverage threshold for closed-end mortgages, treating those as excluded transactions if an institution originated fewer than 25 closed-end mortgage loans in each of the two preceding calendar years. *Id.* at § 1003.3(c)(11). The Bureau has proposed to change the "each" in this text to "either" as well. *See infra* note 46, at 19148.

⁴⁶ 82 FR 19142 (Apr. 25, 2017).

⁴⁷ *Id.* at 19168.

⁴⁸ *Id.* at 19149.

open-end lines of credit in either, rather than each, of the two preceding calendar years.⁴⁹ The use of the word "each" in the financial transaction threshold in the 2015 HMDA Final Rule thus was a drafting error.⁵⁰

The 2017 HMDA Proposal sought comment on this and other proposed changes. The comment period closed on May 25, 2017. The Bureau is in the process of reviewing the comments and preparing a final rule, which the Bureau expects to issue on or before the date on which this proposal would be finalized. Accordingly, this proposal reflects the amended language of the 2017 HMDA Proposal.⁵¹ Further, if this proposal is finalized, the Bureau would adopt final language that reflects not only this proposal but also the final changes that would be adopted pursuant to the 2017 HMDA Proposal's final rule.

C. Questions Regarding the Open-End Transactional Coverage Threshold

Since the Bureau issued the 2015 HMDA Final Rule, many industry stakeholders have expressed concerns over the levels for the transactional coverage thresholds. The Bureau has sought to listen to and understand the basis for these concerns. In the 2015 HMDA Final Rule, the Bureau modified Regulation C's institutional and transactional coverage to better achieve HMDA's purposes in light of current market conditions and to reduce unnecessary burden on financial institutions. The Bureau adopted uniform loan volume thresholds for depository and nondepository institutions. The loan volume thresholds require an institution that originated at least 25 closed-end mortgage loans or at least 100 open-end lines of credit in each of the two preceding calendar years to report HMDA data, provided that the institution meets all of the other criteria for institutional coverage.

As discussed above, the Bureau did not have robust data for making the estimates that went into establishing the open-end coverage threshold. The Bureau now has some reason to question whether it struck the appropriate balance in establishing a threshold of 100 open-end lines of credit.

⁴⁹ *Id.*

⁵⁰ *Id.* at 19148. The proposal similarly would change the transactional coverage threshold for closed-end mortgage loans. *Id.*

⁵¹ The 2017 HMDA Proposal also added a new category of excluded transaction that would not count towards the institutional transaction threshold, and amended § 1003.2(g)(1)(v) and (g)(2)(ii) accordingly. Those amendments are not reflected in this proposal but are still under consideration by the Bureau.

³⁸ *Id.* at 66286.

³⁹ *Id.*

⁴⁰ *Id.* at 66162.

⁴¹ *Id.* The estimate of the number of institutions that would be excluded by the transaction coverage threshold was relative to the number that would have been covered under the Bureau's proposal that led to the 2015 HMDA Final Rule. Under that proposal, a financial institution would have been required to report its open-end lines of credit if it had originated at least 25 closed-end mortgage loans in each of the preceding two years without regard to how many open-end lines of credit the institution originated. *See* 79 FR 51731 (Aug. 29, 2014).

⁴² *Id.* at 66281.

⁴³ *Id.* at 66162.

⁴⁴ 12 CFR 1003.2(g)(1)(v) and (g)(2)(ii). The final rule excluded certain transactions from the

In striking that balance, the Bureau estimated, based upon 2013 data, that under that threshold 749 depository institutions would be required to report their open-end lines of credit. Since 2013, the number of dwelling-secured open-end lines of credit originated has increased by 36 percent and continues to grow.⁵² To the extent that institutions that are originating fewer than 100 open-end lines of credit share in that growth, the number of institutions at the margin that will be required to report under the 2015 HMDA Final Rule open-end transaction coverage threshold necessarily will increase.

The data available to the Bureau with respect to open-end line of credit institutions by banks and thrifts is not sufficiently robust to allow the Bureau to estimate with any precision the number of such institutions that have crossed over the open-end transactional threshold in the 2015 HMDA Final Rule. However, there is reliable data with respect to credit unions which are required to report open-end originations in their Call Reports. The Bureau's review of credit union Call Report data indicates that the number of credit unions that originated 100 or more open-end lines of credit in 2015 was up 31 percent over 2013.⁵³ If there were a comparable increase among banks and thrifts, that would imply that the total number of open-end reporters under the transactional coverage threshold would be 980, as compared to the estimate of 749 in the 2015 HMDA Final Rule.⁵⁴ Of course, if volumes have increased at these institutions, the breadth and importance of the credit they extend may also have increased and therefore

⁵² Experian-Oliver Wyman Market Intelligence Reports show that in 2013 there were 1.14 million home-equity lines of credit originated. In 2016 that number grew to 1.55 million.

⁵³ The 2015 HMDA Final Rule contained aggregated estimates for credit unions, banks, and thrifts. In developing those estimates, the Bureau had constructed separate estimates for credit unions using the credit union Call Report data. Specifically, the Bureau estimated that in 2013 there were 534 credit unions that originated 100 or more open-end lines of credit. Based on 2015 credit union Call Report data, that number is now 699.

⁵⁴ The estimates contained in the 2015 HMDA Final Rule and those stated in text are based on origination volumes for a single-year. The two-year lookback period intended in the 2015 HMDA Final Rule and contained in the 2017 HMDA Proposal and in this proposal as well—that is, the exclusion for institutions that fell below the transactional coverage threshold in either of the two preceding years—would likely reduce the number of reporters below those stated in text at least during the first year after the rule takes effect. On the other hand, the fact that the estimates are based upon credit union Call Report data which, as noted in the 2015 HMDA Final Rule, exclude open-end lines of credit originated in a first position may mean that the estimates understate the number of reporters.

the benefits from collecting and reporting those data may have as well.

Additionally, information received by the Bureau since issuing the 2015 HMDA Final Rule has caused the Bureau to question its assumption, as set forth above, that low-complexity (tier 3) institutions process their home-equity lines of credit on the same data platforms as their closed-end mortgages, which in turn drove the Bureau's corresponding assumptions that the one-time costs for these institutions would be minimal. The Bureau has heard anecdotal evidence suggesting that one-time costs could be as high as \$100,000 for tier 3 institutions. The Bureau likewise has heard anecdotal evidence suggesting that the ongoing costs for these institutions—which the Bureau estimated would be under \$10,000 per year and add under \$60 per line of credit—could be at least three times higher.

These reports, coupled with the additional evidence discussed above with respect to the number of institutions that would be covered by the open-end transactional coverage test contained in the 2015 HMDA Final Rule, have led the Bureau to believe that it is appropriate to seek comment to determine whether an adjustment in the threshold is appropriate. Although this could be accomplished by delaying the effective date for the reporting requirement for open-end lines of credit in toto, for the reasons set forth above and those articulated in the 2015 HMDA Final Rule, the Bureau continues to believe that it is vitally important to begin to collect data on the burgeoning market for home-equity lines of credit. Accordingly, in light of the considerations set forth above, the Bureau is proposing to increase temporarily the open-end transactional coverage threshold—and to make a parallel change in the institutional coverage threshold—so that institutions originating fewer than 500 open-end lines of credit in either of the two preceding calendar years will not be required to commence collecting or reporting data on their open-end lines of credit until the Bureau has the opportunity to reassess whether to adjust the threshold.

In developing a proposed temporary adjustment of the threshold, the Bureau has examined the coverage estimates contained in the 2015 HMDA Final Rule, as well as the Bureau's analysis of more recent credit union Call Report data.

As shown above in Table 8 from the 2015 HMDA Final Rule, the Bureau had estimated, using 2013 data, that a 500 line-of-credit threshold would have

reduced the number of reporting institutions from 749 to 231, a 69 percent reduction, while reducing the share of lines of credit reported from 88 percent to 76 percent, a fourteen percent reduction.⁵⁵ Of the 231 depositories that the Bureau estimated were originating 500 or more open-end lines of credit, 175 were credit unions. The Bureau's review of credit union Call Report data from 2015 suggests that the number of credit unions originating 500 or fewer lines of credit has increased, but at a slightly slower pace than the increase in credit unions originating between 100 and 499 open-end lines of credit.⁵⁶ Assuming comparable trends among banks and thrifts, the Bureau now estimates that in 2015, 289 depository institutions originated 500 or more open-end lines of credit, as compared to an estimated 980 such institutions that originated at least 100 such lines. On average, the institutions that would be excluded by increasing the threshold to 500 originated fewer than 250 open-end lines of credit per year.⁵⁷ At the same time, the Bureau estimates that under a 500 loan open-end transactional coverage threshold, roughly three-quarters of the loan application volume in the open-end market would be reported.⁵⁸

The Bureau has considered, as an alternative, increasing the open-end transactional coverage threshold to 1,000. The Bureau estimates that there are approximately 110 depository institutions that originated between 500 and 1,000 open-end lines of credit in 2015.⁵⁹ Increasing the open-end

⁵⁵ 2015 HMDA Final Rule, *supra* note 8, at 66281. Note that the estimates contained in the 2015 HMDA Final Rule were based on origination volumes in a single year (2013), and did not reflect the intended two-year lookback period for determining whether reporting would be required.

⁵⁶ According to the Bureau's analysis of credit union Call Report data, in 2015 there were 219 credit unions that reported originating 500 or more open-end lines of credit.

⁵⁷ This estimate is based on an analysis of the credit union Call Report data for 2015. The Bureau also has reviewed 2013 and 2014 credit union Call Report data which likewise shows an average at or below 250 for credit unions originating between 100 and 500 open-end lines of credit.

⁵⁸ The 2015 HMDA Final Rule estimated that an open-end transactional coverage threshold of 500 would cover 76 percent of the market. The credit union Call Report data suggests that the share of the credit union market covered by credit unions originating at least 500 open-end lines increased by 6 percent in 2015 relative to 2013. However, we conservatively rely on the estimate contained in the 2015 HMDA Final Rule.

⁵⁹ The estimates contained in the 2015 HMDA Final Rule were predicated on an estimate that in 2013 there were 93 credit unions that originated between 500 and 1,000 open-end lines of credit. The Bureau's analysis of 2015 credit union Call Report data shows that in 2015 there were 95 such credit unions. The Bureau thus assumes that the

transactional coverage threshold to 1,000 and applying that test to institutions that originated at least 1,000 open-end lines of credit in each of the prior two years (*i.e.*, in 2014 and 2015) would have relieved approximately 90 depository institutions of the obligation to report on their open-end lines of credit in 2016 relative to a 500 threshold. In 2016, those institutions originated, on average, close to 1,000 open-end lines of credit per year.⁶⁰ Furthermore, a 1,000 loan open-end transactional coverage threshold would reduce coverage of the open-end line of credit market to approximately 68 percent and would reduce coverage of the credit union open-end line of credit marketplace to just 49 percent.⁶¹

Beyond that, the Bureau believes that institutions that have originated at least 500 dwelling-secured open-end lines of credit in each of the last two years—and that are averaging closer to 1,000 such lines—are, at a minimum, moderately-complex operations able to shoulder the costs of collecting and reporting data on their open-end lines of credit. For example, information supplied to the Bureau from the credit league of one State indicates that of the seven credit unions in that State that had originated more than 250 home-equity lines of credit in the first six months of 2016 (and thus were on track to originate 500 for the year), six had assets over \$1 billion.

For all these reasons, the Bureau is proposing to amend the open-end transactional coverage threshold in Regulation C as adopted by the 2015 HMDA Final Rule, effective January 1, 2018, to increase the threshold from 100 to 500 and is proposing to amend the threshold, effective January 1, 2020, to restore it to 100. The Bureau is proposing a parallel change in the institutional coverage threshold. The Bureau believes that this two-year period will give the Bureau sufficient time to assess whether the change being proposed should be made permanent or whether the threshold should be set at some lower level, and to finalize its determination in time to allow

total number of depository institutions originating between 500 and 1,000 open-end lines of credit held constant between 2013 and 2015.

⁶⁰ According to the Bureau's calculations, of the credit unions originating between 500 and 1,000 open-end lines of credit in 2015, fewer than 80 percent had done so in both 2014 and 2015. Those credit unions originated, on average, 959 and 1,032 open-end lines of credit in 2014 and 2015 respectively.

⁶¹ The estimates in the 2015 HMDA Final Rule were predicated on an estimate that an open-end transactional coverage threshold of 1,000 would reduce coverage of the credit union marketplace to 50 percent. The Bureau's review of 2015 credit union Call Report data indicates that remains true.

institutions who may be covered under the permanent threshold but not by the temporary threshold to complete their implementation process.

The Bureau seeks comment on whether to increase temporarily the open-end transactional coverage threshold and, if so, whether to raise the threshold to 500 or to a larger or smaller number. The Bureau also seeks comment on whether, if it elects to increase the open-end transactional coverage threshold, it should do so for a period of two years or a longer or shorter period of time.

The Bureau notes that it is not proposing to adjust the closed-end transactional coverage threshold. As explained above, in establishing that threshold the Bureau was able to base its determination on a robust dataset that enabled the Bureau to evaluate the implications of potential alternative thresholds. This was possible because, prior to January 1, 2017, under Regulation C depository institutions that originated even a single closed-end mortgage and met the location and asset coverage criteria generally were required to report on closed-end mortgage applications under HMDA.

Relying on these data, the Bureau was able to evaluate the implications of alternative potential transactional coverage threshold for closed-end mortgage loans. The Bureau recognized that setting a threshold above 25 closed-end loans would not significantly impact the value of HMDA data at the national level. But the Bureau also recognized that public officials, community advocates, and researchers rely on HMDA data to analyze access to credit at the neighborhood level and to target programs to assist underserved communities and consumers and that, therefore, it was appropriate to consider local impacts in setting a transactional coverage threshold.⁶² For example, had the threshold for closed-end mortgage loans been set at 500 loans—the highest level the Bureau considered although well below thresholds urged by some industry stakeholders—more than 5,000 census tracts would have lost 20 percent or more of the then currently-reported HMDA data, of which one-third would have been tracts designated as low- to moderate-income (LMI).⁶³ In contrast, the 25-loan transactional threshold established by the 2015 HMDA Final Rule resulted in only 46 census tracts losing 20 percent or more of their data. Further, the closed-end transactional coverage threshold established by the 2015 HMDA Final Rule also increased

reporting by nondepository institutions—and thus increased visibility into their share of the market—by reducing their preexisting threshold from 100 to 25, thereby leveling the playing field.⁶⁴

Additionally, because many depository financial institutions originating even a small number of loans were at the time of the 2015 HMDA Final Rule required to report under HMDA, in estimating the one-time and incremental ongoing costs of implementing and complying with the final rule, the Bureau was able to draw upon actual experience of institutions of various sizes in collecting and reporting HMDA data.

Despite the objections the Bureau has heard since issuing the 2015 HMDA Final Rule to the transactional coverage threshold for closed-end mortgage loans, the Bureau does not have reason to believe that it underestimated the costs of implementation or overestimated the adverse consequences of establishing a higher threshold for analyses at the local level. The Bureau also continues to believe that there are significant benefits in obtaining increased visibility into the originations by nondepositories that originate fewer than 100 closed-end mortgages. For these reasons, as well as those set forth in the 2015 HMDA Final Rule, the Bureau does not believe it is necessary or appropriate to reconsider that threshold and therefore is not proposing to do so.

The Bureau is not proposing in this notice to change the effective date for any other provision of the 2015 HMDA Final Rule or to make any other substantive changes to that rule.

III. Legal Authority

The Bureau is issuing this proposal pursuant to its authority under the Dodd-Frank Act and HMDA. This proposed rule consists of amendments to the 2015 HMDA Final Rule.⁶⁵ Section 1061 of the Dodd-Frank Act transferred to the Bureau the “consumer financial protection functions” previously vested in certain other Federal agencies, including the Board.⁶⁶ The term “consumer financial protection

⁶⁴ The current nondepository institution coverage test includes a loan-volume or asset test, where only nondepository institutions that originated at least 100 applicable loans in the preceding calendar year or had assets of more than \$10 million on the preceding December 31 and meet the other applicable criteria are required to report HMDA data. See Section 1026.2 (definition of financial institution).

⁶⁵ 2015 HMDA Final Rule, *supra* note 8, at 66136–37.

⁶⁶ 12 U.S.C. 5581. Section 1094 of the Dodd-Frank Act also replaced the term “Board” with “Bureau” in most places in HMDA. 12 U.S.C. 2803 *et seq.*

⁶² 2015 HMDA Final Rule, *supra* note 8, at 66147.

⁶³ *Id.* at 66279.

function” is defined to include “all authority to prescribe rules or issue orders or guidelines pursuant to any Federal consumer financial law, including performing appropriate functions to promulgate and review such rules, orders, and guidelines.”⁶⁷ Section 1022(b)(1) of the Dodd-Frank Act authorizes the Bureau’s Director to prescribe rules “as may be necessary or appropriate to enable the Bureau to administer and carry out the purposes and objectives of the Federal consumer financial laws, and to prevent evasions thereof.”⁶⁸ Both HMDA and title X of the Dodd-Frank Act are Federal consumer financial laws.⁶⁹ Accordingly, the Bureau has authority to issue regulations to administer HMDA.

HMDA section 305(a) broadly authorizes the Bureau to prescribe such regulations as may be necessary to carry out HMDA’s purposes.⁷⁰ These regulations may include “classifications, differentiations, or other provisions, and may provide for such adjustments and exceptions for any class of transactions, as in the judgment of the Bureau are necessary and proper to effectuate the purposes of [HMDA], and prevent circumvention or evasion thereof, or to facilitate compliance therewith.”⁷¹

A number of HMDA provisions specify that covered institutions must compile and make their HMDA data publicly available “in accordance with regulations of the Bureau” and “in such formats as the Bureau may require.”⁷² HMDA section 304(j)(7) also directs the Bureau to make every effort in prescribing regulations under that subsection to minimize the costs incurred by a depository institution in complying with such regulations.⁷³ HMDA also authorizes the Bureau to

issue regulations relating to the timing of HMDA disclosures.⁷⁴

In preparing this proposed rule, the Bureau has considered the changes below in light of its legal authority under HMDA and the Dodd-Frank Act. The Bureau has determined that each of the changes addressed below is consistent with the purposes of HMDA and is authorized by one or more of the sources of statutory authority identified in this part.

IV. Section-by-Section Analysis

Section 1003.2 Definitions

2(g) Financial Institution

2(g)(1) Depository Financial Institution

2(g)(1)(v)

2(g)(1)(v)(B)

Regulation C as amended by the 2015 HMDA Final Rule defines “depository financial institution” as a bank, savings association or credit union that meets certain criteria. One of those criteria is that the institution either (A) originated at least 25 closed-end mortgages loans in each of the two preceding calendar years; or (B) originated at least 100 open-end lines of credit in each of the two preceding calendar years. For depositories that do not meet the closed-end mortgage loan component of this test, their status as a depository financial institution under Regulation C turns, in part, on their volume of open-end line of credit originations. Because, as discussed above in section II, the Bureau is proposing to increase temporarily the open-end transactional coverage threshold from 100 to 500, the Bureau is proposing to make a parallel, temporary change in the institutional coverage threshold included in § 1003.2(g) as well. Under this proposed amendment, effective January 1, 2018, a depository institution that did not originate at least 25 closed-end mortgage loans in each of the two preceding years would not be deemed to be a depository financial institution under Regulation C unless it originated 500 or more open-end lines of credit in each of the two preceding years and met the other applicable criteria included in § 1003.2(g)(i).

In accordance with the proposal with respect to the open-end transactional coverage threshold, the Bureau is proposing conforming amendments to the definition of depository financial institution effective January 1, 2020, to

revert to the definition established by the 2015 HMDA Final Rule, *i.e.*, to set the open-end institutional coverage threshold at 100 lines of credit.

As a result, under this proposal, for calendar years 2018 and 2019, financial institutions that do not meet the closed-end mortgage loan component of the test and that originate between 100 and 499 open-end lines of credit would not meet the definition of “depository financial institution.” Absent further amendments by the Bureau, beginning in calendar year 2020, such depositories would meet the definition of “depository financial institution.”

The Bureau solicits comment on this proposal.

2(g)(2) Nondepository Financial Institution

2(g)(2)(ii)

2(g)(2)(ii)(B)

Under the 2015 HMDA Final Rule a “nondepository financial institution” is defined as a for-profit mortgage lending institution other than a bank, savings association, or credit union that meets certain criteria. One of those criteria is an institutional coverage threshold that is identical to the threshold for depository institutions discussed above. For the reasons discussed above in section II and the section-by-section analysis of § 1003.2(g)(1)(v)(B), the Bureau is proposing conforming amendments to § 1003.2(g)(ii)(B), which includes the open-end loan volume threshold for coverage of nondepository financial institution. Under this proposal, for calendar years 2018 and 2019, the open-end loan volume threshold for institutional coverage of nondepository institutions would be raised from 100 to 500. Absent further amendments by the Bureau, beginning in calendar year 2020, such nondepository institutions would meet the definition of “nondepository financial institution.”

Comments 2(g)–3 and 2(g)–5 each assumed that the open-end institutional threshold was 100. The proposal would amend these comments effective January 1, 2018, to reflect the temporary higher threshold proposed herein and further amends the comment effective January 1, 2020, to restore the original threshold.

Section 1003.3 Exempt Institutions and Excluded Transactions

3(c) Excluded transactions

3(c)(12)

Under Regulation C as amended by the 2015 HMDA Final Rule, an open-end line of credit is an “excluded

⁶⁷ 12 U.S.C. 5581(a)(1)(A).

⁶⁸ 12 U.S.C. 5512(b)(1).

⁶⁹ Dodd-Frank Act section 1002(14), 12 U.S.C. 5481(14) (defining “Federal consumer financial law” to include the “enumerated consumer laws” and the provisions of title X of the Dodd-Frank Act); Dodd-Frank Act section 1002(12), 12 U.S.C. 5481(12) (defining “enumerated consumer laws” to include HMDA).

⁷⁰ 12 U.S.C. 2804(a).

⁷¹ *Id.*

⁷² See, e.g., HMDA section 304(a)(1), (j)(2)(A), (j)(3), (m)(2), 12 U.S.C. 2803(a)(1), (j)(2)(A), (j)(3), (m)(2); see also HMDA section 304(b)(6)(I), 12 U.S.C. 2803(b)(6)(I) (requiring covered institutions to use “such form as the Bureau may prescribe” in reporting credit scores of mortgage applicants and mortgagors). HMDA section 304(k)(1) also requires depository institutions covered by HMDA to make disclosure statements available “[i]n accordance with procedures established by the Bureau pursuant to this section.” 12 U.S.C. 2803(k)(1).

⁷³ 12 U.S.C. 2803(j)(7).

⁷⁴ HMDA section 304(j)(2)(A), 12 U.S.C. 2803(j)(2)(A) (setting maximum disclosure periods except as provided under other HMDA subsections and regulations prescribed by the Bureau); HMDA section 304(n), 12 U.S.C. 2803(n).

transaction” and thus not subject to the collection, reporting, and disclosure requirements of Regulation C, if the financial institution originated fewer than 100 open-end lines of credit in each of the two preceding calendar years. As discussed above in section II, the Bureau has previously proposed to amend this provision to substitute the word “either” for “each,” and the Bureau reflects the language of the 2017 HMDA Proposal here. Additionally, for the reasons previously discussed, the Bureau is proposing, effective January 1, 2018, to increase the open-end transactional coverage threshold from 100 to 500 lines of credit. The Bureau is further proposing, effective January 1, 2020, to restore the open-end transactional coverage threshold to the level adopted by the 2015 HMDA Final Rule, *i.e.*, 100 lines of credit.

Under this proposal, for calendar years 2018 and 2019, a financial institution that originates between 100 and 499 open-end lines of credit in either of the two preceding calendar years would not be required to collect, report, and disclose data on open-end lines of credit. Absent further amendments by the Bureau, beginning in calendar year 2020, such a financial institution would be required to do so.

The Bureau previously proposed to clarify that financial institutions may voluntarily report open-end lines of credit or closed-end mortgage loans even if the institution may exclude those loans pursuant to the transactional thresholds included in § 1003.3(c)(11) or (12) under the 2015 HMDA Final Rule.⁷⁵ This proposal reflects this amended language of the 2017 HMDA Proposal and amends that language to reflect the temporary higher threshold proposed herein effective January 1, 2018 and further amends the comment effective January 1, 2020 to restore the original threshold. As noted above, the Bureau is in the process of reviewing the comments on the 2017 HMDA Proposal and preparing a final rule, which the Bureau expects to issue on or before the date on which this proposal would be finalized.

Comment 2(c)(12)–1 assumed that the open-end transactional threshold was 100. The proposal would amend this comment effective January 1, 2018, to reflect the temporary higher threshold proposed herein and further amends the comment effective January 1, 2020, to restore the original threshold.

V. Section 1022(b) of the Dodd-Frank Act

In developing the proposed rule, the Bureau has considered the potential benefits, costs and impacts required by section 1022(b)(2) of the Dodd-Frank Act. Specifically, section 1022(b)(2) calls for the Bureau to consider the potential benefits and costs of a regulation to consumers and covered persons, including the potential reduction of consumer access to consumer financial products or services, the impact on depository institutions and credit unions with \$10 billion or less in total assets as described in section 1026 of the Dodd-Frank Act, and the impact on consumers in rural areas. The Bureau has consulted with, or offered to consult with, the prudential regulators, the Department of the Treasury, the Securities and Exchange Commission, the Department of Housing and Urban Development, the Federal Housing Finance Agency, the Federal Trade Commission, the Department of Veterans Affairs, the Department of Agriculture, the Department of Justice, and the Department of the Treasury regarding consistency with any prudential, market, or systemic objectives administered by these agencies.

The Bureau previously considered the costs, benefits, and impacts of the 2015 HMDA Final Rule’s major provisions, including the institutional coverage threshold and the open-end transactional coverage threshold.⁷⁶

Compared to the baseline established by the 2015 HMDA Final Rule, the proposed temporary increase in the open-end transactional coverage threshold would generally benefit financial institutions that originate between 100 and 499 open-end lines of credit in either of the two preceding calendar years by, at a minimum, allowing them to delay incurring one-time costs and delay the start of ongoing compliance costs associated with collecting and reporting data on open-end lines of credit. Some institutions may incur costs because they have already planned to report open-end lines of credit and now will not be required to and will need to change their systems. The Bureau does not have a reliable basis to estimate those costs. However, as noted above, the Bureau previously proposed to clarify that financial institutions may voluntarily report open-end lines of credit or closed-end mortgage loans even if the institution may exclude those loans pursuant to the transactional thresholds

included in § 1003.3(c)(11) or (12) under the 2015 HMDA Final Rule. If the Bureau finalizes this clarification, a temporary increase in the open-end transactional coverage threshold will obviate the need for institutions that are prepared to report open-end lines of credit to change their system. However, to the extent institutions that already have incurred costs in preparing for compliance elect to take advantage of the two-year temporary increase in the open-end transactional coverage threshold, unless the Bureau elects during the two-year review period to make the increase permanent, these institutions would incur one-time expenses which, when added to expenses already incurred, may be greater than the one-time costs that would have been incurred had the institutions completed their compliance work by January 1, 2018. As noted above, the Bureau estimates that roughly 690 such institutions would be able to take advantage of the two-year temporary increase in the open-end transactional coverage threshold.

The Bureau believes that temporarily increasing the open-end transactional coverage threshold for two years would reduce the benefits to consumers from the open-end reporting provisions of the 2015 HMDA Final Rule as those benefits are described in the rule. However, the Bureau believes that such impact may be minimal because the temporary increase in the open-end transactional coverage threshold would still, in the aggregate, result in reporting on approximately three-quarters of all open-end lines of credit. However, the Bureau recognizes that there may be particular localities where the impact of the temporary increase in the open-end transactional coverage threshold would be more pronounced. The Bureau lacks data to be able to estimate the extent to which that may be true.

To the extent there are benefits to covered persons resulting from the temporary increase in the open-end transactional coverage threshold, the Bureau believes those benefits would flow almost exclusively to insured depository institutions and credit unions with under \$10 billion assets and to a large extent to depository institutions servicing consumers in rural communities. The Bureau does not believe that the proposed temporary increase in the open-end transactional coverage threshold would reduce consumer access to consumer financial products and services, and it may increase consumer access by decreasing the possibility that certain financial institutions increase their pricing as a result of the requirements of the 2015

⁷⁵ 82 FR 19142, 19165 (April 25, 2017).

⁷⁶ 2015 HMDA Final Rule, *supra* note 8, at 66282–66287.

HMDA Final Rule or seek to cap the number of open-end lines of credit they originate to stay under the open-end transactional coverage threshold.

The Bureau requests comment on this discussion as well as submission of additional information that could inform the Bureau's consideration of the potential benefits, costs, and impacts of this proposed rule.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA),⁷⁷ as amended by the Small Business Regulatory Enforcement Fairness Act of 1996,⁷⁸ requires each agency to consider the potential impact of its regulations on small entities, including small businesses, small governmental units, and small not-for-profit organizations.⁷⁹ The RFA defines a "small business" as a business that meets the size standard developed by the Small Business Administration (SBA) pursuant to the Small Business Act.⁸⁰

The RFA generally requires an agency to conduct an initial regulatory flexibility analysis (IRFA) and a final regulatory flexibility analysis (FRFA) of any rule subject to notice-and-comment rulemaking requirements, unless the agency certifies that the rule would not have a significant economic impact on a substantial number of small entities.⁸¹ The Bureau also is subject to certain additional procedures under the RFA involving the convening of a panel to consult with small entity representatives prior to proposing a rule for which an IRFA is required.⁸²

As discussed above, the Bureau believes that none of the proposed changes would create a significant impact on any covered persons, including small entities. Therefore, an IRFA is not required for this proposal.

Accordingly, the undersigned certifies that this proposal, if adopted, would not have a significant economic impact on

a substantial number of small entities. The Bureau requests comment on the analysis above and requests any relevant data.

VII. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), Federal agencies are generally required to seek the Office of Management and Budget (OMB) approval for information collection requirements prior to implementation. The information collection requirements contained in Regulation C have been previously approved by OMB and assigned OMB control number 3170-0008. You may access this information collection on www.reginfo.gov by selecting "Information Collection Review" from the main menu, clicking on "Search," and then entering the OMB control number. Under the PRA, the Bureau may not conduct or sponsor and, notwithstanding any other provision of law, a person is not required to respond to an information collection unless the information collection displays a valid control number assigned by OMB.

The Bureau has determined that this proposed rule would not have any new or revised information collection requirements (recordkeeping, reporting, or disclosure requirements) on covered entities or members of the public that would constitute collections of information requiring OMB approval under the PRA. The Bureau welcomes comments on this determination or any other aspects of this proposal for purposes of the PRA. Comments should be submitted to the Bureau as instructed in the **ADDRESSES** part of this notice and to the attention of the Paperwork Reduction Act Officer. All comments will become a matter of public record.

List of Subjects in 12 CFR Part 1003

Banks, Banking, Credit unions, Mortgages, National banks, Savings associations, Reporting and recordkeeping requirements.

Authority and Issuance

For the reasons set forth above, the Bureau proposes to amend Regulation C, 12 CFR part 1003, as amended October 28, 2015, at 80 FR 66128, and effective January 1, 2018, as set forth below:

PART 1003—HOME MORTGAGE DISCLOSURE (REGULATION C)

■ 1. The authority citation for part 1003 continues to read as follows:

Authority: 12 U.S.C. 2803, 2804, 2805, 5512, 5581.

[The following amendments would be effective January 1, 2018, further amending

the sections as amended October 28, 2015, at 80 FR 66128.]

■ 2. Amend § 1003.2 by revising paragraphs (g)(1)(v)(B) and (g)(2)(ii)(B) to read as follows:

§ 1003.2 Definitions.

* * * * *

(g) * * *

(1) * * *

(v) * * *

(B) In each of the two preceding calendar years, originated at least 500 open-end lines of credit that are not excluded from this part pursuant to § 1003.3(c)(1) through (10); and

(2) * * *

(ii) * * *

(B) In each of the two preceding calendar years, originated at least 500 open-end lines of credit that are not excluded from this part pursuant to § 1003.3(c)(1) through (10).

* * * * *

■ 3. Amend § 1003.3 by revising paragraph (c)(12) to read as follows:

§ 1003.3 Exempt institutions and excluded transactions.

* * * * *

(c) * * *

(12) An open-end line of credit, if the financial institution originated fewer than 500 open-end lines of credit in either of the two preceding calendar years; or

■ 4. In Supplement I to Part 1003:

■ a. Under *Section 1003.2—Definitions*, under 2(g) *Financial Institution*, paragraphs 3 and 5 are revised.

■ b. Under *Section 1003.3—Exempt Institutions And Excluded Transactions*, under 3(c) *Excluded Transactions*, in *Paragraph 3(c)(12)*, paragraph 1 is revised and paragraph 2 is added.

The revisions and addition read as follows:

Supplement I to Part 1003—Official Interpretations

* * * * *

Section 1003.2—Definitions

* * * * *

2(g) Financial Institution

* * * * *

3. *Merger or acquisition—coverage of surviving or newly formed institution.*

After a merger or acquisition, the surviving or newly formed institution is a financial institution under § 1003.2(g) if it, considering the combined assets, location, and lending activity of the surviving or newly formed institution and the merged or acquired institutions or acquired branches, satisfies the criteria included in § 1003.2(g). For example, A and B merge. The surviving

⁷⁷ Public Law 96-354, 94 Stat. 1164 (1980).

⁷⁸ Public Law 104-21, section 241, 110 Stat. 847, 864-65 (1996).

⁷⁹ 5 U.S.C. 601 through 612. The term "small organization" means any not-for-profit enterprise which is independently owned and operated and is not dominant in its field, unless an agency establishes [an alternative definition under notice and comment]." 5 U.S.C. 601(4). The term "small governmental jurisdiction" means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand, unless an agency establishes [an alternative definition after notice and comment]." 5 U.S.C. 601(5).

⁸⁰ 5 U.S.C. 601(3). The Bureau may establish an alternative definition after consulting with the SBA and providing an opportunity for public comment. *Id.*

⁸¹ 5 U.S.C. 601 *et seq.*

⁸² 5 U.S.C. 609.

or newly formed institution meets the loan threshold described in § 1003.2(g)(1)(v)(B) if the surviving or newly formed institution, A, and B originated a combined total of at least 500 open-end lines of credit in each of the two preceding calendar years. Likewise, the surviving or newly formed institution meets the asset-size threshold in § 1003.2(g)(1)(i) if its assets and the combined assets of A and B on December 31 of the preceding calendar year exceeded the threshold described in § 1003.2(g)(1)(i). Comment 2(g)–4 discusses a financial institution’s responsibilities during the calendar year of a merger.

* * *

5. *Originations.* Whether an institution is a financial institution depends in part on whether the institution originated at least 25 closed-end mortgage loans in each of the two preceding calendar years or at least 500 open-end lines of credit in each of the two preceding calendar years. Comments 4(a)–2 through –4 discuss whether activities with respect to a particular closed-end mortgage loan or open-end line of credit constitute an origination for purposes of § 1003.2(g).

* * * * *

Section 1003.3—Exempt Institutions and Excluded Transactions

* * * * *

3(c) Excluded Transactions.

* * * * *

Paragraph 3(c)(12).

1. *General.* Section 1003.3(c)(12) provides that an open-end line of credit is an excluded transaction if a financial institution originated fewer than 500 open-end lines of credit in either of the two preceding calendar years. For example, assume that a bank is a financial institution in 2019 under § 1003.2(g) because it originated 50 closed-end mortgage loans in 2017, 75 closed-end mortgage loans in 2018, and met all of the other requirements under § 1003.2(g)(1). Also assume that the bank originated 75 and 85 open-end lines of credit in 2017 and 2018, respectively. The closed-end mortgage loans that the bank originated, or for which it received applications, during 2019 are covered loans and must be reported, unless they otherwise are excluded transactions under § 1003.3(c). However, the open-end lines of credit that the bank originated, or for which it received applications, during 2019 are excluded transactions under § 1003.3(c)(12) and need not be reported. See comments 4(a)–2 through

–4 for guidance about the activities that constitute an origination.

2. *Voluntary reporting.* A financial institution voluntarily may report open-end lines of credit and applications for open-end lines of credit that are excluded transactions because the financial institution originated fewer than 500 open-end lines of credit in either of the two preceding calendar years.

[The following amendments would be effective January 1, 2020, further amending the sections as amended October 28, 2015, at 80 FR 66128.]

■ 5. Amend § 1003.2 by revising paragraphs (g)(1)(v)(B) and (g)(2)(ii)(B) to read as follows:

§ 1003.2 Definitions.

* * * * *

(g) * * *

(1) * * *

(v) * * *

(B) In each of the two preceding calendar years, originated at least 100 open-end lines of credit that are not excluded from this part pursuant to § 1003.3(c)(1) through (10); and

(2) * * *

(ii) * * *

(B) In each of the two preceding calendar years, originated at least 100 open-end lines of credit that are not excluded from this part pursuant to § 1003.3(c)(1) through (10).

* * * * *

■ 6. Amend § 1003.3 by revising paragraph (c)(12) to read as follows:

§ 1003.3 Exempt institutions and excluded transactions.

* * * * *

(c) * * *

(12) An open-end line of credit, if the financial institution originated fewer than 100 open-end lines of credit in either of the two preceding calendar years; or

■ 7. In Supplement I to Part 1003: ■ a. Under *Section 1003.2—Definitions*, under 2(g) *Financial Institution*, paragraphs 3 and 5 are revised.

■ b. Under *Section 1003.3—Exempt institutions and excluded transactions*, under 3(c) *Excluded transactions*, in paragraph 3(c)(12), paragraph 1 is revised and paragraph 2 is added.

The revisions and addition read as follows:

Supplement I to Part 1003—Official Interpretations

* * * * *

Section 1003.2—Definitions

* * * * *

2(g) *Financial Institution*

* * * * *

3. *Merger or acquisition—coverage of surviving or newly formed institution.*

After a merger or acquisition, the surviving or newly formed institution is a financial institution under § 1003.2(g) if it, considering the combined assets, location, and lending activity of the surviving or newly formed institution and the merged or acquired institutions or acquired branches, satisfies the criteria included in § 1003.2(g). For example, A and B merge. The surviving or newly formed institution meets the loan threshold described in § 1003.2(g)(1)(v)(B) if the surviving or newly formed institution, A, and B originated a combined total of at least 100 open-end lines of credit in each of the two preceding calendar years.

Likewise, the surviving or newly formed institution meets the asset-size threshold in § 1003.2(g)(1)(i) if its assets and the combined assets of A and B on December 31 of the preceding calendar year exceeded the threshold described in § 1003.2(g)(1)(i). Comment 2(g)–4 discusses a financial institution’s responsibilities during the calendar year of a merger.

* * *

5. *Originations.* Whether an institution is a financial institution depends in part on whether the institution originated at least 25 closed-end mortgage loans in each of the two preceding calendar years or at least 100 open-end lines of credit in each of the two preceding calendar years. Comments 4(a)–2 through –4 discuss whether activities with respect to a particular closed-end mortgage loan or open-end line of credit constitute an origination for purposes of § 1003.2(g).

* * * * *

Section 1003.3—Exempt Institutions and Excluded Transactions

* * * * *

3(c) Excluded transactions.

* * * * *

Paragraph 3(c)(12).

1. *General.* Section 1003.3(c)(12) provides that an open-end line of credit is an excluded transaction if a financial institution originated fewer than 100 open-end lines of credit in either of the two preceding calendar years. For example, assume that a bank is a financial institution in 2022 under § 1003.2(g) because it originated 50 closed-end mortgage loans in 2020, 75 closed-end mortgage loans in 2021, and met all of the other requirements under § 1003.2(g)(1). Also assume that the bank originated 75 and 85 open-end lines of credit in 2020 and 2021, respectively. The closed-end mortgage loans that the bank originated, or for

which it received applications, during 2022 are covered loans and must be reported, unless they otherwise are excluded transactions under § 1003.3(c). However, the open-end lines of credit that the bank originated, or for which it received applications, during 2022 are excluded transactions under § 1003.3(c)(12) and need not be reported. See comments 4(a)–2 through –4 for guidance about the activities that constitute an origination.

2. *Voluntary reporting.* A financial institution voluntarily may report open-end lines of credit and applications for open-end lines of credit that are excluded transactions because the financial institution originated fewer than 100 open-end lines of credit in either of the two preceding calendar years.

Dated: July 13, 2017.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2017–15220 Filed 7–19–17; 8:45 am]

BILLING CODE 4810-AM-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0698; Directorate Identifier 2017–NM–047–AD]

RIN 2120-AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2017–02–03, which applies to certain The Boeing Company Model 767–200, –300, and –400ER series airplanes. AD 2017–02–03 requires inspection of the plastic potable water coupling, and corrective actions if necessary; installation of new spray shrouds; and inspection of previously installed spray shields, and related investigative and corrective actions if necessary. Since we issued AD 2017–02–03, we have determined that it is necessary to modify a hose assembly installation for certain airplanes, and add airplanes to the applicability. This proposed AD would add airplanes to the applicability and, for certain airplanes, require hose assembly removals and installations. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by September 5, 2017.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2017–0698.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2017–0698; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Stanley Chen, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6585; fax: 425–917–6590; email: stanley.chen@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about

this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA–2017–0698; Directorate Identifier 2017–NM–047–AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On January 11, 2017, we issued AD 2017–02–03, Amendment 39–18782 (2 FR 10541, February 14, 2017) (“AD 2017–02–03”), for certain The Boeing Company Model 767–200, –300, and –400ER series airplanes. AD 2017–02–03 requires inspection of the plastic potable water couplings, corrective actions if necessary, and installation of new spray shrouds. It also requires inspection of the prior installed spray shield to determine it has two slits and is installed correctly, and related investigative and corrective actions if necessary. AD 2017–02–03 resulted from a report of a malfunction of the engine indication and crew alerting system (EICAS) during flight. We issued AD 2017–02–03 to prevent an uncontrolled water leak from a defective potable water system coupling, which could cause the main equipment center (MEC) line replaceable units (LRUs) to become wet, resulting in an electrical short and potential loss of several functions essential for safe flight.

Actions Since AD 2017–02–03 Was Issued

Since we issued AD 2017–02–03, we have determined that additional airplanes are subject to the unsafe condition and therefore it is necessary to add airplanes to the applicability. We have also determined that the service information specified in AD 2017–02–03 does not adequately address the identified unsafe condition for certain airplanes; therefore, we find it necessary to require, for certain airplanes, removing three hose assemblies and installing four new hose assemblies.

Related Service Information Under 14 CFR Part 51

We reviewed Boeing Alert Service Bulletin 767–38A0073, Revision 3,

dated September 8, 2016 (“Boeing Alert Service Bulletin 767–38A0073, R3”). The service information describes procedures for, among other actions, removing three hose assemblies and installing four new hose assemblies. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA’s Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or

develop in other products of the same type designs.

Proposed AD Requirements

This proposed AD would retain certain requirements of AD 2017–02–03. Although this proposed AD does not explicitly restate the actions in Boeing Alert Service Bulletin 767–38A0073, Revision 2, dated August 10, 2015, that are part of the requirements of AD 2017–02–03, this proposed AD would retain certain requirements. Those requirements are referenced in Boeing Alert Service Bulletin 767–38A0073, R3, which, in turn, is referenced in paragraph (g) of this proposed AD. Paragraph (g) of this proposed AD

would require accomplishment of the actions identified as “RC” (required for compliance) in the Accomplishment Instructions of Boeing Alert Service Bulletin 767–38A0073, R3. This proposed AD would also add airplanes to the applicability. For information on the procedures and compliance times, see this service information at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2017–0698.

Costs of Compliance

We estimate that this proposed AD affects 139 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections (retained actions from AD 2017-02-03) (129 airplanes).	Up to 10 work-hours × \$85 per hour = \$850	\$0	\$850	\$109,650
Installation (retained actions from AD 2017-02-03) (129 airplanes).	3 work-hours × \$85 per hour = \$255	330	585	75,465
Inspections (new proposed action) (10 airplanes).	Up to 10 work-hours × \$85 per hour = \$850	0	850	8,500
Installation (new proposed actions) (15 airplanes).	3 work-hours × \$85 per hour = \$255	330	585	8,775

We estimate the following costs to do any necessary on-condition actions that

would be required based on the results of the inspection. We have no way of

determining the number of aircraft that might need these actions:

ESTIMATED COST FOR ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
Up to 4 work-hours × \$85 per hour = \$340	\$53	Up to \$393.

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, “General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures

the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have 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.

For the reasons discussed above, I certify that the proposed regulation:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under the DOT Regulatory Policies and

Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2017-02-03, Amendment 39-18782 (82 FR 10541, February 14, 2017), and adding the following new AD:

The Boeing Company: Docket No. FAA-2017-0698; Directorate Identifier 2017-NM-047-AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by September 5, 2017.

(b) Affected ADs

This AD replaces AD 2017-02-03, Amendment 39-18782 (82 FR 10541, February 14, 2017) (“AD 2017-02-03”).

(c) Applicability

This AD applies to The Boeing Company Model 767-200, -300, and -400ER series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 767-38A0073, Revision 3, dated September 8, 2016 (“Boeing Alert Service Bulletin 767-38A0073, R3”).

(d) Subject

Air Transport Association (ATA) of America Code 38, Water/waste.

(e) Unsafe Condition

This AD was prompted by a report of a malfunction of the engine indication and crew alerting system (EICAS) during flight. We are issuing this AD to prevent an uncontrolled water leak from a defective potable water system coupling, which could cause the main equipment center (MEC) line replaceable units (LRUs) to become wet, resulting in an electrical short and potential loss of several functions essential for safe flight.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection of Couplings and Installation of Spray Shrouds

Except as required by paragraph (h) of this AD: At the applicable times specified in paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 767-38A0073, R3, do all applicable actions identified as “RC” (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin 767-38A0073, R3.

Note 1 to paragraph (g) of this AD: Operators can take optional protective measures to cover or shield their equipment against water spray when performing the Potable Water System Leakage Test, as specified in Boeing Alert Service Bulletin 767-38A0073, R3.

(h) Exceptions to the Service Information

(1) Where Boeing Alert Service Bulletin 767-38A0073, R3, uses the phrase “after the original issue date of this service bulletin,” for purposes of determining compliance with

the requirements of this AD, March 16, 2017 (the effective date of AD 2017-02-03) must be used.

(2) Where Boeing Alert Service Bulletin 767-38A0073, R3, uses the phrase “after the Revision 2 date of this service bulletin,” for purposes of determining compliance with the requirements of this AD, March 16, 2017 (the effective date of AD 2017-02-03) must be used.

(3) Where Boeing Alert Service Bulletin 767-38A0073, R3, specifies a compliance time “after the Revision 3 date of this service bulletin,” for purposes of determining compliance with the requirements of this AD, the phrase “after the effective date of this AD” must be used.

(i) Credit for Previous Actions

(1) For airplanes in Groups 4 through 8, 10, 12, and 13, as identified in Boeing Alert Service Bulletin 767-38A0073, R3: This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 767-38A0073, dated November 12, 2013; Boeing Service Bulletin 767-38A0073, Revision 1, dated November 5, 2014; or Boeing Alert Service Bulletin 767-38A0073, Revision 2, dated August 10, 2015.

(2) For airplanes in Groups 1 through 3, and Group 9, Configuration 2, as identified in Boeing Alert Service Bulletin 767-38A0073, R3: This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 767-38A0073, Revision 2, dated August 10, 2015.

(j) Parts Installation Prohibition

As of the effective date of this AD, no person may install any plastic potable water coupling having part number (P/N) CA620 series or P/N CA625 series on any airplane.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet

the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(4)(i) and (k)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled “RC Exempt,” then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(l) Related Information

(1) For more information about this AD, contact Stanley Chen, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM-150S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6585; fax: 425-917-6590; email: stanley.chen@faa.gov.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740-5600; telephone 562-797-1717; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on July 12, 2017.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017-15120 Filed 7-19-17; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 31

[REG-128483-15]

RIN 1545-BN12

Return Due Date and Extended Due Date Changes

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal**

Register, the IRS is issuing temporary regulations that update the due dates and extensions of time to file certain tax returns and information returns. The text of those regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by October 18, 2017.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–128483–15), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–128483–15), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent via the Federal eRulemaking Portal at www.regulations.gov (IRS REG–128483–15).

FOR FURTHER INFORMATION CONTACT: Concerning these proposed regulations, Jonathan R. Black, (202) 317–6845; concerning submissions of comments and/or requests for a hearing, Regina Johnson (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend 26 CFR parts 1 and 31. The temporary regulations update the due dates for the income tax returns of corporations and partnerships to reflect section 2006(a) of the Surface Transportation and Veterans Health Care Choice Improvement Act of 2015 (the Surface Transportation Act), Public Law 114–41, 129 Stat. 443 (2015), which amended section 6072 of the Internal Revenue Code. Additionally, the temporary regulations change the duration of automatic extensions of time to file certain tax returns and information returns. The temporary regulations also update the information return due dates to reflect section 201 of the Protecting Americans from Tax Hikes Act of 2015 (PATH Act), Public Law 114–113, Div. Q, 129 Stat. 2242 (2015). The text of those temporary regulations also serves as the text of these proposed regulations, except that the proposed regulations are proposed to be applicable for returns filed on or after the date a Treasury Decision incorporating them as final regulations is published in the **Federal Register**. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations.

Special Analysis

Certain IRS regulations, including these, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory assessment is not required. These regulations do not impose a collection of information on small entities, therefore the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. These regulations only update the due dates and extensions of time to file certain collections of information and include some existing regulatory language concerning collections of information that affect small entities for the convenience of the reader. Pursuant to section 7805(f) of the Internal Revenue Code, these proposed regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact on small businesses.

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in the preamble under the **ADDRESSES** heading. Treasury and the IRS request comments on all aspects of the proposed regulations. All comments submitted will be made available at www.regulations.gov or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Jonathan R. Black of the Office of the Associate Chief Counsel (Procedure and Administration).

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 31

Employment taxes, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social security, Unemployment compensation.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 31 are proposed to be amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Revise paragraph (b)(2)(v)(C) and add paragraph (g) to § 1.1446–3 to read as follows:

§ 1.1446–3 Time and manner of calculating and paying over the 1446 tax.

* * * * *

(b) * * *

(2) * * *

(v) * * *

(C) [The text of proposed § 1.1446–3(b)(2)(v)(C) is the same as the text of § 1.1446–3T(b)(2)(v)(C) published elsewhere in this issue of the **Federal Register**.]

* * * * *

(g) *Applicability date.* The requirements of paragraph (b)(2)(v)(C) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 3.** Revise paragraph (a)(1) and add paragraph (c) to § 1.6012–6 to read as follows:

§ 1.6012–6 Returns by political organizations.

(a) * * * (1) [The text of proposed § 1.6012–6(a)(1) is the same as the text of § 1.6012–6T(a)(1) published elsewhere in this issue of the **Federal Register**.]

* * * * *

(c) *Applicability date.* The requirements of paragraph (a)(1) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 4.** Revise paragraphs (e)(2) and (f) of § 1.6031(a)–1 to read as follows:

§ 1.6031(a)–1 Return of partnership income.

* * * * *

(e) * * *

(2) [The text of proposed § 1.6031(a)–1(e)(2) is the same as the text of § 1.6031(a)–1T(e)(2) published elsewhere in this issue of the **Federal Register**.]

* * * * *

(f) *Applicability date.* The requirements of paragraph (e)(2) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 5.** Revise § 1.6032-1 to read as follows:

§ 1.6032-1 Returns of banks with respect to common trust funds.

(a) [The text of proposed § 1.6032-1(a) is the same as the text of § 1.6032-1T(a) published elsewhere in this issue of the **Federal Register**].

(b) The requirements of paragraph (a) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 6.** Revise paragraphs (e) and (k) of § 1.6033-2 to read as follows:

§ 1.6033-2 Returns by exempt organizations (taxable years beginning after December 31, 1969) and returns by certain nonexempt organizations (taxable years beginning after December 31, 1980).

* * * * *

(e) [The text of proposed § 1.6033-2(e) is the same as the text of § 1.6033-2T(e) published elsewhere in this issue of the **Federal Register**].

* * * * *

(k) *Applicability date.* The requirements of paragraph (e) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 7.** Revise paragraph (a)(3)(ii) and add paragraph (d) to § 1.6041-2 to read as follows:

§ 1.6041-2 Return of information as to payments to employees.

(a) * * *
(3) * * *

(ii) [The text of proposed § 1.6041-2(a)(3)(ii) is the same as the text of § 1.6041-2T(a)(3)(ii) published elsewhere in this issue of the **Federal Register**].

* * * * *

(d) *Applicability date.* The requirements of paragraph (a)(3)(ii) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 8.** Revise § 1.6041-6 to read as follows:

§ 1.6041-6 Returns made on Forms 1096 and 1099 under section 6041; contents and time and place for filing.

(a) and (b) [The text of proposed § 1.6041-6(a) and (b) is the same as the text of § 1.6041-6T(a) and (b) published elsewhere in this issue of the **Federal Register**].

(c) *Applicability date.* The requirements of paragraphs (a) and (b) of

this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 9.** Revise paragraphs (a) and (d)(1) and (2) and add paragraph (g) to § 1.6072-2 to read as follows:

§ 1.6072-2 Time for filing returns of corporations.

(a) [The text of proposed § 1.6072-2(a) is the same as the text of § 1.6072-2T(a) published elsewhere in this issue of the **Federal Register**].

* * * * *

(d) * * *

(1) and (2) [The text of proposed § 1.6072-2(d)(1) and (2) is the same as the text of § 1.6072-2T(d)(1) and (2) published elsewhere in this issue of the **Federal Register**].

* * * * *

(g) *Applicability date.* The requirements of paragraphs (a) and (d)(1) and (2) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 10.** Revise paragraphs (a) and (c) of § 1.6081-1 to read as follows:

§ 1.6081-1 Extension of time for filing returns.

(a) [The text of proposed § 1.6081-1(a) is the same as the text of § 1.6081-1T(a) published elsewhere in this issue of the **Federal Register**].

* * * * *

(c) *Applicability dates.* The requirements of paragraph (a) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 11.** Revise paragraphs (a)(1) and (h) of § 1.6081-2 to read as follows:

§ 1.6081-2 Automatic extension of time to file certain returns filed by partnerships.

(a) * * * (1) [The text of proposed § 1.6081-2(a)(1) is the same as the text of § 1.6081-2T(a)(1) published elsewhere in this issue of the **Federal Register**].

* * * * *

(h) *Applicability date.* The requirements of paragraph (a)(1) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 12.** Revise the introductory text of paragraph (a), redesignate paragraph (e) as paragraph (g), revise newly

redesignated paragraph (g), and add paragraphs (e) and (f) to § 1.6081-3 to read as follows:

§ 1.6081-3 Automatic extension of time for filing corporation income tax returns.

(a) [The text of the introductory text of proposed § 1.6081-3(a) is the same as the text of the introductory text of § 1.6081-3T(a) published elsewhere in this issue of the **Federal Register**].

* * * * *

(e) and (f) [The text of proposed § 1.6081-3(e) and (f) is the same as the text of § 1.6081-3T(e) and (f) published elsewhere in this issue of the **Federal Register**].

(g) *Applicability date.* The requirements of paragraphs (a), (e), and (f) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 13.** Revise paragraphs (a)(1) and (f) of § 1.6081-5 to read as follows:

§ 1.6081-5 Extensions of time in the case of certain partnerships, corporations and U.S. citizens and residents.

(a) * * *

(1) [The text of proposed § 1.6081-5(a)(1) is the same as the text of § 1.6081-5T(a)(1) published elsewhere in this issue of the **Federal Register**].

* * * * *

(f) *Applicability date.* The requirements of paragraph (a)(1) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 14.** Revise paragraphs (a)(1) and (g) of § 1.6081-6 to read as follows:

§ 1.6081-6 Automatic extension of time to file estate or trust income tax return.

(a) * * * (1) [The text of proposed § 1.6081-6(a)(1) is the same as the text of § 1.6081-6T(a)(1) published elsewhere in this issue of the **Federal Register**].

* * * * *

(g) *Applicability date.* The requirements of paragraph (a)(1) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

■ **Par. 15.** Revise the section heading and paragraphs (a), (b)(1) and (3), and (c) through (f) of § 1.6081-9 to read as follows:

§ 1.6081-9 Automatic extension of time to file exempt or political organization returns.

(a) [The text of proposed § 1.6081-9(a) is the same as the text of § 1.6081-9T(a)

published elsewhere in this issue of the **Federal Register**].

(b) * * *

(1) [The text of proposed § 1.6081–9(b)(1) is the same as the text of § 1.6081–9T(b)(1) published elsewhere in this issue of the **Federal Register**].

* * * * *

(3) [The text of proposed § 1.6081–9(b)(3) is the same as the text of § 1.6081–9T(b)(3) published elsewhere in this issue of the **Federal Register**].

* * * * *

(c) through (e) [The text of proposed § 1.6081–9(c) through (e) is the same as the text of § 1.6081–9T(c) through (e) published elsewhere in this issue of the **Federal Register**].

(f) *Applicability date*. The requirements of paragraphs (a), (b)(1) and (3), and (c) through (e) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT THE SOURCE

■ **Par. 16.** The authority citation for part 31 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 17.** Revise paragraph (a)(3) and add paragraph (g) to § 31.6071(a)–1 to read as follows:

§ 31.6071(a)–1 Time for filing returns and other documents.

(a) * * *

(3) [The text of proposed § 31.6071(a)–1(a)(3) is the same as the text of § 31.6071(a)–1T(a)(3) published elsewhere in this issue of the **Federal Register**].

* * * * *

(g) *Applicability date*. The requirements of paragraph (a)(3) of this section are applicable for returns filed on or after the date a Treasury Decision incorporating these amendments as final regulations is published in the **Federal Register**.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2017–15211 Filed 7–18–17; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

32 CFR Part 644

33 CFR Chapter II

36 CFR Parts 312, 327, 328, 330, and 331

[COE–2017–0004]

United States Army, Corps of Engineers; Subgroup to the DoD Regulatory Reform Task Force, Review of Existing Rules

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Request for comment.

SUMMARY: In accordance with Executive Order 13777, “Enforcing the Regulatory Reform Agenda,” the United States Army, Corps of Engineers Subgroup to the DoD Regulatory Reform Task Force is seeking input on its existing regulations that may be appropriate for repeal, replacement, or modification. See the **SUPPLEMENTARY INFORMATION** section below for additional guidance.

DATES: Interested parties should submit written comments to the address shown below on or before September 18, 2017, to be considered.

ADDRESSES: You may send comments, identified by docket number COE–2017–0004, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Docket number COE–2017–0004. Follow the instructions for sending comments.
- *Email:* CorpsRegulatoryReview@usace.army.mil and include docket number COE–2017–0004 in the subject line of the message.
- *Mail:* Headquarters, U.S. Army Corps of Engineers, Attn: CECW–CO–N (Ms. Mary Coulombe), 441 G Street NW., Washington, DC 20314–1000.
- *Hand Delivery/Courier:* Due to security requirements, we cannot receive comments by hand delivery or courier.

Instructions: Direct your comments to docket number COE–2017–0004. All comments received will be included in the public docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the commenter indicates that the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do

not submit information that you consider to be CBI, or otherwise protected, through regulations.gov or email. The regulations.gov Web site is an anonymous access system, which means we will not know your identity or contact information unless you provide it in the body of your comment. If you send an email directly to the Corps without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, we recommend that you include your name and other contact information in the body of your comment and also include your contact information with any disk or CD–ROM you submit. If we cannot read your comment because of technical difficulties and cannot contact you for clarification, we may not be able to consider your comment. Electronic comments should avoid the use of any special characters, any form of encryption, and be free of any defects or viruses.

Docket: For access to the docket to read background documents or comments received, go to www.regulations.gov. All documents in the docket are listed. Although listed in the index, some information is not publicly available, such as CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form.

FOR FURTHER INFORMATION CONTACT: Ms. Mary Coulombe, 202–761–1228, mary.j.coulombe@usace.army.mil.

SUPPLEMENTARY INFORMATION: On February 24, 2017, the President signed Executive Order (E.O.) 13777, “Enforcing the Regulatory Reform Agenda,” which established a Federal policy “to alleviate unnecessary regulatory burdens” on the American people.

Section 3(a) of the E.O. directs Federal agencies to establish a Regulatory Reform Task Force (Task Force). One of the duties of the Task Force is to evaluate existing regulations and “make recommendations to the agency head regarding their repeal, replacement, or modification.” The E.O. further asks that each Task Force “attempt to identify regulations that:

- (i) Eliminate jobs, or inhibit job creation;
- (ii) are outdated, unnecessary, or ineffective;
- (iii) impose costs that exceed benefits;
- (iv) create a serious inconsistency or otherwise interfere

with regulatory reform initiatives and policies; (v) are inconsistent with the requirements of section 515 of the Treasury and General Government Appropriation Act, 2001 (44 U.S.C. 3516 note), or the guidance issued pursuant to that provision in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility; or (vi) derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.”

Section 3(e) of the E.O. 13777 calls on the Task Force to “seek input and other assistance, as permitted by law, from entities significantly affected by Federal regulations, including State, local, and tribal governments, small businesses, consumers, non-governmental organizations, trade associations” on regulations that meet some or all of the criteria above. Through this notice, the United States Army, Corps of Engineers is soliciting such input from the public to inform evaluation of the United States Army, Corps of Engineers existing regulations by the Task Force’s United States Army, Corps of Engineers Subgroup. Although the agency will not respond to each individual comment, the United States Army, Corps of Engineers may follow-up with respondents to clarify comments. The United States Army, Corps of Engineers values public feedback and will consider all input that it receives. In addition to the regulations listed below, we are open to receiving comments on other Corps of Engineers regulations as well.

The Corps regulations subject to this review are:

- 32 CFR part 644—Real Estate Handbook
- 33 CFR part 203—Emergency Employment of Army and Other Resources, Natural Disaster Procedures
- 33 CFR part 207—Navigation Regulations
- 33 CFR part 208—Flood Control Regulations
- 33 CFR part 209—Administrative Procedure
- 33 CFR part 210—Procurement Activities of the Corps of Engineers
- 33 CFR part 214—Emergency Supplies of Drinking Water
- 33 CFR part 220—Design Criteria for Dam and Lake Projects
- 33 CFR part 221—Work for Others
- 33 CFR part 222—Engineering and Design
- 33 CFR part 223—Boards, Commissions, and Committees
- 33 CFR part 230—Procedures for Implementing NEPA
- 33 CFR part 236—Water Resource Policies and Authorities: Corps of Engineers Participation in Improvements for Environmental Quality
- 33 CFR part 238—Water Resources Policies and Authorities: Flood Damage Reduction Measures in Urban Areas
- 33 CFR part 239—Water Resources Policies and Authorities: Federal Participation in Covered Flood Control Channels
- 33 CFR part 240—General Credit for Flood Control
- 33 CFR part 241—Flood Control Cost-sharing Requirements Under the Ability to Pay Provision
- 33 CFR part 242—Flood Plain Management Services Program Establishment of Fees for Cost Recovery
- 33 CFR part 245—Removal of Wrecks and Other Obstructions
- 33 CFR part 263—Continuing Authorities Programs
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- 33 CFR part 277—Water Resources Policies and Authorities: Navigation Policy: Cost Apportionment of Bridge Alterations
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- 33 CFR part 320—General Regulatory Policies
- 33 CFR part 321—Permits for Dams and Dikes in Navigable Waters of the United States
- 33 CFR part 322—Permits for Structures or Work In or Affecting Navigable Waters of the United States
- 33 CFR part 323—Permits for Discharges of Dredged or Fill Material into Waters of the United States
- 33 CFR part 324—Permits for Ocean Dumping of Dredged Material
- 33 CFR part 325—Processing of Department of the Army permits
- 33 CFR part 326—Enforcement
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- 33 CFR part 328—Definition of Waters of the United States
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- 33 CFR part 330—Nationwide Permit Program
- 33 CFR part 331—Administrative Appeal Process
- 33 CFR part 332—Compensatory Mitigation for Losses of Aquatic Resources
- 33 CFR part 334—Danger Zone and Restricted Area Regulations
- 33 CFR part 335—Operation and Maintenance of Army Corps of Engineers Civil Works Projects Involving the Discharge of Dredged or Fill Material into Waters of the United States or Ocean Waters
- 33 CFR part 336—Factors to be Considered in the Evaluation of Army Corps of Engineers Dredging Projects Involving the Discharge of Dredged Material into Waters of the United States and Ocean Waters
- 33 CFR part 337—Practice and Procedure
- 33 CFR part 338—Other Corps Activities Involving the Discharge of Dredged Material or Fill into Waters of the United States
- 33 CFR part 384—Intergovernmental Review of Department of the Army Corps of Engineers Programs and Activities
- 33 CFR part 385—Programmatic Regulations for the Comprehensive Everglades Restoration Plan
- 36 CFR part 312—Prohibition of Discriminatory Practices in Water Resources Development Projects
- 36 CFR part 327—Rules and Regulations Governing Public Use of Water Resource Development Projects Administered by the Chief of Engineers
- 36 CFR part 328—Regulation of Seaplane Operations at Civil Works Water Resource Development Projects Administered by the Chief of Engineers
- 36 CFR part 330, Regulation of Law Enforcement Services Contracts at Civil Works Water Resources Projects Administered by the Chief of Engineers
- 36 CFR part 331—Regulations Governing the Protection, Use, and Management of the Falls of Ohio National Wildlife Conservation Area, Kentucky and Indiana

Dated: July 17, 2017.

Jeffery A. Anderson,

Colonel, U.S. Army, Chief of Staff.

[FR Doc. 2017–15231 Filed 7–19–17; 8:45 am]

BILLING CODE 3720–58–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2016–0110; A–1–FRL–9965–12Region 1]

Air Plan Approval; ME; Regional Haze 5-Year Progress Report

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve Maine's regional haze progress report, submitted on February 23, 2016, as a revision to its State Implementation Plan (SIP). Maine's SIP revision addresses requirements of the Clean Air Act (CAA) and EPA's rules that require states to submit periodic reports describing progress toward reasonable progress goals (RPGs) established for regional haze and a determination of the adequacy of the State's existing regional haze SIP. Maine's progress report notes that Maine has implemented the measures in the regional haze SIP due to be in place by the date of the progress report and that visibility in federal Class I areas affected by emissions from Maine is improving and has already met the applicable RPGs for 2018. EPA is proposing approval of Maine's determination that the State's regional haze SIP is adequate to meet these reasonable progress goals for the first implementation period covering through 2018 and requires no substantive revision at this time.

DATES: Written comments must be received on or before August 21, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R01-OAR-2016-0110 at <http://www.regulations.gov>, or via email to arnold.anne@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, the 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. The 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: Anne McWilliams, Air Quality Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square—Suite 100, (Mail Code OEP05-02), Boston, MA 02109—3912, telephone number (617) 918-1697, fax number (617) 918-0697, email mcwilliams.anne@epa.gov.

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

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I. Background

States are required to submit a progress report in the form of a SIP revision that evaluates progress towards the RPGs for each mandatory Class I Federal area¹ (Class I area) within the state and in each Class I area outside the state which may be affected by emissions from within the state. *See* 40 CFR 51.308(g). In addition, the provisions under 40 CFR 51.308(h) require states to submit, at the same time as the 40 CFR 51.308(g) progress report, a determination of the adequacy of the state's existing regional haze SIP. The progress report SIP is due five years after submittal of the initial regional haze SIP. On December 9, 2010, the Maine Department of Environmental Protection (ME DEP) submitted the State's first regional haze SIP in accordance with 40 CFR 51.308.²

On February 23, 2016, ME DEP submitted a revision to the Maine SIP detailing the progress made in the first planning period toward implementation of the Long Term Strategy (LTS) outlined in its 2010 regional haze SIP submittal, the visibility improvement measured at the Class I areas affected by emissions from Maine, and a determination of the adequacy of the State's existing regional haze SIP. EPA is proposing to approve Maine's February 23, 2016 SIP submittal.

¹ Areas designated as mandatory Class I Federal areas consist of national parks exceeding 6000 acres, wilderness areas and national memorial parks exceeding 5000 acres, and all international parks that were in existence on August 7, 1977 (42 U.S.C. 7472(a)). Listed at 40 CFR part 81 Subpart D.

² On April 24, 2012, EPA approved Maine's Regional Haze SIP submittal addressing the requirements of the first implementation period for regional haze. *See* 77 FR 24385.

II. EPA's Evaluation of Maine's SIP Revision

On February 23, 2016, Maine submitted its “Regional Haze 5-Year Progress Report” (Progress Report) to EPA as a SIP revision.

Maine is home to three Class I areas: Acadia National Park (Acadia), Roosevelt-Campobello International Park (RCIP), and Moosehorn Wilderness Area (Moosehorn). Emissions from Maine sources were also found to be contributing to visibility impairment at nearby Great Gulf Wilderness Area (Great Gulf) in New Hampshire. *See* 76 FR 73956 (November 29, 2011).

Through the consultation process, Maine agreed to pursue the coordinated course of action agreed to by the Mid-Atlantic/Northeast Visibility Union (MANE-VU)³ to assure reasonable progress toward preventing any future, and remedying any existing, impairment of visibility in the mandatory Class I areas within the MANE-VU region. These strategies are commonly referred to as the MANE-VU “Ask.” The MANE-VU “Ask” includes: A timely implementation of best available retrofit technology (BART) requirements; 90 percent or more reduction in sulfur dioxide (SO₂) emissions at 167 electrical generating units (EGUs) “stacks” identified by MANE-VU (or comparable alternative measures); lower sulfur fuel oil (with limits specified for each State); and continued evaluation of other control measures.⁴ In summary, Maine is on track to fulfill the MANE-VU “Ask” by meeting the deadlines for BART requirements, as of the date of the Progress Report, for all BART-eligible facilities described in the Progress Report, adopting a low sulfur fuel oil strategy requiring the use of 0.0015% sulfur by weight in distillate and 0.5% sulfur by weight residual fuel oil by July 1, 2018, and reducing SO₂ emissions by 57% from the State's one identified contributing EGU, Florida Power and Light's Wyman Station (Wyman). An additional reduction in SO₂ emissions from Wyman is expected with the

³ MANE-VU is a collaborative effort of State governments, Tribal governments, and various federal agencies established to initiate and coordinate activities associated with the management of regional haze, visibility and other air quality issues in the Northeastern United States. Member State and Tribal governments include: Connecticut, Delaware, the District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Penobscot Indian Nation, Rhode Island, and Vermont.

⁴ The MANE-VU “Ask” was structured around the finding that SO₂ emissions were the dominate visibility impairing pollutant at the Northeastern Class I areas and electrical generating units comprised the largest SO₂ emission sector. *See* “Regional Haze and Visibility in the Northeast and Mid-Atlantic States,” January 31, 2001.

implementation of 0.5% sulfur by weight residual oil requirement by July 1, 2018.

A. Regional Haze Progress Report

This section includes the EPA’s analysis of Maine’s Progress Report SIP submittal, and an explanation of the basis of our proposed approval.

Maine’s 2010 regional haze SIP included the following key measures: Implementation of BART for eligible sources, reducing the sulfur in fuel oil content, and reducing SO₂ emissions from the Maine EGU identified as contributing to visibility impairment at nearby Class I areas.

In the Maine 2010 Regional Haze SIP, ME DEP identified 10 facilities subject to BART. For eight of these facilities, the existing controls were determined to be BART. The remaining two sources eligible for BART controls were: Wyman Boiler #3 and Verso Androscoggin at Jay Boilers #1 and #2. As documented in Table 3–1 of the Maine Progress Report, each of these two sources has implemented a permit revision, approved in EPA’s April 24, 2012 approval of Maine’s regional haze SIP (77 FR 24385), which requires the use of 0.7% sulfur by weight fuel oil by the BART deadline of 2013.⁵

Maine’s Progress Report notes the implementation of the MANE–VU “Ask” for sulfur content of fuel oil. The Maine statute, approved by the EPA as part of Maine’s regional haze plan, lowers the sulfur content of all distillate fuel oils to 0.0015% sulfur by weight and residual oils to 0.5% sulfur beginning July 1, 2018.⁶

Maine has two EGUs among the 167 EGUs stacks identified for control of sulfur dioxide emission in the MANE–VU “Ask.” These stacks are Wyman units #3 and #4. As previously discussed above, unit #3 was required to

reduce the sulfur in fuel content to 0.7% by 2013 with a further reduction to 0.5% sulfur by weight in 2018, as required by Maine’s sulfur in fuels statute. Unit #4 is following the same timeline. The Progress Report indicates a 1,138 ton/year SO₂ (or 57%) emission reduction from Wyman thus far. An additional reduction in SO₂ emission is expected from the required use of 0.5% sulfur by weight fuel oil by 2018.

The Maine Progress Report also includes the status of SO₂ emission reductions from states that affect Class I areas in MANE–VU relative to the MANE–VU “Ask.”⁷ Maine consulted with states in the eastern United States that affect visibility at the Class I areas at Acadia, Moosehorn, and RCIP, outlining how they could meet the MANE–VU “Ask” and help achieve the progress goals for Class I areas in Maine and other MANE–VU States. These emission reductions were included in the modeling that predicted progress toward meeting RPGs. The EPA is proposing that Maine’s summary of the status of the implementation of measures in its Progress Report adequately addresses the applicable provisions under 40 CFR 51.308(g), as the State demonstrated the implementation of measures within Maine, including applying BART at subject sources.

During the development of the regional haze SIP for the first planning period, MANE–VU and Maine determined that SO₂ was the greatest contributor to anthropogenic visibility impairment at the State’s Class I areas. Therefore, the bulk of visibility improvement achieved in the first planning period was expected to result from reductions in SO₂ emissions from sources inside and outside of the State. Table 6–1 of Maine’s 2016 Progress Report details the SO₂ emission

reductions from the 2002 Maine regional haze SIP baseline to 2014 for not only the targeted Wyman units, but all Maine EGUs.⁸ The Maine EGUs show an emission reduction from 2,022 tons SO₂ in 2002 to 856 tons SO₂ in 2014, a reduction of 57%. Oxides of nitrogen (NO_x) emissions from these same sources were also reduced from 1,154 tons in 2002 to 539 tons in 2014, a reduction of 53%.

EPA is proposing to find that Maine has adequately addressed the applicable provisions of 40 CFR 51.308(g). Maine has detailed the SO₂ and NO_x reductions from the 2002 regional haze baseline by using the most recently available year of data at the time of the development of Maine’s Progress Report, which is 2014.

The provisions under 40 CFR 51.308(g) also require that States with Class I areas within their borders provide information on current visibility conditions and the difference between current visibility conditions and baseline visibility conditions expressed in terms of five-year averages of these annual values.

Maine is home to three Class I areas; Acadia, RCIP, and Moosehorn. Maine relies on the Interagency Monitoring of Protected Visual Environments (IMPROVE) program monitoring network for visibility measurements. One IMPROVE monitor is located within Acadia. A second IMPROVE monitor is located one mile northeast of Moosehorn. The Moosehorn monitor also serves as the monitor for nearby RCIP. In the Progress Report, ME DEP provides the data in deciviews (dv)⁹ for the baseline 2000–2004 five-year average visibility, the most recent 2010–2014 five-year average visibility, the 2018 RPG from the 2010 regional haze SIP, and the calculated visibility improvement. See Table 1.

TABLE 1—OBSERVED VISIBILITY VS. ESTABLISHED VISIBILITY GOALS (deciviews) FOR ACADIA AND MOOSEHORN

	Baseline 2000–2004 5-year average visibility (dv)	Most recent 2010–2014 5-year average visibility (dv)	Visibility improvement (dv)	2018 Reasonable progress goal (dv)	Meets 2018 progress goals?
20% Most Impaired Days					
Acadia	22.9	17.5	5.4	19.4	Yes.

⁵ See EPA’s Proposed Approval of Maine’s Regional Haze SIP (76 FR 73956, November 29, 2011) for a full discussion of Maine’s BART analysis.

⁶ Maine’s Sulfur in Fuel Statute 38 MRSA Section 603–A subsection 2(A) was approved into the Maine SIP on April 24, 2012. See 79 FR 24385.

⁷ Memorandum from NESCAUM to MANE–VU “Overview of State and Federal Actions Relative to MANE–VU Asks” dated March 28, 2013. <http://www.nescaum.org/documents/summary-memo-mane-vuasks-20130328-fianl.pdf>.

⁸ Maine’s Progress Report SIP includes annual unit-level emissions data for SO₂ and NO_x from

EGUs from EPA’s Clean Air Markets Division (CAMD) for the years 2002 and 2014.

⁹ The deciview is a measure for tracking progress in improving visibility. Each deciview change is an incremental change in visibility perceived by the human eye. The preamble to the Regional Haze Rule provides additional details about the deciview (64 FR 35714 (July 1, 1999)).

TABLE 1—OBSERVED VISIBILITY VS. ESTABLISHED VISIBILITY GOALS (deciviews) FOR ACADIA AND MOOSEHORN—Continued

	Baseline 2000–2004 5-year average visibility (dv)	Most recent 2010–2014 5-year average visibility (dv)	Visibility improvement (dv)	2018 Reasonable progress goal (dv)	Meets 2018 progress goals?
Moosehorn	21.7	16.5	5.2	19.0	Yes.
20% Least Impaired Days					
Acadia	8.8	7.0	1.8	8.3	Yes.
Moosehorn	9.2	6.7	2.5	8.6	Yes.

The baseline visibility for Acadia and Moosehorn was 22.9 dv and 21.7 dv, respectively, on the 20% most impaired days. On the 20% least impaired days, the baseline visibility was 8.8 dv and 9.2 dv for these two sites, respectively. The most recent five-year average data for both sites shows an improvement of more than 5 dv on the 20% most visibility impaired days and no visibility degradation on the 20% least impaired days. The 2016 Progress Report demonstrates that the State has already achieved the 2018 RPG for the 20% most impaired days and ensured no visibility degradation for the 20% least impaired days for the first planning period. The Class I area outside of Maine affected by sources in Maine also has achieved the 2018 RPGs.

EPA is proposing to find that Maine provided the required information regarding visibility conditions to meet the applicable provisions under 40 CFR 51.308(g), specifically providing baseline visibility conditions (2000–2004), current conditions based on the most recently available IMPROVE monitoring data (2010–2014), and a comparison with the RPGs.

In its Progress Report SIP, Maine presents data from statewide emissions inventories developed for the years 2002, 2011, and 2014 (EGUs only), and projected inventories for 2018 for SO₂, NO_x, fine particulate matter (PM_{2.5}), and volatile organic compounds (VOC).¹⁰ Maine's emissions inventories include the following source classifications; Point EGUs, Point Non-EGU, Area, On-Road Mobile, and Non-road. From 2002 through 2014, Maine's overall EGU SO₂ emissions were reduced from 2,022 tons to 856 tons, well below the 2018 projected level of 7,422 tons. The largest SO₂ sector, Point Non-EGU, saw

emissions drop from 21,709 tons in 2002 to 6,434 tons in 2011, well below the 18,492 tons projected for 2018. Overall, State SO₂ emissions dropped from 39,589 tons in 2002 to 15,528 tons in 2011, below the 2018 projection of 31,830 tons. Statewide NO_x emissions experienced a similar decrease. Overall, State NO_x emissions dropped from 91,928 tons in 2002 to 62,633 tons in 2011. The 2018 projected NO_x emissions is 41,922 tons. Additional NO_x reductions are expected from the mobile sector. Finally, ME DEP indicated that based on 2011 emission data, the State has already achieved the 2018 projected emissions reduction for direct PM_{2.5} (2% reduction) and VOC (20% reduction).

EPA is proposing that Maine has adequately addressed the applicable provisions under 40 CFR 51.308. ME DEP compares the most recent updated emission inventory data available at the time of development of the Progress Report with the baseline emissions in the regional haze SIP. The Progress Report appropriately details the 2011 SO₂, NO_x, PM_{2.5}, and VOC reductions achieved, by sector, thus far in the regional haze planning period. In addition, the State provided the most recent annual SO₂ and NO_x emission data for EGUs.

In its Progress Report SIP, Maine states that sulfates continue to be the biggest single contributor to regional haze at Acadia, Moosehorn, RCI, and Great Gulf. While Maine mainly focused its analysis on addressing large SO₂ emissions from point sources, the State did not find any significant changes in NO_x and PM_{2.5} which might impede or limit progress during the first planning period. In addition, ME DEP cited the 2013 Northeast States for Coordinated Air Use Management (NESCAUM) report, discussed below, which indicates that all of the MANE–VU Class I areas are on track to meet the 2018

visibility goals established by the States in their Regional Haze SIPs.¹¹

EPA is proposing to conclude that Maine has adequately addressed the applicable provisions under 40 CFR 51.308(g). The State adequately demonstrated that there are no significant changes in emissions of SO₂, PM_{2.5}, or NO_x within the State which have impeded progress in reducing emissions and improving visibility in the Class I areas impacted by Maine sources.

In its Progress Report SIP, ME DEP states that the elements and strategies relied on in its original Regional Haze SIP are sufficient to enable Maine and neighboring States to meet all RPGs. To support this conclusion, ME DEP notes in Table 7–1 of the Progress Report that the 2014 EGU SO₂ emissions from the entire MANE–VU area are already less than the 2018 projections for that area (323,704 tons versus 365,024 tons). In addition, Maine discusses visibility data from *Tracking Visibility Progress, 2004–2011*, prepared by NESCAUM, which updated the progress at MANE–VU Class I areas during the five-year period ending in 2014. The data included information for the Maine Class I areas, between 2000 and 2014, in the context of short- and long-term visibility goals. The report indicates that visibility impairment on the best and worst days from 2000–2014 have dropped at Acadia, Moosehorn, and Great Gulf. Maine notes the NESCAUM report indicates that all the MANE–VU Class I states continue to be on track to meet their 2018 RPGs for improved visibility and that further progress may occur through recently adopted or proposed regulatory programs. Based upon the NESCAUM report and visibility data, Maine states in its Progress Report that visibility improvement at Acadia,

¹⁰ The 2002 inventory is the MANE–VU V3.3 which is projected to 2018. The 2011 inventory is based on the 2011 National Emission Inventory (NEI). The 2014 inventory was the most recent year of Clean Air Markets Division (CAMD) inventory data as reported to EPA.

¹¹ NESCAUM for MANE–VU, “Tracking Visibility Progress 2004–2011,” revised May 24, 2013. <http://www.nescaum.org/documents/manevu-trends-2004-2011-report-final-20130430.pdf/view>. The report was later updated with 2014 IMPROVE data.

Moosehorn, RCIP, and Great Gulf has occurred for the most impaired days and no degradation of visibility has occurred for the least impaired days. Therefore, Maine finds that Acadia, Moosehorn, RCIP, and Great Gulf are on track to meet the RPGs for 2018 based on observed visibility improvement.

EPA is proposing to conclude that Maine has adequately addressed the applicable provisions under 40 CFR 51.308(g). EPA views this requirement as an assessment that should evaluate emissions and visibility trends and other readily available information. In its Progress Report, Maine describes the improving visibility trends using data from the IMPROVE network and the downward emission trends in key pollutants in the State and the MANE-VU region. Maine determined that the State's regional haze SIP is sufficient for the three Class I areas within the State and the Class I area outside of the State impacted by the State's emissions (Great Gulf) to meet their RPGs.

Maine's visibility monitoring strategy relies upon participation in the IMPROVE network. The IMPROVE monitor serving Acadia is located within Acadia National Park. The IMPROVE monitor serving Moosehorn and RCIP is located one mile northeast of Moosehorn. ME DEP finds that there is no indication of a need for additional monitoring sites or equipment.

EPA is proposing to find that Maine has adequately addressed the applicable provisions under 40 CFR 51.308(g) by reviewing the State's visibility monitoring strategy and assessing whether any modifications to the monitoring strategy are necessary.

B. Determination of Adequacy of Existing Regional Haze Plan

In its Progress Report SIP, Maine submitted a negative declaration to EPA regarding the need for additional actions or emission reductions in Maine beyond those already in place and those to be implemented by 2018 according to Maine's regional haze plan.

In the 2016 SIP submittal, Maine determined that the existing Regional Haze SIP requires no substantive revision at this time to achieve the RPGs for the Class I areas affected by the State's sources. The basis for the State's negative declaration is the finding that visibility has improved at all Class I areas in the MANE-VU region. In

addition, SO₂ and PM_{2.5} emissions for the State have decreased beyond the original 2018 projections. While NO_x reductions have yet to fully meet the 2018 projections, additional substantial NO_x reductions are expected by 2018.

EPA is proposing to conclude that Maine has adequately addressed the provisions under 40 CFR 51.308(h) because the visibility and emission trends indicate that Acadia, Moosehorn, RCIP, and Great Gulf are meeting or exceeding the RPGs for 2018, and are expected to continue to meet or exceed the RPGs for 2018.

EPA is soliciting public comments on the issues discussed in this notice or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to this proposed rule by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

III. Proposed Action

EPA is proposing to approve Maine's February 23, 2016 regional haze 5-Year Progress Report SIP as meeting the requirements of 40 CFR 51.308(g) and (h).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act 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 Clean Air Act. Accordingly, this proposed action merely 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 Clean Air Act; 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).

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Regional haze, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: July 5, 2017.

Deborah A. Szaro,

Acting Regional Administrator, EPA New England.

[FR Doc. 2017-15266 Filed 7-19-17; 8:45 am]

BILLING CODE 6560-50-P

Notices

Federal Register

Vol. 82, No. 138

Thursday, July 20, 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

Submission for OMB Review; Comment Request

July 17, 2017.

The Department of Agriculture has submitted the following information collection requirement(s) to Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the 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 burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 21, 2017 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@OMB.EOP.GOV or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control

number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Utilities Service

Title: RUS Specification for Quality Control and Inspection of Timber Products.

OMB Control Number: 0572–0076.

Summary of Collection: The Rural Utilities Service (RUS) is a credit agency of the U.S. Department of Agriculture (USDA) and is authorized to manage loan programs in accordance with the Rural Electrification Act (RE Act) of 1936, 7 U.S.C. 901 *et seq.*, as amended. It makes mortgage loans and loan guarantees to finance telecommunications, electric, and water and waste facilities in rural areas. To ensure the security of loan funds, adequate quality control of timber products is vital to loan security on electric power systems where hundreds of thousands of wood-poles and cross-arms are used. Prior to receiving loan funds, a RUS borrower must enter into a loan contract with RUS. In accordance with Article V, Section 5.14 of the loan contract, “the borrower shall use design standards, construction standards and lists of acceptable materials in conformance with RUS regulations.

Need and Use of the Information: The purchaser or treating company may obtain the services of an inspection agency or third-party oversight organization to perform certain inspection services to insure that the specifications for wood poles and cross-arms are being met. As required by 7 CFR 1728.202(i) copies of test reports on various preservatives must accompany each charge (a charge being a load of poles treated at the same time in a pressure cylinder). Test reports are needed so that the purchaser, the inspectors, and RUS will be able to spot-check the general accuracy of the tests. RUS will use the information in verifying acceptability of poles and cross-arms purchased by RUS borrowers.

Description of Respondents: Business or other for-profit; Not-for-profit institutions.

Number of Respondents: 25.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 20,332.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2017–15234 Filed 7–19–17; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 17, 2017.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the 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 burden 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques and other forms of information technology.

Comments regarding this information collection received by August 21, 2017 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW., Washington, DC 20503. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such

persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Forest Service

Title: Significant Cave Nomination.

OMB Control Number: 0596–NEW.

Summary of Collection: The Federal Cave Resources Protection Act (FCRPA) [Pub. L. 100–691, 107 Stat. 4546] requires the Secretaries of Agriculture and Interior to identify and protect significant caves on Federal lands within their respective jurisdictions. The information covered in this collection applies to caves on Federal lands administered by the Forest Service. The FCRPA does not define what constitutes a “significant” cave, but it does require the Secretaries, in cooperation and consultation with each other, to issue regulations that define criteria for identification of significant caves found at (16 U.S.C. 4303(a)).

Need and Use of the Information: In accordance with FCRPA, the FS collects information from appropriate private sector interests, including “cavers,” to update a list of significant caves under USDA’s jurisdiction. FS will use form FS–2800–0023 “Significant Cave Nomination Worksheet” to collect name, address, telephone number of individual or organization submitting the nomination and the individual who is knowledgeable about the resources in the cave; name and location of the cave, a discussion of how the cave meets the criteria, studies, maps, research papers and other supporting documentation. If this information is not collected FS might not become aware of potentially significant caves’ existence or have insufficient information upon which to base a judgment as to their significance.

Description of Respondents:

Individuals and households.

Number of Respondents: 10.

Frequency of Responses: Reporting: One time.

Total Burden Hours: 110.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2017–15272 Filed 7–19–17; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 17, 2017.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the

Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the 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 burden 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 21, 2017 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@OMB.EOP.GOV or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal Plant and Health Inspection Service

Title: Environmental Monitoring Form.

OMB Control Number: 0579–0117.

Summary of Collection: The mission of the Animal and Plant Health Inspection Service (APHIS) is to provide leadership in ensuring the health and care of animals and plants, to improve the agricultural productivity and competitiveness, and to contribute to the national economy and the public health. The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 ET seq, and the regulations of the Council on Environmental Quality that implements the procedural aspects of NEPA (40 CFR 1500–1508). APHIS’ regulations require APHIS to implement

environmental monitoring for certain activities conducted for pest and disease, control and eradication programs. APHIS Form 2060, Environmental Monitoring Form, will be used to collect information concerning the effects of pesticide used in sensitive habitats.

Need and Use of the Information: APHIS will collect information on the number of collected samples, description of the samples, the environmental conditions at the collection site including wind speed and direction, temperature, and topography. The supporting information contained on the APHIS form 2060 is vital for interpreting the laboratory tests APHIS conducts on its collected samples. If a sample was not accompanied by this form, APHIS would have no way of knowing from which site the sample was taken. Failure to collect this information would prevent APHIS from actively monitoring the effects of pesticides in areas where the inappropriate use of these chemicals could eventually produce disastrous results for vulnerable habitats and species.

Description of Respondents: State, Local or Tribal Government; Business or other for-profit.

Number of Respondents: 110.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 1,100.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2017–15205 Filed 7–19–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Information Collection Activity; Comment Request

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Rural Utilities Service (RUS) invites comments on this information collection for which approval from the Office of Management and Budget (OMB) will be requested.

DATES: Comments on this notice must be received by September 18, 2017.

FOR FURTHER INFORMATION CONTACT: Thomas P. Dickson, Acting Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400

Independence Ave. SW., STOP 1522, Room 5164—South Building, Washington, DC 20250–1522. Telephone: (202) 690–4492. Email: thomas.dickson@wdc.usda.gov.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that will be submitted to OMB for extension.

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 will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on 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. *Comments may be sent to:* Thomas P. Dickson, Acting Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Ave. SW., STOP 1522, Room 5164—South Building, Washington, DC 20250–1522 or email: thomas.dickson@wdc.usda.gov.

Title: Servicing of Water Programs Loans and Grants.

OMB Control Number: 0572–0137.

Type of Request: Extension of a currently approved information collection.

Abstract: The Rural Utilities Service (RUS) Water and Environmental Programs (WEP) provide financing and technical assistance for development and operation of safe and affordable water supply systems and sewage and other waste disposal facilities. WEP provides loans, guaranteed loans and grants for water, sewer, storm water, and solid waste disposal facilities in rural areas and towns of up to 10,000 people. The recipients of the assistance covered by 7 CFR part 1782 must be public entities. These public entities can include municipalities, counties, special purpose districts, federally designated Indian tribes, and corporations not

operated for profit, including cooperatives. The information, for the most part financial in nature, is needed by the Agency to determine if borrowers, based on their individual situations, qualify for the various servicing options.

Estimate of Burden: Public reporting for this collection of information is estimated to average 1.22 hours per response.

Respondents: Business or other for profit and non-profit institutions, and state and local governments.

Estimated Number of Respondents: 493.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 641 hours.

Copies of this information collection can be obtained from Thomas P. Dickson, Program Development and Regulatory Analysis, at (202) 690–4492. Email: thomas.dickson@wdc.usda.gov.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: July 13, 2017.

Christopher A. McLean,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2017–15188 Filed 7–19–17; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Information Collection Activity; Comment Request

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Rural Utilities Service (RUS) invites comments on the following information collection for which RUS intends to request approval from the Office of Management and Budget (OMB).

DATES: Comments on this notice must be received by September 18, 2017.

FOR FURTHER INFORMATION CONTACT:

Thomas P. Dickson, Acting Director, Program Development and Regulatory Analysis, Rural Utilities Service, 1400 Independence Ave. SW., STOP 1522, Room 5164, South Building, Washington, DC 20250–1522. Telephone: (202) 690–4492 or email Thomas.dickson@wdc.usda.gov.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing

provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that RUS is submitting to OMB for revision.

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 will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Comments may be sent to: Thomas P. Dickson, Acting Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, STOP 1522, 1400 Independence Ave. SW., Washington, DC 20250–1522. Telephone: (202) 690–4492 or email: thomas.dickson@wdc.usda.gov.

Title: Electric System Emergency Restoration Plan.

OMB Control Number: 0572–0140.

Type of Request: Revision of a currently approved collection.

Abstract: USDA Rural Development administers rural utilities programs through the Rural Utilities Service (Agency). The Agency manages loan programs in accordance with the Rural Electrification Act (RE Act) of 1936, 7 U.S.C. 901 *et seq.*, as amended. One of the Agency's main objectives is to safeguard loan security. An important part of safeguarding loan security is to make sure Agency financed facilities are utilized responsibly, adequately operated and adequately maintained. Accordingly, RUS borrowers have a duty to RUS to maintain their respective systems. In performing this duty, borrowers further the purposes of the RE Act while also preserving the value of electric systems to serve as collateral for repayment of RUS assistance.

A substantial portion of the electric infrastructure of the United States resides in rural America and is maintained by rural Americans. RUS is uniquely coupled with the electric infrastructure of rural America and its electric borrowers serving rural

America. To ensure that the electric infrastructure in rural America is adequately protected, electric borrowers conduct a Vulnerability and Risk Assessment (VRA) of their respective systems and utilize the results of this assessment to enhance an existing Emergency Restoration Plan (ERP) or to create an ERP. The VRA is utilized to identify specific assets and infrastructure owned or served by the electric utility, to determine the criticality and the risk level associated with the assets and infrastructure including a risk versus cost analysis, to identify threats and vulnerabilities, if present, to review existing mitigation procedures and to assist in the development of new and additional mitigating procedures, if necessary. The ERP provides written procedures detailing response and restoration efforts in the event of a major system outage resulting from a natural or man-made disaster. The annual exercise of the ERP ensures operability and employee competency and serves to identify and correct deficiencies in the existing ERP. The exercise may be implemented individually by a single borrower, or by an individual borrower as a participant in a multi-party (to include utilities, government agencies and other participants or combination thereof) tabletop execution or actual implementation of the ERP.

Electric borrowers maintain ERPs as part of prudent utilities practices. These ERPs are essential to continuous operation of the electric systems. Each electric borrower provides RUS with an annual self-certification that an ERP exists for the system and that an initial VRA has been performed.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .5 hour per response.

Respondents: Not-for-profit institutions.

Estimated Number of Respondents: 625.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 313 hours.

Copies of this information collection can be obtained from Thomas P. Dickson, Program Development and Regulatory Analysis, at (202) 690-4492, or email: thomas.dickson@wdc.usda.gov.

All responses to this notice will be summarized and included in the requests for OMB approval. All

comments will also become a matter of public record.

Christopher A. McLean,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2017-15187 Filed 7-19-17; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Connecticut Advisory Committee

AGENCY: 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 Connecticut Advisory Committee to the Commission will convene by conference call at 12:00 p.m. (EDT) on: Wednesday, August 9, 2017. The purpose of the meeting is to conclude work on the Committee's Advisory Memorandum on Solitary Confinement. The committee will also possibly vote on the Advisory Memorandum.

DATES: Wednesday, August 9, at 12:00 p.m. EDT.

ADDRESSES: Public call-in information: Conference call-in number: 1-888-438-5448 and conference call 3640132.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at ero@usccr.gov or by phone at 202-376-7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 1-888-438-5448 and conference call 3640132. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). 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 conference call-in number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1-800-977-8339 and providing the operator with the toll-free conference call-in number: 1-888-438-5448 and conference call 3640132.

Members of the public are invited to make statements during the open comment period of the meeting or

submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376-7548, or emailed to Evelyn Bohor at ero@usccr.gov. Persons who desire additional information may contact the Eastern Regional Office at (202) 376-7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at <https://database.faca.gov/committee/meetings.aspx?cid=239>; click the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, www.usccr.gov, or to contact the Eastern Regional Office at the above phone numbers, email or street address.

Agenda

Wednesday, August 9, 2017

- Open—Roll Call
- Work on Advisory Memorandum
- Vote on Memorandum, if ready
- Open Comment
- Adjourn

Dated: July 17, 2017.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017-15232 Filed 7-19-17; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the New York Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meetings.

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 meetings of the New York Advisory Committee to the Commission will convene by conference call at 12:00 p.m. (EDT) on: Friday, August 11, 2017 and Friday, August 18 and Friday. The purpose of the meeting is to review and edit the draft report on police practices.

DATES: Friday August 11; Friday and August 18; Friday at 12:00 p.m. EDT.

ADDRESSES: Public call-in information: Conference call-in number: 1-888-267-6301 and conference call 1171256.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at ero@usccr.gov or by phone at 202-376-7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 1-888-267-6301 and conference call 1171256. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). 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 conference call-in number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1-800-977-8339 and providing the operator with the toll-free conference call-in number: 1-888-267-6301 and conference call 1171256.

Members of the public are invited to make statements during the open comment period of the meetings or submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376-7548, or emailed to Evelyn Bohor at ero@usccr.gov. Persons who desire additional information may contact the Eastern Regional Office at (202) 376-7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at <https://database.faca.gov/committee/meetings.aspx?cid=265>; click the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, www.usccr.gov, or to contact the Eastern Regional Office at the above phone numbers, email or street address.

Agenda

Friday, August 11 and Friday August 18, Friday

- Open—Roll Call
- Work on Draft Report
- Vote on Draft Report when ready
- Open Comment
- Adjourn

Dated: July 17, 2017

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017-15233 Filed 7-19-17; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-552-822]

Fine Denier Polyester Staple Fiber From the Socialist Republic of Vietnam: Termination of Less-Than-Fair-Value Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On June 27, 2017, the Department of Commerce (the Department) published its initiation of less-than-fair-value investigations of fine denier polyester staple fiber (fine denier PSF) from China, India, Korea, Taiwan, and Vietnam. On June 29, 2017, DAK Americas LLC; Nan Ya Plastics Corporation, America; and Auriga Polymers Inc., (collectively, the petitioners), withdrew the antidumping duty (AD) petition with respect to Vietnam. Accordingly, we are terminating the AD investigation of fine denier PSF from Vietnam.

DATES: Applicable July 20, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Heaney, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone (202) 482-4475.

SUPPLEMENTARY INFORMATION:

Background

On May 31, 2017, the Department received an AD petition concerning imports of fine denier PSF from Vietnam, filed on behalf of the petitioners.¹ On June 27, 2017, the Department published the initiation of

¹ See Letter to the Secretary of Commerce, Re: "Fine Denier Polyester Staple Fiber from the People's Republic of China, India, the Republic of Korea, Taiwan and the Socialist Republic of Vietnam—Petitions for the Imposition of Antidumping and Countervailing Duties," dated May 31, 2017.

the less-than-fair-value investigation of fine denier PSF from Vietnam.² On June 29, 2017, the petitioners submitted a letter withdrawing the AD petition with respect to Vietnam.³ Section 351.207(b)(1) of the Department's regulations stipulates that the Secretary may terminate an investigation provided it has concluded that termination of the investigation is in the public interest.⁴ Because petitioners have withdrawn their May 31, 2017, petition with respect to Vietnam, and have requested that the Department terminate this investigation, we determine that termination of this investigation is in the public interest, pursuant to 19 CFR 351.207(b)(1).⁵ Accordingly, pursuant to section 734(a)(1)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.207(b)(1), we are terminating the less-than-fair-value investigation with respect to Vietnam.

Scope of the Investigation

The merchandise covered by this investigation is fine denier polyester staple fiber (fine denier PSF), not carded or combed, measuring less than 3.3 decitex (3 denier) in diameter. The scope covers all fine denier PSF, whether coated or uncoated. The following products are excluded from the scope:

(1) PSF equal to or greater than 3.3 decitex (more than 3 denier, inclusive) currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 5503.20.0045 and 5503.20.0065.

(2) Low-melt PSF defined as a bi-component fiber with a polyester core and an outer, polyester sheath that melts at a significantly lower temperature than its inner polyester core currently classified under HTSUS subheading 5503.20.0015.

Fine denier PSF is classifiable under the HTSUS subheading 5503.20.0025. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the investigation is dispositive.

Termination of Investigation

In accordance with section 734(a)(1)(A) of the Act and 19 CFR

² See *Fine Denier Polyester Staple Fiber from the People's Republic of China, India, the Republic of Korea, Taiwan, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair Value Investigations*, 82 FR 29023 (June 27, 2017) (*Initiation Notice*).

³ See Letter from the Petitioners, Re: *Fine Denier Polyester Staple Fiber from the Socialist Republic of Vietnam—Withdrawal of Vietnam Antidumping Duty Petition*, dated June 29, 2017 (*Withdrawal Letter*).

⁴ See 19 CFR 351.207(b)(1) of the Regulations.

⁵ See *Withdrawal Letter* at 1-2.

351.207(b)(1), upon the petitioners' withdrawal of the petition, we are terminating the less-than-fair-value investigation of fine denier PSF with respect to Vietnam.

Dated: July 13, 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. 2017-15141 Filed 7-19-17; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XF543

Fisheries of the Gulf of Mexico and 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 54 assessment webinar III for HMS Sandbar Shark.

SUMMARY: The SEDAR 54 assessment of the HMS Sandbar will consist of a series of assessment webinars. See

SUPPLEMENTARY INFORMATION.

DATES: The SEDAR 54 assessment webinar III will be held on Monday, August 7, 2017, from 1 p.m. to 3 p.m.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer 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: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571-4366; email: Julie.neer@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. SEDAR is a multi-step process including: (1) Data

Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS 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 NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Assessment Process webinars are as follows:

1. Using datasets and initial assessment analysis recommended from the Data Webinar, panelists will employ assessment models to evaluate stock status, estimate population benchmarks and management criteria, and project future conditions.

2. Participants will recommend the most appropriate methods and configurations for determining stock status and estimating population parameters.

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

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other

auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each webinar.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: July 17, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017-15257 Filed 7-19-17; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XF511

Atlantic Coastal Fisheries Cooperative Management Act Provisions; Summer Flounder Fishery

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

ACTION: Notice of determination of compliance for the State of New Jersey.

SUMMARY: This notice announces the Secretary of Commerce's compliance decision under the Atlantic Coastal Fisheries Cooperative Management Act regarding New Jersey recreational management of summer flounder. This notice is necessary to alert the public that the Secretary of Commerce has made a final determination and will not implement a Federal moratorium on fishing, possession, and landing of summer flounder in New Jersey's state waters. The intended effect of this notice is to inform the public of this determination of compliance.

DATES: The date of this determination was July 10, 2017.

FOR FURTHER INFORMATION CONTACT: Emily Gilbert, Fishery Policy Analyst, (978) 281-9244.

SUPPLEMENTARY INFORMATION: In accordance with the Atlantic Coastal Fisheries Cooperative Management Act (Atlantic Coastal Act), 16 U.S.C. 5101 *et seq.*, the Secretary of Commerce (Secretary) announces his determination that the State of New Jersey did not implement the measures required by the Atlantic States Marine Fishery Commission's Addendum XXVIII to the Flounder, Scup, and Black Sea Bass Interstate Fishery Management Plan (Addendum XXVIII). However, the Secretary finds that the management measures New Jersey failed to implement are not necessary for the

conservation of summer flounder. Based on the analysis provided by the State, it is likely that New Jersey's measures will result in similar levels of total removals as the measures outlined in Addendum XXVIII. As a result, the Secretary is not imposing a moratorium in New Jersey state waters.

The Atlantic Coastal Act's noncompliance review and determination process was previously outlined in a notice that published in the **Federal Register** on June 22, 2017, (82 FR 28476) and is not repeated here.

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

Dated: July 17, 2017.

Emily H. Menashes,

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

[FR Doc. 2017-15229 Filed 7-19-17; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XF553

South Atlantic Fishery Management Council; Public Hearings

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

ACTION: Notice of public hearings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold public hearings via webinar pertaining to Amendment 43 to the Snapper Grouper Fishery Management Plan (FMP) for the South Atlantic Region. The amendment would revise the annual catch limit for red snapper in the South Atlantic Economic Exclusive Zone (EEZ).

DATES: The public hearings will be held via webinar on August 8, 2017 at 6 p.m. and August 10, 2017 at 10 a.m. and 6 p.m. An informal Question and Answer (Q&A) session will be held via webinar on August 3, 2017 beginning at 6 p.m.

ADDRESSES: *Council address:* South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571-4366 or toll free: (866) SAFMC-10; fax: (843) 769-4520; email: kim.iverson@safmc.net.

SUPPLEMENTARY INFORMATION: The Q&A session and public hearings will be conducted via webinar. Registration for each webinar is required. Registration

information and public hearing materials will be posted on the Council's Web site at <http://safmc.net/safmc-meetings/public-hearing-and-scoping-meeting-schedule/> by July 27, 2017.

During the Q&A session Council staff will present an overview of the amendment and will be available for informal discussions and to answer questions via webinar. During the public hearings, Council staff will review the amendment and members of the public will have the opportunity to provide formal comments for consideration by the Council.

Written comments may be submitted online beginning July 27, 2017 at: <http://safmc.net/safmc-meetings/public-hearing-and-scoping-meeting-schedule/>. Written comments may also be submitted to the Council office (see **ADDRESSES**). Comments will be accepted until 5 p.m. on August 15, 2017.

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: July 17, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017-15261 Filed 7-19-17; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

United States Global Change Research Program

AGENCY: The National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Request for public nominations.

CONTEXT: The U.S. Global Change Research Program (USGCRP) is mandated under the Global Change Research Act (GCRA) of 1990 to conduct a quadrennial National Climate Assessment (NCA). Under its current, updated decadal strategic plan (<http://go.usa.gov/x9MCQ>), USGCRP is building sustained assessment capacity. The sustained assessment supports the Nation's ability to understand, anticipate, and respond to risks and potential impacts brought about by

global environmental change. Work on the fourth National Climate Assessment is currently underway.

SUMMARY: NOAA, on behalf of USGCRP, is soliciting nominations for Review Editors for the Fourth National Climate Assessment (NCA4). Refer to the NCA4 Outline (accessible via <http://www.globalchange.gov/content/nca4-outline>) for a sense of the areas of expertise we seek.

The report will adhere to the Information Quality Act requirements (http://www.cio.noaa.gov/services_programs/info_quality.html) for quality, transparency, and accessibility as appropriate for a Highly Influential Scientific Assessment (HISA).

DATES: Nominations should be submitted via the web address specified below (<https://contribute.globalchange.gov/>) and must be received by September 8, 2017.

ADDRESSES: Nominations for Review Editors must be submitted electronically via a Web form accessible via (<https://contribute.globalchange.gov/>).

Nominees are asked to identify their areas of expertise based on NCA4's sectoral, regional, and response topics (see NCA4 Table of Contents below). A CV/resume of no more than 4 pages should be included for optimal consideration. There are no limitations on the nominees' place of employment.

INSTRUCTIONS: Response to this notice is voluntary. Responses to this notice may be used by the government for program planning on a non-attribution basis. NOAA therefore requests that no business proprietary information or copyrighted information be submitted in response to this notice. Please note that the U.S. Government will not pay for response preparation, or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT:

David Reidmiller, (202) 419-3470, dreidmiller@usgcrp.gov, U.S. Global Change Research Program.

DATED: Wednesday, July 12, 2017.

Dan Barrie, Program Manager, Assessments Program, NOAA Climate Program Office.

SUPPLEMENTARY INFORMATION:

Background information and additional details on NCA4 can be found at <https://www.globalchange.gov/nca4>.

This notice seeks nominations for Review Editors to NCA4 with pertinent subject matter expertise and scientific background. The roles of the Review Editor include: (a) Ensuring that all substantive comments submitted during the Public Comment Period and via a National Academies panel review (both

currently scheduled for Autumn 2017–Winter 2018) are appropriately addressed, (b) advising Chapter Leads how to handle contentious issues, and (c) ensuring that significant scientific uncertainties are reflected adequately in the text of NCA4. Review Editors do not provide additional comments on assigned draft chapters; rather, they ensure each and every comment has been considered by the author team, and that the ‘annotation’ (*i.e.*, written responses to comments) is responsive to the comment and indicates any revision made to the chapter(s), including the scientific or logical rationale for said action.

Potential nominees should be accomplished scientists and/or science communicators with climate-related proficiency in at least one of the regions, sectors, or responses topics outlined in the NCA4 Outline, (described below in the Appendix and accessible via <http://www.globalchange.gov/content/nca4-outline>). Nominees must have demonstrated technical expertise such that the nominees could contribute to the development of a robust scientific, technical assessment as subject matter experts in one or more of the topics listed in the outline.

Responses to this request for nominations for Review Editors must be submitted by September 8, 2017. Users can access the nominations form via (<https://contribute.globalchange.gov/>). Interested persons may nominate themselves or third parties, and may nominate more than one person. Each nomination must include: (1) The nominee’s full name, title, institutional affiliation, and contact information; (2) the desired chapter(s) the nominee wishes to serve as Review Editor on (*i.e.*, area(s) of expertise); and (3) a short description of his/her qualifications relative to contributing to the report. Nominees are encouraged to submit a CV of no more than 4 pages for optimal consideration.

More information on the function of Review Editors, the tasks (including reporting) expected of them, as well as the tentative dates of commitment can be found at <https://contribute.globalchange.gov>.

Appendix: NCA4 Outline

- I: Overview
- II: Our Changing Climate
- III: National-level Sectoral Overview Chapters
 - Water
 - Energy
 - Land Cover and Land Use Change
 - Forests
 - Ecosystems, Ecosystem Services, and Biodiversity
 - Coastal Effects

- Oceans and Marine Resources
 - Agriculture and Rural Communities
 - Built Environment, Urban Systems, and Cities
 - Transportation
 - Air Quality
 - Human Health
 - Tribal and Indigenous Communities
 - Climate Effects on US International Interests
 - Sectoral Interdependencies and Compounding Stressors: The Science of Complex Systems
 - IV: Regional Analyses
 - Northeast
 - Southeast
 - US Caribbean
 - Midwest
 - Northern Great Plains
 - Southern Great Plains
 - Northwest
 - Southwest
 - Alaska
 - Hawai’i and Pacific Islands
 - V: Response
 - Near-Term Adaptation Needs and Increased Resiliency
 - Mitigation: Avoiding and Reducing Long-Term Risks
- Dated: July 12, 2017.

David Holst,

Acting Chief Financial Officer/CAO, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2017–15235 Filed 7–19–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF551

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Observer Advisory Committee (OAC) subgroup on low sampling rates in partial coverage.

DATES: The meeting will be held Thursday, August 3, 2017, from 9 a.m. to 3 p.m. Alaska time.

ADDRESSES: The meeting will be held by teleconference only: (907) 271–2896.

FOR FURTHER INFORMATION CONTACT: Diana Evans, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION:

Agenda

The agenda will be to discuss progress on the items on the OAC subgroup’s

workplan, posted here: https://www.npfc.org/wp-content/PDFdocuments/conservation_issues/Observer/OACSubgroupWorkplan617.pdf.

Meeting will be listening-only for those that are not on the OAC subgroup.

Special Accommodations

The meeting is via teleconference. Request for auxiliary aids should be directed to Maria Shawback at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: July 17, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017–15260 Filed 7–19–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF546

Pacific Fishery Management Council; Public Meeting (Webinar)

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

ACTION: Notice of public meeting (webinar).

SUMMARY: The Pacific Fishery Management Council’s (Pacific Council) Ad hoc Sacramento River Winter Chinook Workgroup (SRWCW) and Salmon Advisory Subpanel (SAS) will hold a joint meeting via webinar to discuss the results of the Management Strategy Evaluation. The meeting is open to the public.

DATES: The webinar meeting will be held on Thursday, August 3, 2017, from 11 a.m. until business for the day has been completed.

ADDRESSES: The meeting will be held via webinar. A public listening station is available at the Pacific Council office (address below). To attend the webinar (1) join the meeting by visiting this link <https://global.gotomeeting.com/join/955668125>, (2) enter the Webinar ID: 955–668–125, and (3) enter your name and email address (required). After logging in to the webinar, please (1) dial this TOLL number 1–786–535–3211 (not a toll-free number), (2) enter the attendee phone audio access code 955–668–125, and (3) then enter your audio phone pin (shown after joining the webinar). **Note:** We have disabled Mic/Speakers as an option and require all

participants to use a telephone or cell phone to participate. Technical Information and System Requirements: PC-based attendees are required to use Windows® 7, Vista, or XP; Mac®-based attendees are required to use Mac OS® X 10.5 or newer; Mobile attendees are required to use iPhone®, iPad®, Android™ phone or Android tablet (See the *GoToMeeting* WebinarApps). You may send an email to Mr. Kris Kleinschmidt at Kris.Kleinschmidt@noaa.gov or contact him at 503-820-2280, extension 411 for technical assistance. A public listening station will also be available at the Pacific Council office.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Ehlke, Pacific Council; telephone: (503) 820-2410.

SUPPLEMENTARY INFORMATION: The SRWCW was formed in November 2015 and tasked with exploring and evaluating alternative fishery management frameworks for Sacramento River winter Chinook. The SRWCW first met in 2016 and identified three areas of focus: (1) Develop methods for forecasting abundance, (2) develop a suite of alternative control rules and (3) evaluate the performance of these control rules with regard to conservation benefits and fishery costs using a Management Strategy Evaluation (MSE) approach. Since 2016 the group has addressed these tasks and provided progress reports to the Council as information was available. At this webinar, the SRWCW will focus the discussion on the results of the MSE. The SAS will attend to provide input and feedback to the SRWCW. The SRWCW is tentatively scheduled to present preliminary MSE results to the Pacific Fishery Management Council in September 2017, and provide final MSE results in November 2017. The SRWCW may also discuss materials and reports for the Council's September 2017 meeting, and any future meeting plans.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document 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 physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820-2411 at least 10 business days prior to the meeting date.

Dated: July 17, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017-15259 Filed 7-19-17; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XF544

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 Data Scoping webinar.

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 Data Scoping webinar will be held on Tuesday, August 8, 2017, from 9 a.m. until 12 p.m.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is 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 Data Scoping webinar are as follows:

Participants will identify who will be providing updated and/or new datasets.

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: July 17, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017-15258 Filed 7-19-17; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648–XF560

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 Observer Policy 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 Thursday, August 3, 2017 at 9 a.m.

ADDRESSES: The meeting will be held at the Hilton Garden Inn, 100 Boardman Street, Boston, MA 02128; telephone: (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 Committee will discuss recent and planned work related to 2017 priorities, including development of a policy for monitoring commercial fisheries to address multiple information needs and a strategic approach to bycatch monitoring, and recommend appropriate next steps. The Committee will also discuss priorities for 2018; other business will be discussed as necessary.

Special Accommodations

This meeting is physically accessible to people with disabilities. This meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request. 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: July 17, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017–15262 Filed 7–19–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**Patent and Trademark Office**

[Docket No.: PTO–P–2017–0029]

Grant of Interim Extension of the Term of U.S. Patent No. 7,179,464; Benralizumab

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension for a one-year interim extension of the term of U.S. Patent No. 7,179,464.

FOR FURTHER INFORMATION CONTACT: Mary C. Till by telephone at (571) 272–7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to her attention at (571) 273–7755; or by email to Mary.Till@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On June 30, 2017, Kyowa Hakko Kirin Co., Ltd., the patent owner of record, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of U.S. Patent No. 7,179,464. The patent claims methods of using the human biological product benralizumab. The application for patent term extension indicates that a Biological License Application (BLA) 761070 was submitted to the Food and Drug Administration (FDA) on November 16, 2016.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year

as required by 35 U.S.C. 156(d)(5)(B). Because the regulatory review period will continue beyond the original expiration date of the patent, July 21, 2017, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 7,179,464 is granted for a period of one year from the original expiration date of the patent.

Dated: July 17, 2017.

Robert Bahr,

Deputy Commissioner for Patent Examination Policy, United States Patent and Trademark Office.

[FR Doc. 2017–15249 Filed 7–19–17; 8:45 am]

BILLING CODE 3510–16–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE**Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; CNCS Grant Application; Proposed Information Collection; Comment Request**

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS) has submitted a public information collection request (ICR) entitled CNCS Grant Application for review and approval in accordance with the Paperwork Reduction Act of 1995, Pub. L. 104–13, (44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Amy Borgstrom, at 202–606–6930 or email to aborgstrom@cns.gov. Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

DATES: Comments may be submitted, identified by the title of the information collection activity, within August 21, 2017.

ADDRESSES: Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service, by any of the following two methods within 30 days from the date of publication in the **Federal Register**:

(1) *By fax to:* 202–395–6974, Attention: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service; or

(2) *By email to:* smar@omb.eop.gov.

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, 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;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments

A 60-day Notice requesting public comment was published in the **Federal Register** on July 1, 2016 at 81 FR 43192. This comment period ended August 30, 2016. No public comments were received from this Notice.

Description: The CNCS Grant Application is the information collection instrument used for grant competitions which CNCS sponsors when appropriations are available. This is a new information collection that replaces multiple application information collections used in the past. The information collection will otherwise be used in the same manner as the existing applications. CNCS also seeks to continue using the current applications until the revised application is approved by OMB. The current applications are due to expire at various times in the future and will be withdrawn once the new information collection request is approved and the new system is operational.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: Grants and Member Management System.

OMB Number: TBD.

Agency Number: None.

Affected Public: Applicants for funding.

Total Respondents: 13,200.

Frequency: Depending on the availability of appropriations.

Average Time per Response: Six hours.

Estimated Total Burden Hours: 79,200.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Dated: July 13, 2017.

Marlene Zakai,

Director of Strategic Initiatives.

[FR Doc. 2017-15228 Filed 7-19-17; 8:45 am]

BILLING CODE 6050-28-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Health Board; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Health Board (DHB) will take place.

DATES: Open to the public Thursday, August 10, 2017 from 9:15 a.m. to 12:45 p.m. Open to the public Thursday, August 10, 2017 from 1:30 p.m. to 5:00 p.m.

ADDRESSES: The address of the open meeting is the Defense Health Headquarters (DHHQ), Pavilion Salons B–C, 7700 Arlington Blvd., Falls Church, Virginia 22042 (escort required; see guidance in **SUPPLEMENTARY INFORMATION**, “Meeting Accessibility”).

FOR FURTHER INFORMATION CONTACT: CAPT Juliann Althoff, Medical Corps, US Navy, (703) 681–6653 (Voice), (703) 681–9539 (Facsimile), juliann.m.althoff.mil@mail.mil (Email). Mailing address is 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042. Web site: <http://www.health.mil/dhb>. The most up-to-date changes to the meeting agenda can be found on the Web site.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: A copy of the agenda or any updates to the agenda for the August 10,

2017 meeting, is available at the Defense Health Board (DHB) Web site, <https://health.mil/dhb>. Any other materials presented in the meeting, may be obtained at the meeting.

Purpose of the Meeting: The Department of Defense is publishing this notice to announce a Federal Advisory Committee meeting of the DHB. The DHB provides independent advice and recommendations to maximize the safety and quality of, as well as access to, health care for DoD health care beneficiaries. The purpose of the meeting is to provide progress updates on specific taskings before the DHB. In addition, the DHB will receive information briefings on current issues related to military medicine.

Agenda: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165 and subject to availability of space, the meeting is open to the public from 9:15 a.m. to 12:45 p.m. and from 1:30 p.m. to 5:00 p.m. on August 10, 2017. The DHB anticipates receiving a decision brief from the Health Care Delivery and Neurological/Behavioral Health Subcommittees on a pediatric health care services tasking, a panel discussion on operational medicine from the Joint Staff Surgeon and two Combatant Command Surgeons, and a briefing from the Medical Officer of the Marine Corps. Any changes to the agenda can be found at the link provided in this **SUPPLEMENTARY INFORMATION** section.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b, and 41 CFR 102–3.140 through 102–3.165 and subject to availability of space, this meeting is open to the public. Seating is limited and is on a first-come basis. All members of the public who wish to attend the public meeting must register by emailing their name, rank/title, and organization/company to dha.ncr.dhb.mbx.defense-health-board@mail.mil or by contacting Ms. Margaret Welsh at (703) 681–8007 or margaret.s.welsh.ctr@mail.mil.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Ms. Margaret Welsh at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Written Statements: Any member of the public wishing to provide comments to the DHB may do so in accordance with section 10(a)(3) of the Federal Advisory Committee Act, 41 CFR 102–3.105(j) and 102–3.140, and the procedures described in this notice. Written statements may be submitted to the DHB Designated Federal Officer (DFO), CAPT Juliann Althoff, at

juliann.m.althoff.mil@mail.mil and should be no longer than two type-written pages and include the issue, a short discussion, and a recommended course of action. Supporting documentation may also be included, to establish the appropriate historical context and to provide any necessary background information. If the written statement is not received at least five (5) business days prior to the meeting, the DFO may choose to postpone consideration of the statement until the next open meeting. The DFO will review all timely submissions with the DHB President and ensure they are provided to members of the DHB before the meeting that is subject to this notice. After reviewing the written comments, the President and the DFO may choose to invite the submitter to orally present their issue during an open portion of this meeting or at a future meeting. The DFO, in consultation with the DHB President, may allot time for members of the public to present their issues for review and discussion by the DHB.

Dated: July 17, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017-15223 Filed 7-19-17; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2017-ICCD-0105]

Agency Information Collection Activities; Comment Request; Annual Progress Reporting Form for the American Indian Vocational Rehabilitation Services (AIVRS) Program

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), 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 September 18, 2017.

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-0105. 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 216-32, Washington, DC 20202-4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact August Martin, 202-245-7410.

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: Annual Progress Reporting Form for the American Indian Vocational Rehabilitation Services (AIVRS) Program.

OMB Control Number: 1820-0655.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 88.

Total Estimated Number of Annual Burden Hours: 968.

Abstract: The Rehabilitation Services Administration (RSA) of the U.S. Department of Education's (ED) Office

of Special Education and Rehabilitative Services (OSERS) will use this data collection form to capture the performance data from grantees funded under the American Indian Vocational Rehabilitation Services (AIVRS) program (CFDA # 84.250). RSA and ED will use the information gathered annually to: (a) Comply with reporting requirements under the Education Department General Administration Regulations (EDGAR) 34 CFR part 75.118, (b) provide information annually to Congress on activities conducted under this program, and (c) measure performance on the program in accordance with the program indicators identified in the Government Performance Result Act (GPRA). The proposed changes to the existing form will improve user friendliness, clarity of data questions, and accuracy of data reported. Since the ED no longer collects data regarding common measures, the entire section of the report that collects this data is deleted, further reducing burden. These revisions are not significantly different from the original collection, but are proposed to provide clarity, consistency, and usability. In many areas, the data element language has been modified with direct language instead of passive terminology.

Dated: July 14, 2017.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017-15198 Filed 7-19-17; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No. ED-2017-ICCD-0106]

Agency Information Collection Activities; Comment Request; Quick Response Information System (QRIS) 2017-2020 System Clearance

AGENCY: National Center for Education Statistics (NCES), 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 September 18, 2017.

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–0106. 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 NCES Information Collections at NCES.Information.Collections@ed.gov.

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: Quick Response Information System (QRIS) 2017–2020 System Clearance.

OMB Control Number: 1850–0733.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 104,004.

Total Estimated Number of Annual Burden Hours: 31,704.

Abstract: The National Center for Education Statistics (NCES) Quick Response Information System (QRIS) consists of the Fast Response Survey System (FRSS) and the Postsecondary Education Quick Information System (PEQIS). The QRIS currently conducts surveys under OMB generic clearance 1850–0733, which expires in February 2018. This submission requests approval to continue the current clearance conditions through the end of 2020. FRSS primarily conducts surveys of the elementary/secondary sector (districts, schools) and public libraries. PEQIS conducts surveys of the postsecondary education sector. FRSS and PEQIS surveys are cleared under the QRIS generic clearance. The QRIS clearance is subject to the regular clearance process at OMB with a 60-day notice and a 30-day notice as part of the 120-day review period. Each individual FRSS or PEQIS survey is then subject to clearance process with an abbreviated clearance package, justifying the particular content of the survey, describing the sample design, the timeline for the survey activities, and the questionnaire. The review period for each individual survey is 45 days, including a 30-day **Federal Register** notice period. OMB will provide comments as soon after the end of the 30-day notice period as possible. This generic clearance request is for surveys of state education agencies, school districts, schools, postsecondary institutions, and libraries.

Dated: July 17, 2017.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–15271 Filed 7–19–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP17–468–000]

Texas Eastern Transmission, LP; Notice of Application for Certificate of Public Convenience and Necessity

Take notice that on June 30, 2017, Texas Eastern Transmission, LP (Texas Eastern), 5400 Westheimer Court, Houston, Texas 77056, filed with the Federal Energy Regulatory Commission an abbreviated application under

section 7 of the Natural Gas Act requesting a Certificate of Public Convenience and Necessity authorizing Texas Eastern to excavate, elevate, and replace four different sections of pipelines and appurtenant facilities located in Marshall County, West Virginia due to planned long-wall mining activities in October 2018 known as the Marshall County Mine Panel 18W Project. Texas Eastern seeks authorization to perform work due to the anticipated long-wall mining activities of Marshall County Coal Company in Panel 18W of its Marshall County Mine, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may also be viewed on the web at <http://www.ferc.gov> using the “e-Library” link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions regarding this application may be directed to Lisa A. Connolly, Director, Rates and Certificates, Texas Eastern Transmission, LP, P.O. Box 1642, Houston, Texas 77251–1642; Phone: (713) 627–4102, or Fax: (713) 627–5947, or email: lisa.connolly@enbridge.com.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888

First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit five copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit original and five copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on August 3, 2017.

Dated: July 13, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017-15242 Filed 7-19-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16-494-000]

Transcontinental Gas Pipe Line Company, LLC; Notice of Schedule for Environmental Review of the Gulf Connector Expansion Project

On August 16, 2016, Transcontinental Gas Pipe Line Company, LLC (Transco) filed an application in Docket No. CP16-494-000 requesting a Certificate of Public Convenience and Necessity pursuant to section 7(c) of the Natural Gas Act to construct and operate certain natural gas pipeline facilities in Wharton, Hardin, San Patricio and Victoria Counties, Texas. The Gulf Connector Expansion Project (Project) would enable 475,000 dekatherms per day of incremental firm natural gas transportation.

On August 25, 2016, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's Environmental Assessment (EA) for the Project. This instant notice identifies the FERC staff's planned schedule for the completion of the EA for the Project.

Schedule for Environmental Review

Issuance of EA, September 21, 2017
90-day Federal Authorization Decision
Deadline, December 20, 2017

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

Transco proposes to construct new compressor stations in San Patricio, Victoria, and Wharton Counties. The three new compressor stations would total 30,650 horsepower. In addition, there would be modifications to an existing compressor station in Hardin

County and modifications to an existing compressor station in Wharton County. Transco would also decommission a compressor station in Refugio County, use the site as a construction storage yard, and construct a new interconnection in San Patricio County.

Background

On September 22, 2016, the Commission issued a *Notice of Intent to Prepare an Environmental Assessment for the Proposed Gulf Connector Expansion Project and Request for Comments on Environmental Issues* (NOI). The NOI was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the NOI, the Commission received a letter from the Texas Parks and Wildlife Department that included several recommendations for mitigating impacts on migratory birds, wildlife, and vegetation.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to www.ferc.gov/docs-filing/esubscription.asp.

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208-FERC or on the FERC Web site (www.ferc.gov). Using the eLibrary link, select General Search from the eLibrary menu, enter the selected date range and Docket Number excluding the last three digits (*i.e.*, CP16-494), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208-3676, TTY (202) 502-8659, or at FERCOnlineSupport@ferc.gov. The eLibrary link on the FERC Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: July 14, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017-15244 Filed 7-19-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. 2232–522]

Duke Energy Carolinas, LLC; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Federal Energy Regulatory Commission and is available for public inspection:

a. *Type of Application*: Amendment of Project License.

b. *Project No.*: 2232–522.

c. *Date Filed*: May 5, 2017.

d. *Applicant*: Duke Energy Carolinas, LLC (licensee).

e. *Name of Project*: Catawba-Wateree Hydroelectric Project.

f. *Location*: The project includes 11 developments and is located on the Catawba and Wateree Rivers in Burke, McDowell, Caldwell, Catawba, Alexander, Iredell, Mecklenburg, Lincoln, and Gaston Counties, North Carolina, and York, Lancaster, Chester, Fairfield, and Kershaw Counties in South Carolina. The project does not occupy federal land.

g. *Filed Pursuant to*: Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact*: Jeff Lineberger, Director, Water Strategy and Hydro Licensing, Duke Energy Carolinas, LLC, 526 S. Church St., P.O. Box 1006/EC12Y, Charlotte, NC 28202, Jeff.Lineberger@duke-energy.com.

i. *FERC Contact*: Michael Calloway at 202–502–8041, or michael.calloway@ferc.gov.

j. Deadline for filing comments, motions to intervene, and protests is 30 days from the issuance of this notice by the Commission. The Commission strongly encourages electronic filing. Please file motions to intervene, protests, and comments using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>.

Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. 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–2232–522.

k. *Description of Request*: The licensee requests that the Commission amend the project license to include new Water Quality Certificates issued by North Carolina Department of Environmental Quality on February 27, 2017, and South Carolina Department of Health and Environmental Control on April 5, 2017. The new certificates were included in the May 5, 2017, filing. Additionally, the licensee requests that the Commission amend the Flow and Water Quality Implementation Plan and the Water Quality Monitoring Plan in order to: (1) Raise reservoir target elevation by 6 inches at James, Norman, and Wylie developments from May 1 to October 1; (2) change Wylie Hydro Station recreation release from 6,000 cubic feet per second (cfs) to 3,000 cfs; (3) update the Low Inflow Protocol and Emergency Protocol; (4) update status and implementation schedules contained in the Water Quality Monitoring Plan and Flow and Water Quality Improvement Plan; and (5) evaluate other technologies in addition to a bladder dam to provide the additional flow releases at Wateree Spillway.

l. *Locations of the Application*: A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling 202–502–8371. This filing may also 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. You may also register online at <http://www.ferc.gov/docs-filing/subscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 866–208–3676 or email FERCOnlineSupport@ferc.gov, for TTY, call 202–502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*: Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to

intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents*: Any filing must (1) bear in all capital letters the title COMMENTS; PROTEST, or MOTION TO INTERVENE as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to the amendment application. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: July 13, 2017.

Kimberly D. Bose,
Secretary.

[FR Doc. 2017–15247 Filed 7–19–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. IC17–10–000]

Commission Information Collection Activities (FERC Form No. 2 and FERC Form No. 2–A); Comment Request

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Comment request.

SUMMARY: In compliance with the requirements of the Paperwork

Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is submitting its information collection [FERC Form No. 2 (Major Natural Gas Pipeline Annual Report) and FERC Form No. 2-A (Non-major Natural Gas Pipeline Annual Report).] to the Office of Management and Budget (OMB) for review of the information collection requirements. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission previously issued a Notice April 11, 2017, in the **Federal Register** requesting public comments. The Commission received no comments on these collections and is making this notation in its submittal to OMB.

DATES: Comments on the collections of information are due by August 21, 2017.

ADDRESSES: Comments filed with OMB, identified by the OMB Control Nos. 1902-0028 and 1902-0030, should be sent via email to the Office of Information and Regulatory Affairs: oir_submission@omb.gov. Attention: Federal Energy Regulatory Commission Desk Officer. The Desk Officer may also be reached via telephone at 202-395-0710.

A copy of the comments should also be sent to the Commission, in Docket No. IC17-10-000, by either of the following methods:

- *eFiling at Commission's Web site:* <http://www.ferc.gov/docs-filing/efiling.asp>.

- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: <http://www.ferc.gov/help/submission-guide.asp>. For user assistance contact

FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at: (866) 208-3676 (toll-free), or (202) 502-8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at <http://www.ferc.gov/docs-filing/docs-filing.asp>.

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at DataClearance@FERC.gov, by telephone at (202) 502-8663, and by fax at (202) 273-0873.

SUPPLEMENTARY INFORMATION:
Title: FERC Form No. 2 (Annual Report of Major Natural Gas Companies) and FERC Form No. 2-A (Annual Report of Non-major Natural Gas Companies).¹

OMB Control Nos.: 1902-0028 (FERC Form No. 2) and 1902-0030 (FERC Form No. 2-A).

Type of Request: Three-year extension of the FERC Form No. 2 and FERC Form No. 2-A information collection requirements with no changes to the reporting requirements.

Abstract: Pursuant to sections 8, 10 and 14 of the National Gas Act (NGA), (15 U.S.C. 717g-717m, Pub. L. 75-688), the Commission is authorized to make investigations and collect and record data, to prescribe rules and regulations concerning accounts, records and memoranda as necessary or appropriate for purposes of administering the NGA. The Commission includes the filing requirements in 18 CFR parts 260.1 and 260.2.

The forms provide information concerning a company's past performance. The information is compiled using a standard chart of accounts contained in the Commission's Uniform System of Accounts (USoFA).² The forms contain schedules which include a basic set of financial

statements: Comparative Balance Sheet, Statement of Income and Retained Earnings, Statement of Cash Flows, and the Statement of Comprehensive Income and Hedging Activities. Supporting schedules containing supplementary information are filed, including revenues and the related quantities of products sold or transported; account balances for various operating and maintenance expenses; selected plant cost data; and other information.

The information collected in the forms is used by Commission staff, state regulatory agencies and others in the review of the financial condition of regulated companies. The information is also used in various rate proceedings, industry analyses and in the Commission's audit programs and, as appropriate, for the computation of annual charges based on Page 520 of the forms. The Commission provides the information to the public, interveners and all interested parties to assist in the proceedings before the Commission.

Print versions of the Forms No. 2 and 2-A are located on the Commission's Web site at <http://www.ferc.gov/docs-filing/forms.asp#2> and <http://www.ferc.gov/docs-filing/forms.asp#2a> respectively.

Type of Respondents: Each natural gas company whose combined gas transported or stored for a fee exceeds 50 million dekatherms in each of the previous three years must file the Form 2. Each natural gas company not meeting the filing threshold for the Form 2 but having total gas sales or volume transactions exceeding 200,000 dekatherms in each of the previous three calendar years must submit the Form 2-A.

*Estimate of Annual Burden*³: The Commission estimates the annual public reporting burden for the information collections as:

FERC FORM NO. 2: ANNUAL REPORT OF MAJOR NATURAL GAS COMPANIES AND FERC FORM NO. 2-A: ANNUAL REPORT OF NON-MAJOR NATURAL GAS COMPANIES

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden and cost per response ⁴	Total annual burden and total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
FERC Form No. 2	92	1	92	1,629 hrs.; \$124,619	149,868 hrs.; \$11,464,902	\$124,619
FERC Form No. 2-A	66	1	66	253.39 hrs.; 19,384	16,724 hrs.; \$1,279,366	\$19,384

¹ The FERC Form No. 2 and Form 2-A are also part of the Forms Refresh effort (started in Docket No. AD15-11), which is a separate activity and not addressed in this Notice.

² See 18 CFR part 201.

³ Burden is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to Title 5 Code of Federal Regulations 1320.3.

⁴ The estimates for cost per response are derived using the following formula: 2017 Average Burden Hours per Response * \$76.50 per Hour = Average Cost per Response. The hourly cost figure of \$76.50 is the average FERC employee wage plus benefits. We assume that respondents earn at a similar rate.

Comments: Comments are invited on: (1) Whether the collections of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and costs of the collections of information, including the validity of the methodologies and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collections; and (4) ways to minimize the burden of the collections of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 13, 2017.

Kimberly D. Bose,
Secretary.

[FR Doc. 2017-15243 Filed 7-19-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP17-808-000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Algonquin Gas Transmission, LLC—AFT-E Answer to Protests, Docket No. RP17-808.
Filed Date: 6/29/17.
Accession Number: 20170629-5210.
Comments Due: 5 p.m. ET 7/11/17.
Docket Numbers: RP17-858-000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Algonquin Gas Transmission, LLC submits tariff filing per 154.204: Negotiated Rates—US Gas to Macquarie 794260 & 794261 to be effective 7/1/2017.
Filed Date: 6/29/17.
Accession Number: 20170629-5034.
Comments Due: 5 p.m. ET 7/11/17.
Docket Numbers: RP17-859-000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: Iroquois Gas Transmission System, L.P. submits tariff filing per 154.204: 06/29/17 Negotiated Rates—ENI Trading & Shipping (RTS) 7825-02 to be effective 7/1/2017.
Filed Date: 6/29/17.
Accession Number: 20170629-5043.
Comments Due: 5 p.m. ET 7/11/17.
Docket Numbers: RP17-861-000.

Applicants: Texas Gas Transmission, LLC.

Description: Texas Gas Transmission, LLC submits tariff filing per 154.204: Cap Rel Neg Rate Agmts (RE Gas 35433, 34955 to BP 36398, 36399) to be effective 7/1/2017.

Filed Date: 6/29/17.

Accession Number: 20170629-5111.

Comments Due: 5 p.m. ET 7/11/17.

Docket Numbers: RP17-862-000.

Applicants: Gulf South Pipeline Company, LP.

Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: Cap Rel Neg Rate Agmts (Atlanta 8438 to various eff 7-1-17) to be effective 7/1/2017.

Filed Date: 6/29/17.

Accession Number: 20170629-5115.

Comments Due: 5 p.m. ET 7/11/17.

Docket Numbers: RP17-863-000.

Applicants: Gulf South Pipeline Company, LP.

Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: Cap Rel Neg Rate Agmt (PH 41455 to Texla 48365) to be effective 7/1/2017.

Filed Date: 6/29/17.

Accession Number: 20170629-5117.

Comments Due: 5 p.m. ET 7/11/17.

Docket Numbers: RP17-864-000.

Applicants: Gulf South Pipeline Company, LP.

Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: Remove Expiring Agmts from the Tariff to be effective 7/1/2017.

Filed Date: 6/29/17.

Accession Number: 20170629-5120.

Comments Due: 5 p.m. ET 7/11/17.

Docket Numbers: RP17-865-000.

Applicants: Texas Eastern Transmission, LP.

Description: Texas Eastern Transmission, LP submits tariff filing per 154.204: Gulf Markets Project—Cameron Non-Conforming K911327 to be effective 8/1/2017.

Filed Date: 6/29/17.

Accession Number: 20170629-5137.

Comments Due: 5 p.m. ET 7/11/17.

Docket Numbers: RP17-866-000.

Applicants: Natural Gas Pipeline Company of America.

Description: Natural Gas Pipeline Company of America LLC submits tariff filing per 154.204: Amendment Negotiated Rate Filing—Mercuria Energy America to be effective 6/29/2017.

Filed Date: 6/29/17.

Accession Number: 20170629-5165.

Comments Due: 5 p.m. ET 7/11/17.

Docket Numbers: RP17-867-000.

Applicants: Texas Eastern Transmission, LP.

Description: Texas Eastern Transmission, LP submits tariff filing per 154.204: Lebanon Extension Negotiated Rates—Gulfport/City of Hamilton to be effective 8/1/2017.

Filed Date: 6/29/17.

Accession Number: 20170629-5177.

Comments Due: 5 p.m. ET 7/11/17.

Docket Numbers: RP17-868-000.

Applicants: Texas Eastern Transmission, LP.

Description: Texas Eastern Transmission, LP submits tariff filing per 154.403: EPC AUG 2017 FILING to be effective 8/1/2017.

Filed Date: 6/29/17.

Accession Number: 20170629-5190.

Comments Due: 5 p.m. ET 7/11/17.

Docket Numbers: RP17-869-000.

Applicants: Texas Eastern Transmission, LP.

Description: Texas Eastern Transmission, LP submits tariff filing per 154.203: Lebanon Extension Tariff Compliance Filing to be effective 8/1/2017.

Filed Date: 6/29/17.

Accession Number: 20170629-5215.

Comments Due: 5 p.m. ET 7/11/17.

Docket Numbers: RP17-870-000.

Applicants: Tennessee Gas Pipeline Company, L.L.C.

Description: Tennessee Gas Pipeline Company, L.L.C. submits tariff filing per 154.204: Volume No. 2—Cameron LNG, L.L.C Non-Conforming FT-A to be effective 8/1/2017.

Filed Date: 6/29/17.

Accession Number: 20170629-5223.

Comments Due: 5 p.m. ET 7/11/17.

Docket Numbers: RP17-879-000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: Measurement Variance/Fuel Use Factors of Iroquois Gas Transmission System, L.P. under RP17-879.

Filed Date: 6/29/17.

Accession Number: 20170629-5257.

Comments Due: 5 p.m. ET 7/11/17.

Docket Numbers: RP88-67-000.

Applicants: Texas Eastern Transmission, LP.

Description: Texas Eastern Transmission, LP submits the audit report and related work papers of the independent auditor respecting the costs & recoveries under the Settlement for Year 26 & Year 27 (partial period), the most recently completed annual period under the S.

Filed Date: 6/29/17.

Accession Number: 20170629-5131.

Comments Due: 5 p.m. ET 7/11/17.

Docket Numbers: RP17-871-000.

Applicants: NGO Transmission, Inc.
Description: NGO Transmission, Inc. submits tariff filing per 154.204:

Ministerial Filing to Update Preliminary Statement to be effective 8/1/2017.

Filed Date: 6/30/17.

Accession Number: 20170630–5060.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–872–000.

Applicants: Texas Gas Transmission, LLC.

Description: Texas Gas Transmission, LLC submits tariff filing per 154.204: Cap Rel Neg Rate Agmt (Jay-Bee 34446 to MacQuarie 36400) to be effective 7/1/2017.

Filed Date: 6/30/17.

Accession Number: 20170630–5063.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–873–000.

Applicants: Texas Gas Transmission, LLC.

Description: Texas Gas Transmission, LLC submits tariff filing per 154.204: Cap Rel Neg Rate Agmt (Gulfport 35446 to BP 36411) to be effective 7/1/2017.

Filed Date: 6/30/17.

Accession Number: 20170630–5064.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–874–000.

Applicants: Rockies Express Pipeline LLC.

Description: Rockies Express Pipeline LLC submits tariff filing per 154.204: Administrative Updates to FERC Gas Tariff to be effective 8/1/2017.

Filed Date: 6/30/17.

Accession Number: 20170630–5081.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–875–000.

Applicants: WBI Energy Transmission, Inc.

Description: WBI Energy Transmission, Inc. submits tariff filing per 154.204: 2017 Section 46 Removal—Nomination Aggregation to be effective 7/31/2017.

Filed Date: 6/30/17.

Accession Number: 20170630–5082.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–876–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: El Paso Natural Gas Company, L.L.C. submits tariff filing per 154.601: Negotiated Rate Agreement Update Filing (WPX July 2017) to be effective 7/1/2017.

Filed Date: 6/30/17.

Accession Number: 20170630–5087.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–877–000.

Applicants: Southern Star Central Gas Pipeline, Inc.

Description: Southern Star Central Gas Pipeline, Inc. submits tariff filing per 154.204: Vol. 2 Negotiated and Non-Conforming Flexible Park & Loan—Tenaska—Amendment to be effective 7/1/2017.

Filed Date: 6/30/17.

Accession Number: 20170630–5093.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–878–000.

Applicants: Transcontinental Gas Pipe Line Company.

Description: Transcontinental Gas Pipe Line Company, LLC submits tariff filing per 154.203: Texas Eastern OFO Penalty Sharing Report (Rate Schedule S–2) to be effective N/A.

Filed Date: 6/30/17.

Accession Number: 20170630–5102.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–880–000.

Applicants: Dauphin Island Gathering Partners.

Description: Dauphin Island Gathering Partners submits tariff filing per 154.204: Negotiated Rate Filing 7–1–2017 to be effective 7/1/2017.

Filed Date: 6/30/17.

Accession Number: 20170630–5141.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–881–000.

Applicants: Transcontinental Gas Pipe Line Company.

Description: Transcontinental Gas Pipe Line Company, LLC submits tariff filing per 154.204: FOS—FT—Proj Facilities Effective Date to be effective 7/31/2017.

Filed Date: 6/30/17.

Accession Number: 20170630–5147.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–882–000.

Applicants: Northern Natural Gas Company.

Description: Northern Natural Gas Company submits tariff filing per 154.204: 20170630 Negotiated Rate to be effective 7/1/2017.

Filed Date: 6/30/17.

Accession Number: 20170630–5196.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–883–000.

Applicants: Transcontinental Gas Pipe Line Company.

Description: Transcontinental Gas Pipe Line Company, LLC submits tariff filing per 154.204: Non-Conforming Agreements_Dalton to be effective 8/1/2017.

Filed Date: 6/30/17.

Accession Number: 20170630–5200.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–884–000.

Applicants: Trailblazer Pipeline Company LLC.

Description: Trailblazer Pipeline Company LLC submits tariff filing per 154.204: Neg Rate 2017–06–30 TIGT, Shell to be effective 7/1/2017.

Filed Date: 6/30/17.

Accession Number: 20170630–5264.

Comments Due: 5 p.m. ET 7/12/17.

Docket Numbers: RP17–889–000.

Applicants: East Tennessee Natural Gas, LLC.

Description: East Tennessee Natural Gas, LLC submits tariff filing per 154.204: PAL FOSA Evergreen Cleanup to be effective 8/6/2017.

Filed Date: 7/6/17.

Accession Number: 20170706–5134.

Comments Due: 5 p.m. ET 7/18/17.

Docket Numbers: RP17–890–000.

Applicants: Alliance Pipeline L.P.

Description: Alliance Pipeline L.P. submits tariff filing per 154.204: Negotiated Rate PAL 2017–07 (Mieco) to be effective 7/7/2017.

Filed Date: 7/6/17.

Accession Number: 20170706–5152.

Comments Due: 5 p.m. ET 7/18/17.

Docket Numbers: RP17–891–000.

Applicants: Dominion Energy Transmission, Inc.

Description: Dominion Energy Transmission, Inc. submits tariff filing per 154.203: DETI—2017 Overrun and Penalty Revenue Distribution to be effective N/A.

Filed Date: 7/7/17.

Accession Number: 20170707–5015.

Comments Due: 5 p.m. ET 7/19/17.

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: July 7, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–15248 Filed 7–19–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket Nos. CP17-470-000; PF15-25-000]

Freeport LNG Development, L.P.; FLNG Liquefaction 4, LLC; Notice of Applications

Take notice that, on June 29, 2017, Freeport LNG Development, L.P. and FLNG Liquefaction 4, LLC, (Freeport LNG) 333 Clay Street, Suite 5050, Houston, TX 77002, filed an application seeking authorization pursuant to section 3(a) of the Natural Gas Act, and parts 153 and 380 of the regulations of the Federal Energy Regulatory Commission (FERC or Commission), to site, construct, and operate additional natural gas liquefaction facilities at Freeport LNG Development, L.P.'s existing Quintana Island Terminal in Brazoria County, Texas, as well as associated pretreatment and pipeline facilities, for the purpose of liquefying domestic natural gas for export to foreign countries.

Any questions regarding the application should be directed to: John Tobola, Freeport LNG Development, L.P., 333 Clay Street, Suite 5050, Houston, TX 77002, (713) 980-2888, JTobola@freeportlng.com; or Lisa M. Tonery, Partner, Orrick, Herrington & Sutcliffe LLP, 51 West 52nd Street, New York, NY 10019-6142, (212) 506-3710, lttonery@orrick.com.

This filing is available for review at the Commission's Washington, DC offices, or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "e-Library" link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, or call toll-free at (866) 208-3676, or for TTY, contact (202) 502-8659.

On June 3, 2015, FERC granted Freeport LNG's request to initiate the pre-filing review process for the Train 4 Project. During the pre-filing process, Freeport LNG participated in meetings with local, state, and federal officials, as well as individual and agency stakeholders, to identify and resolve issues of potential concern at an early juncture. On August 19, 2015, FERC issued a Notice of Intent to prepare an Environmental Assessment for the Project and Request for Comments. Now, as of the filing of the application on June 29, 2017, the pre-filing process for this project has ended. From this time forward, Freeport LNG's

proceeding will be conducted in Docket No. CP17-470-000, as noted in the caption of this Notice.

There are two ways to become involved in the Commission's review of this Project. First, any person wishing to obtain legal status by becoming a party to the proceeding for this project should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 CFR 385.214, 385.211 (2016), by the comment date below. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission, and will receive copies of all documents filed by the applicant and by all other parties. A party must submit filings made with the Commission by mail, hand delivery, or internet, in accordance with Rule 2001 of the Commission's Rules of Practice and Procedure, *id.* 385.2001. A copy must be served on every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the e-filing link. The Commission strongly encourages electronic filings.

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying the requested authorization will be issued.

Comment Date: 5:00 p.m. Eastern Daylight Savings Time August 4, 2017.

Dated: July 14, 2017.

Kimberly D. Bose,
Secretary.

[FR Doc. 2017-15245 Filed 7-19-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. 1494-441]

Grand River Dam Authority: Notice of Application for Temporary Variance and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Temporary variance from the Article 401 reservoir elevation rule curve in order to keep reservoir levels in the Grand Lake O' the Cherokees (Grand Lake) higher than normal for the period of August 16, 2017 through October 31, 2017.

b. *Project No.:* 1494-441.

c. *Date Filed:* July 11, 2017.

d. *Applicant:* Grand River Dam Authority (GRDA).

e. *Name of Project:* Pensacola Hydroelectric Project.

f. *Location:* The project is located on the Grand River in Craig, Delaware, Mayes, and Ottawa Counties, Oklahoma.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)-825(r).

h. *Applicant Contact:* Daniel S. Sullivan, Chief Executive Officer, Grand River Dam Authority, P.O. Box. 409, Vinita, OK 74301; telephone: (918) 256-5545.

i. *FERC Contact:* B. Peter Yarrington, telephone (202) 502-6129, email peter.yarrington@ferc.gov or Jeremy Jessup, telephone (202) 502-6779, email jeremy.jessup@ferc.gov.

j. *Deadline for filing comments, motions to intervene, and protests is 15 days from the issuance date of this notice by the Commission.*

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll

free at 1-866-208-3676, or for TTY, (202) 502-8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail a copy to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please include the project number (P-1494-441) on any comments or motions filed.

k. *Description of Request:* GRDA requests a temporary variance to deviate from the Article 401 reservoir elevation rule curve during the period of August 16, 2017 through October 31, 2017. GRDA says the requested variance would protect safety and property by reducing the risk of vessel groundings in late summer, improve recreation during a peak recreation season, and provide additional water storage to assist in making releases for maintenance of dissolved oxygen concentrations downstream.

This temporary variance request is separate from the application GRDA filed May 6, 2016, which proposes a permanent amendment of the project's Article 401 rule curve requirements. The May 6, 2016 permanent amendment application is currently under Commission review.

Under GRDA's proposed temporary variance, between August 16 and September 15, 2017, GRDA would maintain the reservoir at elevation 743 feet Pensacola Datum (PD), which is up to two feet higher than the current rule curve. Between September 16 and September 30, the elevation would be lowered from 743 to 742 feet PD, which is up to two feet higher than the current rule curve. Between October 1 and October 31, the reservoir would then be maintained at elevation 742 feet PD, which is up to one foot higher than the current rule curve. After October 31, reservoir elevations would follow the current rule curve.

As part of its application, GRDA includes a Storm Adaptive Management Plan that would be followed to address high water conditions upstream and downstream of Grand Lake during major precipitation events in the river basin. GRDA also includes a Drought Adaptive Management Plan that would be followed to determine project operation, including deviations from the rule curve elevations, to allow releases for maintenance of downstream water quality and reliable operation of GRDA's downstream Salina Pumped Storage Project if certain drought conditions occur.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the

Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502-8371. This filing may also be viewed on the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number excluding the last three digits in the docket number field to access the document. 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.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* All filings must (1) bear in all capital letters the title COMMENTS, PROTEST, or MOTION TO INTERVENE as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the amendment application. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an

issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: July 13, 2017.

Kimberly D. Bose,
Secretary.

[FR Doc. 2017-15246 Filed 7-19-17; 8:45 am]

BILLING CODE 6717-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:19 a.m. on Tuesday, July 18, 2017, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision, corporate, and resolution activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Thomas M. Hoenig, seconded by Director Keith A. Noreika (Acting Comptroller of the Currency), concurred in by Director Richard Cordray (Director, Consumer Financial Protection Bureau), and Chairman Martin J. Gruenberg, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: July 18, 2017.

Federal Deposit Insurance Corporation.

Robert E. Feldman,
Executive Secretary.

[FR Doc. 2017-15350 Filed 7-18-17; 4:15 pm]

BILLING CODE 6714-01-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 August 16, 2017.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *QCR Holdings, Inc., Moline, Illinois*; to acquire 100 percent of the voting shares of Guaranty Bank and Trust Company, Cedar Rapids, Iowa.

B. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Southside Bancshares, Inc., Tyler, Texas*; to merge with Diboll State Bancshares, Inc., and thereby indirectly acquire First Bank & Trust East Texas, both of Diboll, Texas.

C. 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. *Simmons First National Corporation, Pine Bluff, Arkansas*; to merge with Southwest Bancorp, Inc.,

Stillwater, Oklahoma, and thereby indirectly acquire Bank SNB, Stillwater, Oklahoma.

Board of Governors of the Federal Reserve System, July 17, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017-15251 Filed 7-19-17; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM**Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB**

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend, without revision, the recordkeeping and disclosure requirements associated with Regulation R.

On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Board may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghribi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452-3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263-4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503 or by fax to (202) 395-6974.

SUPPLEMENTARY INFORMATION: Final approval under OMB delegated authority of the extension for three years, without revision, of the following report:

Report title: Recordkeeping and Disclosure Requirements Associated with Regulation R.

Agency form number: FR 4025.

OMB Control number: 7100-0316.

Frequency: On occasion.

Respondents: Commercial banks and savings associations.

Estimated number of respondents: Section 701 disclosures to customers: 1,500; Section 701 disclosures to brokers: 1,500, Section 723 recordkeeping: 75; Section 741 disclosures to customers: 750.

Estimated average hours per response: Section 701 disclosures to customers: 5 minutes; Section 701 disclosures to brokers: 15 minutes, Section 723 recordkeeping: 15 minutes; Section 741 disclosures to customers: 5 minutes.

Estimated annual burden hours: 75,563.

General description of report:

Sections 701, 723, and 741 contain information collection requirements. Details of the requirements for each section are provided below.

Section 701. Section 701(a)(2)(i) and (b) require banks (or their broker-dealer partners) that utilize the exemption provided in this section to make certain disclosures to high net worth or institutional customers. Specifically, these banks must clearly and conspicuously disclose (i) the name of the broker-dealer and (ii) that the bank employee participates in an incentive compensation program under which the bank employee may receive a fee of more than a nominal amount for referring the customer to the broker-dealer and payment of this fee may be contingent on whether the referral results in a transaction with the broker-dealer.

In addition, one of the conditions of the exemption is that the broker-dealer and the bank have a contractual or other written arrangement containing certain elements, including notification and information requirements. The bank must provide its broker-dealer partner with the name of the bank employee receiving a referral fee under the exemption and certain other identifying information relating to the bank employee.

Section 723. Section 723(e)(1) requires a bank that desires to exclude a trust or fiduciary account in determining its compliance with the chiefly compensated test in section 721, pursuant to a de minimis exclusion 5, to maintain records demonstrating that

the securities transactions conducted by or on behalf of the account were undertaken by the bank in the exercise of its trust or fiduciary responsibilities with respect to the account.

Section 741. Section 741(a)(2)(ii)(A) requires a bank relying on this exemption, which permits banks to effect transactions in the shares of a money market fund, to provide customers with a prospectus for the money market fund securities, not later than the time the customer authorizes the bank to effect the transaction in such securities, if the class or series of securities are not no-load. In situations where a bank effects transactions under the exemption as part of a program for the investment or reinvestment of deposit funds of, or collected by, another bank, the Section permits either the effecting bank or the deposit-taking bank to provide the customer a prospectus for the money market fund securities.

Legal authorization and confidentiality: The Board's Legal Division has determined that section 3(a)(4)(F) of the Exchange Act (15 U.S.C. 78c(a)(4)(F)) authorizes the Board and the SEC to require the information collection. The FR 4025 is required to obtain a benefit because banks wishing to utilize exemptions provided by the rules 701, 723, and 741 are required to comply with the recordkeeping and disclosure requirements. If an institution considers the information to be trade secrets and/or privileged, such information could be withheld from the public under section (b)(4) of the Freedom of Information Act (5 U.S.C. 552(b)(4)). Additionally, to the extent that such information may be contained in an examination report, such information maybe also be withheld from the public under section (b)(8) of the Freedom of Information Act (5 U.S.C. 552 (b)(8)).

Current Actions: On April 3, 2017, the Board published a notice in the **Federal Register** (82 FR 16210) requesting public comment for 60 days on the extension, without revision, of the Recordkeeping and Disclosure Requirements Associated with Regulation R. The comment period for this notice expired on June 2, 2017. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, July 17, 2017.

Ann E. Misback

Secretary of the Board.

[FR Doc. 2017-15263 Filed 7-19-17; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0407]

Pilot Project Program Under the Drug Supply Chain Security Act; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing its intent to establish a pilot project program under the Drug Supply Chain Security Act (the DSCSA Pilot Project Program) to assist in development of the electronic, interoperable system that will identify and trace certain prescription drugs as these are distributed within the United States. Under this program, FDA will work with stakeholders to establish one or more pilot projects to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. Participation in the DSCSA Pilot Project Program will be voluntary and will be open to pharmaceutical distribution supply chain members. FDA will be particularly interested in participation reflecting the diversity of the supply chain, including large and small entities from all industry sectors. This notice describes the proposed DSCSA Pilot Project Program, including proposed instructions for submitting a request to participate. FDA is soliciting comments on the proposed collection of information associated with establishment of the DSCSA Pilot Project Program before submitting the proposed collection to the Office of Management and Budget (OMB) for approval. FDA does not intend to begin the proposed DSCSA Pilot Project Program or accept requests to participate in the program until OMB has approved the proposed collection of information.

DATES: Submit written or electronic comments on this pilot project program by *September 18, 2017*.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before *September 18, 2017*. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of *September 18, 2017*. Comments 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 comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-0407 for "Pilot Project Program under the Drug Supply Chain Security Act; Request for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.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.

FOR FURTHER INFORMATION CONTACT: Daniel Bellingham, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 50, Rm. 4285, Silver Spring, MD 20993-0002, 301-796-3130, DSCSAPilotProjects@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113-54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA added the new sections 581 and 582 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360eee and 360eee-1, respectively). Under section 582(j) of the FD&C Act, FDA is required

to establish one or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain.

FDA will be establishing the DSCSA Pilot Project Program to implement section 582(j) of the FD&C Act. This program will assist the development of the interoperable electronic system to be established by 2023. The new system has the potential to reduce diversion of drugs distributed domestically as well as help reduce the influx of counterfeit drugs from foreign sources. The program will be designed to explore issues related to utilizing the product identifier for product tracing, improving the technical capabilities of the supply chain, identifying the system attributes that are necessary to implement the requirements established under the DSCSA, and any other issues identified by FDA (see section 582(j)(2)(B) of the FD&C Act). Particular program goals include assessing the ability of supply chain members to: Satisfy the requirements of section 582 of the FD&C Act; identify, manage, and prevent the distribution of suspect and illegitimate products as defined in section 581(21) and 581(8) of the FD&C Act, respectively; and demonstrate the electronic, interoperable exchange of product tracing information across the pharmaceutical distribution supply chain, in addition to identifying the system attributes needed to implement the requirements of section 582, particularly the requirement to utilize a product identifier for product tracing and verification purposes. FDA plans to coordinate with stakeholders who reflect the diversity of the pharmaceutical distribution supply chain, including large and small entities from all industry sectors. The pilot project is designed to allow industry to identify and evaluate the most efficient systems for their unique operational systems.

II. The Proposed DSCSA Pilot Project Program

FDA will be seeking pilot project participants from the pharmaceutical distribution supply chain (authorized manufacturers, repackagers, wholesale distributors, and dispensers) and other stakeholders. FDA expects that participants will propose the design and execution of their pilot project in their submission to FDA; however, FDA intends to meet with all pilot project participants to ensure that the learnings from the pilot project(s) will be

complementary in informing the direction of the development of the electronic, interoperable system that will go into effect in 2023. FDA encourages supply chain members to focus their proposed pilot project(s) on the DSCSA requirements related to the interoperable, electronic tracing of products at the *package level*. Specifically, the pilot project(s) should focus on the requirements for package-level tracing and verification that go into effect in 2023. Such pilot projects will be more useful than pilot projects dedicated to lot-level tracing. If there are adequate pilot project submissions, FDA may establish more than one pilot project to accomplish the goals of the DSCSA Pilot Project Program.

A. Products Eligible for Proposed Pilot Projects

Proposed pilot projects may include any prescription drug that is a "product" within the meaning of section 581(13) of the FD&C Act. At its discretion, FDA may also consider proposed pilot projects involving product types outside the scope of section 581(13) of the FD&C Act (*e.g.*, over-the-counter medicines) that could further the objectives of the DSCSA Pilot Project Program. Each package and homogenous case of product that is part of a pilot project should bear a "product identifier" as described in sections 581(14) and 582(a)(9) of the FD&C Act.

B. Potential Issues To Examine and Evaluation Methods To Use in Proposed Pilot Projects

On April 5 and 6, 2016, FDA held a public workshop entitled "Proposed Pilot Project(s) under the Drug Supply Chain Security Act (DSCSA)." This public workshop provided a forum for members of the pharmaceutical distribution supply chain to discuss the design objectives of pilot projects established by FDA under section 582(j) of the FD&C Act. Based on the information gathered at that workshop and from the comments submitted to the public docket for the workshop (Docket No. FDA-2016-N-0407), FDA has identified several potential issues to examine, and evaluation methods to use, in pilot projects established under the DSCSA Pilot Project Program. These potential issues and evaluation methods are summarized in table 1. This table is intended only to assist in the design of potential pilot projects; it does not represent FDA's views or policies regarding the issues described in the table. For ease of reference, the potential issues to examine and evaluation methods have been grouped by focus areas for the pilot projects.

TABLE 1—POTENTIAL ISSUES TO EXAMINE AND EVALUATION METHODS TO USE IN PROPOSED PILOT PROJECTS

Pilot project focus area	Potential issues to examine	Potential evaluation methods
Product Identifier	<ul style="list-style-type: none"> • Processes related to the requirement for manufacturers to affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce. • Methods used to issue and manage serial numbers (e.g., including a contract manufacturer's role if applicable or how a repackager associates its product identifier with the product identifier assigned by the original manufacturer). • Different representations for the product identifier (e.g., different formats of NDC or serial number). 	<ul style="list-style-type: none"> • Impacts of different representations of the product identifier on systems or processes. —Number of errors. —Time to process. —Time to reconcile these differences.
Barcode Quality	<ul style="list-style-type: none"> • Readability of barcode printed or affixed including impact of environmental and human factors. • Application of linear and 2D barcodes on product 	<ul style="list-style-type: none"> • Barcode read error rates. —Number of items unnecessarily quarantined or held up. —Time and resource impacts.
Interoperability	<ul style="list-style-type: none"> • Distinguishing which barcode to read/use and when. • Process and technical challenges due to variety of solutions expected (e.g., type of database used and system architecture for exchanging information among trading partners). • Maintaining the integrity of information contained in the barcode of serialized product throughout the distribution supply chain (e.g., a trading partner goes out of business or one acquires another business). • Different methods for exchanging information (e.g., the use of Electronic Data Interchange, Electronic Product Code Information Services, and other solutions separately). 	<ul style="list-style-type: none"> • For both decentralized and centralized models, time implications. —To investigate suspect and illegitimate products. —For notifications required within the statutory timelines. —Related to scaling up from pilot to full production. • Product tracing information (across multiple partners). —Capability to retrieve the information. —Accuracy of the information (within and between systems).
Data/Database/System Issues.	<ul style="list-style-type: none"> • Data quality from beginning to end of the product lifecycle and vice versa. • System performance when full or partially loaded with data. • Data format or processes for data transfer —Use of technical standards for defining data attributes to enable interoperable transfers. —Methods to handle the “master data” (product-specific data) and transaction data separately to minimize “master data” redundancy. • Integration into individual/company data systems • Control and access to data by trading partners, FDA or other Federal or State officials (data governance). • Ability of the system to record product status (e.g., to indicate expired, illegitimate, in error, quarantined) at all packaging levels. 	<ul style="list-style-type: none"> • Security and access. —Evaluate and document access levels for trading partners. • System Performance and Effectiveness. —Time to access and use product tracing information, once that data is received into a system. —Quality of product tracing information. —Number of breaches to system. —Number of attempts to breach the system that were prevented or minimized. • Data and product flow. —Number of unsuccessful attempts to access data and operational impacts. —Number of system interactions within one, and amongst multiple, trading partners. —Time and resource changes on operations when data and product not moving at same time (e.g., product arrives before data arrives). —Time for location/ownership/status changes to be reflected in the system. —Time of product flow delays and associated costs due to system or data problems.
Aggregation/Disaggregation	<ul style="list-style-type: none"> • Multiple levels of adoption of inference, by different trading partners.. —Impact of inference gaps, changes or errors in data, particularly downstream when searching or examining the data; how can errors be corrected. 	<ul style="list-style-type: none"> • Number of system and product interactions within one, and amongst multiple, trading partners. • Time required to conduct aggregate/disaggregate operations and transactions. • Accuracy of aggregation data (measure error counts). • Time to gather aggregation/disaggregation data for investigations and notifications. • Time to resolve errors in data.
Verification/Notification	<ul style="list-style-type: none"> • Process for investigation of suspect or illegitimate product, including any communication or coordination. —Making and responding to verification requests —Making, responding, and terminating notifications —Responding to requests for information —Testing boundaries of the system 	<ul style="list-style-type: none"> • Response times: Current vs. future process. • Time needed to obtain product tracing information to respond to a request for verification. • Time needed to make, respond to, or terminate a notification. • Time to gather product tracing information to support an investigation for a suspect or illegitimate product, or a recall.

TABLE 1—POTENTIAL ISSUES TO EXAMINE AND EVALUATION METHODS TO USE IN PROPOSED PILOT PROJECTS—
Continued

Pilot project focus area	Potential issues to examine	Potential evaluation methods
Exception Handling/Errors/ Inconsistencies.	<ul style="list-style-type: none"> Identify 'honest errors' (e.g., over/under shipments, clerical errors or aggregation errors). Correcting 'honest errors' 	<ul style="list-style-type: none"> Percentage of items that are successfully verified vs. those that were targeted for verification. Number of connections/queries needed to gather product tracing information in response to a verification or notification request. Percent errors detected: compare exceptions introduced vs. exceptions detected. —Identify the first step in the process where error detected. Number of new or changed processes needed to accomplish DSCSA goals. —Time and resource impacts. 'Honest Errors'. —Number of items unnecessarily quarantined and held up. —Time required to detect and correct errors. —Impact on trading partners to correct errors. Barcode read error rates. —Number of items unnecessarily quarantined or held up. —Time and resource impacts.
Special Scenarios	<ul style="list-style-type: none"> Situations when data and product do not move together. Situations when serialized product are sold and distributed along with non-serialized product. 	<ul style="list-style-type: none"> Error rates for special processes. —Number of items unnecessarily quarantined or held up. —Time and resource impacts. Accuracy of linkage between original manufacturer product identifier and repackager-issued product identifier.

FDA also received input from the workshop participants and in the comments submitted to the public docket on factors that the Agency should take into consideration when establishing pilot projects. These factors described in the comments include the extent to which the pilot projects:

- Represent the mix of products and levels of packaging in the supply chain.
- Include a diverse set of supply chain stakeholders (types and sizes) and transaction types.
- Use adaptive design to make the pilot projects more efficient.
- Target known weaknesses in the supply chain.
- Can be completed in time to provide useful information for trading partners.
- Evaluate human factors that could present implementation challenges.
- Simulate illegitimate products/ transactions to test a process or system.
- Document costs to implement, use, and maintain piloted solutions.

Although the Agency intends to take these factors into consideration when establishing pilot projects, FDA also recognizes that a single pilot project is unlikely to satisfy every factor. Accordingly, FDA may establish a pilot project based on a request to participate in the program that does not satisfy one or more of the factors listed in this document.

C. Proposed Instructions for Submitting a Request To Participate in the Proposed DSCSA Pilot Project Program

Once the DSCSA Pilot Project Program is established, volunteers interested in participating in the DSCSA Pilot Project Program will be able to submit a request to participate by email to a designated FDA email address for the program. For a group of entities that partner to participate in a pilot project, only one submission and one point-of-contact for the proposed pilot project should be provided in the request to participate. Requests to participate may also consider other ideas for a pilot project that are not included in this notice.

D. Proposed Content of the Submission for a Request To Participate in the Proposed DSCSA Pilot Project Program

The following information should be included in the request:

- Contact information for the submitter or point of contact, if different from the submitter (name, mailing address, phone number, email address).
- Names of all partnering entities that would participate in such pilot project (name of company and name of company representative).
- Type(s) of each partnering entity participating in the pilot project (partnering entities include authorized

trading partners or other supply chain stakeholders).

- Number of employees for each partnering entity that would participate in such pilot project.
- Proposed start and finish dates of the pilot project.
- Commitment to start the pilot project within 4 months of receiving a letter of acceptance from FDA.
- Product(s) that will be used in the pilot project.
- Location(s) where pilot project will be performed (facility address).
- Description of the proposed pilot project, including, but not limited to, the goals, objectives, processes that will be studied, and evaluation methods.

E. Initiation and Duration of Proposed Pilot Projects

The selected participants should be ready to start their pilot project within 4 months of receiving a letter of acceptance from FDA into the program. The duration of a pilot project should not exceed 6 months. FDA may consider a pilot project with a later start date or longer duration depending on the proposed goal(s) and objective(s). Each pilot project is expected to be completed within the proposed duration time period. This time period does not include an additional 30-days for completion of a final report (see section G. Proposed Reports).

F. Participation in Proposed Pilot Projects

Prior to launching a pilot project, FDA will hold a design strategy meeting with the selected pilot participant(s) to review the goal(s) and objective(s) for the pilot project and discuss the plans and other pertinent details. The participant(s) will be responsible for conducting their pilot project. A group of entities (members of the pharmaceutical distribution supply chain and other stakeholders, including trade associations) that partner to conduct a pilot project may be considered a single participant for purposes of the DSCSA Pilot Project Program. The partners in any pilot project that is selected into the program will be responsible for the funding and resources necessary to conduct the pilot project, and for determining each partner's role and responsibility in their pilot project. Pilot project participants will also be expected to submit reports on the progress of their pilot projects to FDA (see section G. Proposed Reports). Participants should evaluate their pilot project using the evaluation methods they identified during the pilot project design process.

G. Proposed Reports

Each pilot project is expected to be completed within the proposed duration time period, and participants will be expected to report progress to FDA while the pilot project is being conducted, in addition to a final report within 30 days of completing the pilot project. These reports will provide insight into the systems and process needed to comply with certain DSCSA requirements for enhance drug distribution security.

1. Progress Report(s)

Each pilot project program participant is expected to provide reports on the progress of their pilot project to FDA. The progress reports are intended to capture the ongoing work during the pilot project, including but not limited to, current status or results, changes, challenges, and/or lessons learned. FDA will work with participants to develop an appropriate schedule for the submission of progress reports based on the design and duration of the pilot project. Because the duration of a pilot project should not exceed 6 months, the frequency of progress reports will vary based on the length of the individual pilot project. Pilot projects of relatively shorter duration may result in shorter time intervals between progress reports. For example, FDA may ask for monthly progress reports for a 6-month pilot

project, however for a one-month pilot project, FDA may ask for weekly progress reports.

2. Final Report

Within 30 business days of completing a pilot project, each participant is expected to provide a final report to FDA that captures the description, objectives, methods, evaluation, costs and key findings and lessons learned from the project. Timely completion of pilot project and the final report will support FDA's DSCSA implementation, including the statutory requirements under section 582(j) to consider information from pilot projects in the development of guidances for unit-level tracing and standards for the interoperable data exchange in section 582(h)(3) and (4) of the FD&C Act. FDA may also request that the participants meet with the Agency upon the completion of their pilot project or the final report.

H. Proposed Final DSCSA Pilot Project Program Report

To ensure that all supply chain members benefit from the information generated by the DSCSA Pilot Project Program, FDA intends to make the following information about each of the program's pilot projects available to the public in a final program report: (1) The names and industry sector(s) of the pilot project participant(s); (2) the pilot project's objectives and evaluation methods; (3) the duration of the pilot project; and (4) the key findings and lessons learned from the pilot project. The information related to the DSCSA Pilot Project Program and the final program report will be posted on FDA's Web site.

I. Proposed Recordkeeping

Any records generated by a participant for conducting a pilot project should be maintained as an entity would as in a normal course of business. For participants that involve partnering entities, the partnering entities can decide who is responsible for the records generated by conducting a pilot project. FDA recommends that the progress reports and the final report that participants create and submit to FDA for a pilot project should be maintained for at least 1 year after completion of the pilot project.

J. Initiation of FDA's DSCSA Pilot Project Program

FDA does not intend to begin the proposed DSCSA Pilot Project Program or accept requests to participate in the program until OMB has approved the

proposed collection of information described in this notice.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from OMB for each collection of information that 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** to solicit comment for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with the DSCSA Pilot Project Program, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The estimated burden for the information collection associated with the DSCSA Pilot Project Program consists of the following:

Submitting a request to participate and reporting activities. FDA estimates that no more than 10 respondents (*i.e.*, the submitter or point of contact identified on the request to participate) will submit a request to participate, and that it will take approximately 80 hours to complete a request and submit the request to FDA. FDA estimates that certain respondents will coordinate with partnering entities to submit a request to participate; the burden estimate associated with that coordination follows. FDA estimates that it will select no more than eight participants for the pilot program. The estimated total time for respondents to submit a request to participate in the program is 800 hours. Once the request

to participate is accepted, the submitter is now a participant of the DSCSA Pilot Project Program. FDA estimates that the eight respondents (*i.e.*, participants) will submit an average of five progress reports to FDA. Because the duration of a pilot project should not exceed 6 months, the frequency of progress reports will vary based on the length of the individual pilot project. Pilot projects of relatively shorter duration may result in shorter time intervals between progress reports so that the reports will be sufficient to capture progress while the pilot project is ongoing. FDA estimates that it will take approximately 8 hours to compile and submit each progress report. The estimated total number of hours for submitting progress reports would be 320 hours. After completion of their pilot project, each respondent will provide one final report to FDA. FDA estimates that it will take the eight respondents approximately 40 hours to submit a final report. The estimated total number of hours for submitting the final report is 320 hours. The total hours for the estimated reporting burden are 1,440 hours (table 2).

Recordkeeping activities. Recordkeeping activities include storing and maintaining records related to submitting a request to participate in the program and compiling reports. Respondents can use current record retention capabilities for electronic or paper storage to achieve these activities. FDA estimates that no more than 10 respondents will have recordkeeping activities related to program participation. FDA believes that it will take 0.5 hour/year to ensure that the documents related to submitting a request to participate in the program are

retained properly for a minimum of 1 year after the pilot project is completed (as recommended by FDA). The resulting total to maintain the records related to submitting a request is 5 hours annually. For retaining records related to progress reports and the final report properly for a minimum of 1 year after the pilot project is completed (as recommended by FDA), FDA estimates that it will take approximately 0.5 hour/year. As noted previously, FDA estimates that the eight respondents will submit an average of five progress reports and one final report to FDA. The estimated total for maintaining progress reports and the final report is 20 and 4 hours, respectively. The total recordkeeping burden is estimated to be 29 hours (table 3).

In developing its burden estimate for records associated with the proposed pilot projects, FDA has taken account of existing industry practices for keeping records in the normal course of their business. In particular, FDA is aware of various supply chain stakeholders that have conducted pilot projects over the past few years, including some pilot projects that occurred before the DSCSA was enacted. These pilot projects covered topics related to serialization, movement of product data, aggregation of data, and verification of product identifiers of returned products. Members of the supply chain who conduct pilot projects of their own accord created associated records as a matter of usual and customary business practice. Therefore, the burden estimates for like records associated with the proposed FDA pilot project program are not included in the calculation of the recordkeeping burden (see 5 CFR 1320.3(b)(2)). FDA welcomes

comments on the activities identified for conducting a pilot project that FDA considers to be usual and customary business practice.

Third-party disclosure activities. For those pilot projects that involve a participant composed of partnering entities in the program, FDA is taking into consideration the time that partnering entities will spend coordinating with each other in a pilot project. For the initial request to participate, FDA estimates that eight respondents will work with their respective partnering entities, and the average number of partnering entities will be two. FDA estimates that each respondent will spend 8 hours coordinating with each partnering entity. Thus, for eight respondents with an average of two partnering entities, the estimated total burden for coordinating with partnering entities related to the submission of the request to participate in the program is 128 hours. FDA estimates that seven respondents will need to coordinate with an average of two partnering entities to create progress reports and the final report to submit to FDA. Earlier, FDA estimated that an average of five progress reports will be submitted to FDA per respondent. If a respondent has an average of 2 partners, it will coordinate 10 times with those partners on the progress reports. FDA estimates that for each progress report, it will take 4 hours to coordinate with each partner, resulting in a total of 280 hours. FDA estimates that for each final report, it will take approximately 20 hours to coordinate with each partner, resulting in a total of 280 hours. The total estimation for third-party disclosure burden is 688 hours (table 4).

TABLE 2—ESTIMATED REPORTING BURDEN ¹

DSCSA pilot project program	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total hours
Requests to participate	10	1	10	80	800
Progress reports	8	5	40	8	320
Final report to FDA	8	1	8	40	320
Total					1,440

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—RECORDKEEPING BURDEN ¹

DSCSA Pilot project program	Number of recordkeepers	Number of records per recordkeeper	Total records	Hours per record	Total hours
Records related to requests to participate	10	1	10	0.5 (30 minutes) ...	5
Records related to progress reports	8	5	40	0.5 (30 minutes) ...	20
Records related to the final report to FDA	8	1	8	0.5 (30 minutes) ...	4

TABLE 3—RECORDKEEPING BURDEN ¹—Continued

DSCSA Pilot project program	Number of recordkeepers	Number of records per recordkeeper	Total records	Hours per record	Total hours
Total	29

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—THIRD-PARTY DISCLOSURE BURDEN ¹

DSCSA pilot project program	Number of respondents	Number of disclosures per respondent	Total disclosures	Hours per disclosure	Total hours
Coordination with partnering entities related to requests to participate	8	2	16	8	128
Coordination with partnering entities related to progress reports	7	10	70	4	280
Coordination with partnering entities related to final reports	7	2	14	20	280
Total	688

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 14, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.
 [FR Doc. 2017–15203 Filed 7–19–17; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–3068]

Patient-Focused Drug Development for Hereditary Angioedema; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting and an opportunity for public comment on “Patient-Focused Drug Development for Hereditary Angioedema.” Patient-Focused Drug Development is part of FDA’s performance commitment under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patients’ perspectives on the impact of hereditary angioedema (HAE) on daily life. FDA also is seeking patients’ views on treatment approaches for HAE.

DATES: The public meeting will be held on September 25, 2017, from 9 a.m. to 3 p.m. Registration to attend must be received by August 10, 2017. Submit

either electronic or written comments on the public meeting by November 20, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 20, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 20, 2017. Comments 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 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. Since your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2017–N–3068 for “Patient-Focused Drug

Development for Hereditary Angioedema.” Received comments, 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.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.

FDA will post the agenda approximately 5 days before the meeting at <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm542319.htm>.

FOR FURTHER INFORMATION CONTACT:

Barbara Kass, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1125,

Silver Spring, MD 20993, 240–402–6887; or Loni Warren Henderson, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1118, Silver Spring, MD 20993, 240–402–8180, PatientFocused_CBER@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected HAE as the focus of a public meeting under the Patient-Focused Drug Development initiative. This initiative involves obtaining a better understanding of patients’ perspectives on the challenges posed by HAE and the impact of current therapies for this condition. The Patient-Focused Drug Development initiative is being conducted to fulfill FDA performance commitments that are part of the PDUFA reauthorization under Title I of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144). The full set of performance commitments is available on the FDA Web site at <http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf>.

FDA committed to obtaining the patient perspective on 20 disease areas during the course of PDUFA V. For each disease area, the Agency is conducting a public meeting to discuss the disease and its impact on patients’ daily lives, the types of treatment benefits that matter most to patients, and patients’ perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On April 11, 2013, FDA published a notice in the **Federal Register** (78 FR 21613), announcing the disease areas for meetings in fiscal years (FYs) 2013–2015, the first 3 years of the 5-year PDUFA V time frame. The Agency used several criteria outlined in that notice to develop the list of disease areas. FDA obtained public comment on the Agency’s proposed criteria and potential disease areas through a public docket and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. FDA initiated a second public process for determining the disease areas for FY 2016–2017 and published a notice in the **Federal Register** on July 2, 2015 (80 FR 38216), announcing the selection of eight

disease areas. More information, including the list of disease areas and a general schedule of meetings, is posted at <https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm347317.htm>.

II. Purpose and Scope of the Meeting

As part of the Patient-Focused Drug Development, FDA will obtain input on the symptoms and other aspects of the disease that matter most to patients with HAE. FDA also intends to seek patients’ perspectives on current approaches to treating HAE. FDA expects that this information will come directly from patients, caregivers, and patient advocates.

HAE is a rare genetic disorder that affects less than 200,000 individuals in the United States. It is associated with episodic recurrent attacks of swelling of the body caused by abnormalities in a protein called C1-Esterase Inhibitor. Most cases occur because there is either not enough of the protein or because the protein does not work normally to help prevent swelling of the body.

In individuals with HAE, the swelling attacks may involve various areas of the body, including the gastrointestinal tract, arms, legs, face, or throat and larynx (voice box). Symptoms of this condition often begin during childhood but may also appear in adulthood. The swelling episodes are usually self-limited; may or may not be associated with any triggering factors; and in severe cases involving the larynx, may be life-threatening. If not recognized early and left untreated, swelling of the larynx, called laryngeal edema, may acutely restrict airflow to the lungs and could result in death. Gastrointestinal tract swellings are often associated with nausea, vomiting, and abdominal pain, which can be severe and require hospitalization. Several FDA-approved therapies affecting different biological mechanisms are available to treat or prevent acute attacks of HAE.

The questions that will be asked of patients and patient representatives at the meeting are listed in this section and organized by topic. The two main topics for discussion are: (1) Symptoms and impact on activities of daily life that matter most to patients; and (2) perspectives on current approaches to treatment. For each topic, a brief patient/caregiver panel discussion will begin the dialogue. This will be followed by a facilitated discussion, inviting comments from other patient and caregiver participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through electronic or written comments,

which can be submitted to the Dockets Management Staff (see **ADDRESSES**). For context, please indicate if you are commenting as a patient with HAE or on behalf of a child or loved one.

Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

(1) Of all of the symptoms that you experience because of your condition, which one of these symptoms has the most significant impact on your life? Examples may include nausea, vomiting, abdominal pain, swelling of extremities, facial swelling, tongue swelling, hoarseness or loss of voice, shortness of breath, and difficulty urinating.

(2) Are there specific activities that are important to you that you cannot do at all or as well as you would like because of your condition? Please describe, using specific examples. Examples may include: Participating in physical activities; and attending work or school and family or social activities, during or between attacks.

(3) How have your condition and its symptoms changed over time?

(4) What worries you most about your condition?

Topic 2: Patients' Perspectives on Current Approaches to Treatment

(1) What are you currently doing to treat your condition and its symptoms?

- What, if anything, are you doing to prevent acute HAE attacks? Examples may include treatments with prescription medicines; over-the-counter products; and other therapies, including non-drug therapies.

- What, if anything, do you self-administer for acute HAE attacks?
- If you give yourself medication for acute HAE attacks, which types of attacks, with respect to body location(s), are you comfortable treating yourself?

- What treatment has your health professional used for your acute HAE attacks? Examples may include prescription medicines; over-the-counter products; and other therapies, including non-drug therapies.

(2) How well do these treatments work for you?

(3) What are the most significant disadvantages or complications of your current treatments, and how do they affect your daily life?

(4) How has your treatment regimen changed over time and why?

(5) What aspects of your condition are not improved by your current treatment regimen?

(6) What treatment has had the most positive impact on your quality of life?

(7) Short of a complete cure for your condition, what specific things would

you look for in an ideal treatment for your condition?

(8) If you had the opportunity to consider participating in a clinical trial studying experimental treatments, what things would you consider when deciding whether or not to participate?

III. Meeting Attendance and Participation

Registration: If you wish to attend this meeting, visit <https://www.eventbrite.com/e/patient-focused-drug-development-for-hereditary-angioedema-public-meeting-tickets-32300298061>. Persons interested in attending this public meeting must register by August 10, 2017. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations due to a disability, please contact Barbara Kass or Loni Warren Henderson (see **FOR FURTHER INFORMATION CONTACT**) no later than September 18, 2017.

Requests for Oral Presentations: Patients and patient representatives who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients and patient representatives also must send to PatientFocused_CBER@fda.hhs.gov a brief summary of responses to the topic questions by August 3, 2017. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient representatives who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Transcripts: Please be advised that, as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the Internet at <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm542320.htm>.

Dated: July 13, 2017.

Anna K. Abram,

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

[FR Doc. 2017-15202 Filed 7-19-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-3857]

Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act; Public Meetings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meetings; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing three public meetings entitled “Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act (DSCSA).” These public meetings are intended to provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to discuss with FDA, and provide input on, strategies and issues related to the enhanced drug distribution security provisions of the DSCSA.

DATES: The public meetings will be held on: August 23, 2017, from 9 a.m. to 4 p.m.; December 5 and 6, 2017, from 9 a.m. to 4 p.m.; and February 28, 2018, from 9 a.m. to 4 p.m.

ADDRESSES: The public meetings will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503A, Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Comments: To permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public meeting topics. You may submit comments as follows. Please note that the deadlines for submitting either electronic or written comments are 30 days after the meeting to which the comments relate. Comments 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. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of the specified date. See the **SUPPLEMENTARY INFORMATION** section for registration dates and for the deadlines for submitting electronic or written comments related to these public meetings (table 1).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-3857 for "Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act; Public Meetings; Request for Comments." Received comments, 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.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.

FOR FURTHER INFORMATION CONTACT:

Daniel Bellingham, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3130, CDERODSIRPublicMeetings@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II, Pub. L. 113-54) was signed into

law. The DSCSA outlines critical steps to build an electronic, interoperable system by 2023 to identify and trace certain prescription drugs as they are distributed within the United States. This system will enhance FDA's ability to protect U.S. consumers from exposure to drugs that may be counterfeit, diverted, stolen, intentionally adulterated, or otherwise harmful by improving the detection and removal of potentially dangerous drugs from the drug supply chain. Section 582(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee-1(i)), which was added by the DSCSA, directs FDA to hold public meetings to enhance the safety and security of the pharmaceutical distribution supply chain and provide opportunities for comment from stakeholders.

II. Purpose of the Public Meetings

FDA will hold public meetings on August 23, 2017, December 5 and 6, 2017, and February 28, 2018, on enhanced drug distribution security. The purpose of these public meetings is to provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to discuss with FDA, and provide input on, strategies and issues related to the enhanced drug distribution security provisions of the DSCSA. These public meetings will focus on the following topics for discussion:

- What supply chain security should look like in 2023
- What is needed for enhanced drug distribution security
- What is needed for electronic interoperability
- Standards for product tracing
- Data architecture options for an electronic interoperable system
- The management and maintenance of product tracing data
- The use of aggregation and inference for enhanced product tracing and verification
- Building capacity for a unit-level system for product tracing and verification

FDA may include additional discussion topics. Materials for each public meeting will be provided on FDA's Web site at <https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm> 10 days before each public meeting.

III. Registration for the Public Meetings

To request registration for the public meetings, provide your information including name, company or organization, address, telephone number, and email address to FDA at

<https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm>. Registration requests for each meeting should be received during the time periods specified in table 1. FDA is limiting attendance due to restricted space. In addition, FDA may limit the number of participants from each organization based on space limitations. FDA recommends that each organization determine who should register for the public meeting to

represent his/her organization. This will help ensure that the meeting will have broad and varied representation, including across the pharmaceutical distribution supply chain. Registrants will receive confirmation of participation for their chosen meeting from FDA within 14 days of the date of each meeting. There is no registration fee for the public meetings. There will be no onsite registration. If registration

reaches maximum capacity, FDA will post a notice closing registration for the meeting on FDA's Web site at <https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm>. If you need special accommodations due to a disability, please contact Daniel Bellingham (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the public meeting.

TABLE 1—PUBLIC MEETING INFORMATION

Public meeting	Topics	Date/Time	Relevant section of this document or electronic address
# 1	<ul style="list-style-type: none"> Supply chain security in 2023 Enhanced drug distribution security needs. Advance registration	August 23, 2017, 9 a.m. to 4 p.m. by July 31, 2017	Online registration only at https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm . No onsite registration. See "Comments". See FOR FURTHER INFORMATION CONTACT .
	Comment period closes	September 22, 2017	
# 2	<ul style="list-style-type: none"> Electronic interoperability Standards for data exchange Data architecture Aggregation and inference. Advance registration	December 5–6, 2017, 9 a.m. to 4 p.m. October 2–27, 2017	Online registration only at https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm . No onsite registration. See "Comments". See FOR FURTHER INFORMATION CONTACT .
	Comment period closes	January 5, 2018	
# 3	<ul style="list-style-type: none"> Further refinement of enhanced drug distribution security needs. Building capacity for a unit-level system. Advance registration	February 28, 2018, 9 a.m. to 4 p.m. January 2–26, 2018	Online registration only at https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm . No onsite registration. See "Comments". See FOR FURTHER INFORMATION CONTACT .
	Comment period closes	March 30, 2018	

IV. Webcasting of the Public Meeting

Portions of each public meeting will be recorded and webcast on the day of the meeting. Information for how to access the webcast will be available at <https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm> within 7 days prior to each public meeting. The webcast will be conducted in listening mode only.

Dated: July 14, 2017.

Anna K. Abram,

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

[FR Doc. 2017–15204 Filed 7–19–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0597]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the

Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 21, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0620. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance. Index of Legally Marketed Unapproved New Animal Drugs for Minor Species—21 CFR part 516 OMB Control Number 0910-0620—Extension

The Minor Use and Minor Species Animal Health Act of 2004 (the MUMS Act) (Pub. L. 108-282) added section 572 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ccc-1), which authorizes FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats). In enacting the MUMS Act, Congress sought to encourage the development of these

new animal drugs. Congress recognized that the markets for drugs intended to treat these species, diseases, or conditions are so small that there are often insufficient economic incentives to motivate drug companies to develop data to support approvals. Further, Congress recognized that some minor species populations are too small or their management systems too diverse to make it practical to conduct traditional studies to demonstrate safety and effectiveness of animal drugs for such uses. As a result of these limitations, drug companies have generally not been willing or able to collect data to support legal marketing of drugs for these species, diseases, or conditions. Consequently, Congress enacted the MUMS Act to provide incentives to develop new animal drugs for minor species, while still ensuring appropriate safeguards for animal and human health. Section 572 of the FD&C Act provides for a public index listing of legally marketed unapproved new animal drugs for minor species. FDA regulations in part 516 (21 CFR part 516) specify, among other things, the criteria and procedures for requesting eligibility for indexing and for

requesting addition to the index, as well as the annual reporting requirements for index holders. The administrative procedures and criteria for indexing a new animal drug for use in a minor species are set forth in 21 CFR 516.111 through 516.171. Section 516.165 sets forth the annual reporting requirements for index holders. FDA needs the information to determine: (1) The eligibility of a new animal drug for indexing; (2) that a qualified expert panel proposed to review certain information regarding the new animal drug meets the selection criteria listed in the regulations; (3) whether the Agency agrees with the recommendation of a qualified expert panel that a drug be added to the index; and (4) whether there may be grounds for removing a drug from the index.

In the **Federal Register** of December 21, 2016 (81 FR 93689), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment, which was outside the scope of the comment requests in the notice.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
516.119—requires a foreign drug company to submit and update the name and address of a permanent U.S. resident agent	2	1	2	1	2
516.121—written request for a meeting with FDA to discuss the requirements for indexing a new animal drug	30	2	60	4	240
516.123—written request for an informal conference and a requestor's written response to an FDA initial decision denying a request	3	1	3	8	24
516.125—correspondence and information associated with investigational use of new animal drugs intended for indexing	2	3	6	20	120
516.129—content and format of a request for determination of eligibility for indexing	30	2	60	20	1,200
516.141—information to be submitted to FDA by a requestor seeking to establish a qualified expert panel	20	1	20	16	320
516.143—content and format of the written report of the qualified expert panel	20	1	20	120	2,400
516.145—content and format of a request for addition to the Index	20	1	20	20	400
516.161—content and format of a request for modification of an indexed drug	1	1	1	4	4
516.163—information to be contained in a request to FDA to transfer ownership of a drug's index file to another person	1	1	1	2	2
516.165—requires drug experience reports and distributor statements to be submitted to FDA	10	2	20	8	160
Total					4,872

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
516.141—requires the qualified expert panel leader to maintain a copy of the written report and all notes or minutes relating to panel deliberations that are submitted to the requestor for 2 years after the report is submitted	30	2	60	*.5	30
516.165—requires the holder of an indexed drug to maintain records of all information pertinent to the safety or effectiveness of the indexed drug, from foreign and domestic sources	10	2	20	1	20
Total					50

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

*30 minutes.

We based our estimates in tables 1 and 2 on our experience with the MUMS indexing program and the requests for eligibility for indexing and for addition to the index, as well as the periodic drug experience reports submitted during the past 3 years. The burden has not changed since the last OMB approval.

Dated: July 13, 2017.

Anna K. Abram,

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

[FR Doc. 2017–15206 Filed 7–19–17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2017–0002; Internal Agency Docket No. FEMA–B–1724]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency

(FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before October 18, 2017.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

You may submit comments, identified by Docket No. FEMA–B–1724, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) patrick.sacbibit@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after

FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at http://floodsrp.org/pdfs/srp_fact_sheet.pdf.

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each

community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online

through the FEMA Map Service Center at www.msc.fema.gov for comparison. (Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Roy E. Wright,
Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Watershed-based studies:

Community	Community map repository address
Lower Sabine Watershed	
Maps Available for Inspection Online at: http://www.fema.gov/preliminaryfloodhazarddata	
Newton County, Texas and Incorporated Areas	
City of Newton	City Hall, 101 West North Street, Newton, TX 75966.
Unincorporated Areas of Newton County	Newton County Court House, 110 Court Street, Newton, TX 75966.

II. Non-watershed-based studies:

Community	Community map repository address
Lafayette Parish, Louisiana and Incorporated Areas	
Maps Available for Inspection Online at: http://www.fema.gov/preliminaryfloodhazarddata	
Project: 16-06-3197S Preliminary Date: February 15, 2017	
City of Broussard	City Hall, 310 East Main Street, Broussard, LA 70518.
City of Lafayette	Department of Planning, Zoning and Development, 220 West Willow Street, Building B, Lafayette, LA 70501.
City of Youngsville	City Hall, 305 Iberia Street, Youngsville, LA 70592.
Unincorporated Areas of Lafayette Parish	Department of Planning, Zoning and Development, 220 West Willow Street, Building B, Lafayette, LA 70501.

[FR Doc. 2017-15179 Filed 7-19-17; 8:45 am]
BILLING CODE 9110-12-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR957000.L63100000.
HD0000.17XL1109AF.HAG 17-00]

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 August 21, 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. 22 S., R. 24 E., accepted April 7, 2017
- T. 30 S., R. 2 W., accepted April 18, 2017
- T. 26 S., R. 2 W., accepted April 18, 2017
- T. 38 S., R. 4 W., accepted May 9, 2017
- T. 33 S., R. 2 E., accepted May 9, 2017
- T. 20 S., R. 9 W., accepted May 9, 2017
- T. 39 S., R. 2 W., accepted May 9, 2017
- T. 15 S., R. 1 W., accepted May 9, 2017
- T. 15 S., R. 11 E., accepted May 9, 2017
- T. 31 S., R. 12 W., accepted May 9, 2017
- T. 21 S., R. 29 E., accepted May 18, 2017
- T. 30 S., R. 5 W., accepted May 18, 2017
- T. 28 S., R. 11 W., accepted May 18, 2017
- T. 20 S., R. 4 W., accepted May 31, 2017
- T. 20 S., R. 3 W., accepted May 31, 2017
- T. 30 S., R. 3 W., accepted June 16, 2017
- T. 21 S., R. 4 W., accepted June 16, 2017
- T. 31 S., R. 4 W., accepted June 23, 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 Chief Cadastral Surveyor 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 Chief Cadastral Surveyor 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 Chief Cadastral Surveyor 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.

F. David Radford,

*Acting Chief Cadastral Surveyor of Oregon/
Washington.*

[FR Doc. 2017-15215 Filed 7-19-17; 8:45 am]

BILLING CODE 4310-33-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-CR-23588; PPWOCRADIO,
PCU00RP14.R50000]

Agency Information Collection

Activities: Archeology Permits and Reports

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service, NPS) have sent an Information Collection Request (ICR) to OMB for review and approval that includes establishment of a common form. The

NPS will be the “host agency” of the common form. Other agencies that may use the information collection are listed below. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This information collection is scheduled to expire on July 31, 2017. We 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. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before August 21, 2017.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or OIRA_Submission@omb.eop.gov (email). Please provide a copy of your comments to Tim Goddard, Information Collection Clearance Officer, National Park Service, 12201 Sunrise Valley Drive, MS–242, Reston, VA 20192 (mail); or tim_goddard@nps.gov (email). Please include “1024–0037” in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Karen Mudar at Karen_Mudar@nps.gov (email) or 202–354–2103 (telephone). You may review the ICR online at <http://www.reginfo.gov>. Follow the instructions to review Department of the Interior collections under review by OMB.

I. Abstract

Section 4 of the Archeological Resources Protection Act (ARPA) of 1979 (16 U.S.C 470cc), and Section 3 of the Antiquities Act (AA) of 1906 (54 U.S.C. 320301–320303), authorize any individual or institution to apply to Federal land managing agencies to scientifically excavate or remove archeological resources from public or Indian lands. Archeological investigations that require permits include excavation, shovel-testing, coring, pedestrian survey (with and without removal of artifacts), underwater archeology, photogrammetry, and rock art documentation. Individuals, academic and scientific institutions, museums, and businesses that propose to conduct archeological field investigations must obtain a permit before the project may begin.

To apply for a permit, applicants submit DI Form 1926 (Application for Permit for Archeological Investigations).

In general, an application includes, but is not limited to, the following information:

- Statement of Work.
- Statement of Applicant’s Capabilities.
- Statement of Applicant’s Past Performance.
- Curriculum vitae for Principal Investigator(s) and Project Director(s).
- Written consent by State or tribal authorities to undertake the activity on State or tribal lands that are managed by Federal land managing agencies, if required by the State or tribe.
- Curation Authorization.
- Detailed Schedule of All Project Activities.

Persons receiving a permit must submit a final report upon completion of the field component of the research project.

Potential and actual other agencies, besides NPS, that may use the common form and this collection include:

- U.S. Department of Agriculture
- U.S. Forest Service
- U.S. Department of Commerce
- National Oceanic and Atmospheric Administration
- U.S. Department of Defense
- Department of the Air Force
- Department of the Army
- U.S. Army Corps of Engineers
- Department of the Navy
- United States Marine Corps
- U.S. Coast Guard
- Army National Guard
- U.S. Department of Energy
- U.S. Department of Health and Human Services
- U.S. Department of Homeland Security
- Bureau of Customs and Border Protection
- Federal Emergency Management Agency
- U.S. Department of Housing and Urban Development
- U.S. Department of the Interior
- Bureau of Indian Affairs
- Bureau of Land Management
- Bureau of Reclamation
- U.S. Fish and Wildlife Service
- Bureau of Ocean Energy Management
- Office of Surface Mining
- U.S. Geological Survey
- U.S. Department of Justice
- Bureau of Prisons
- U.S. Department of Transportation
- Federal Aviation Administration
- Federal Highway Administration
- Federal Railroad Administration
- Federal Transit Administration
- U.S. Department of Veterans Affairs
- Other Agencies
- General Services Administration
- National Aeronautics and Space Administration
- Tennessee Valley Authority

The Presidio Trust of San Francisco
II. Data
 OMB Control Number: 1024-0037.
 Title: Archeology Permit Applications and Reports, 43 CFR parts 3 and 7.

Form Number(s): DI Form 1926.
 Type of Request: Extension of a currently approved collection.
 Description of Respondents: Individuals or organizations wishing to

excavate or remove archeological resources from public or Indian lands.
 Respondent's Obligation: Required to obtain or retain a benefit.
 Number of Respondents: 100.
 Frequency of Collection: On occasion.

Activity	Total annual responses	Completion time per response (hours)	Total annual burden hours	Total dollar value of annual burden hours (\$50.78 per hour)
Form DI-1926, "Application for Permit for Archeological Investigations":				
Private	43	2.5	* 108	\$5,484.24
Individual	1	2.5	* 3	152.34
Government	6	2.5	15	761.70
Reports				
Private	43	1.0	43	2,183.54
Individual	1	1.0	1	50.78
Government	6	1.0	6	304.68
Totals	100	* 176	8,937.28

* Rounded by ROCIS.

Estimated Annual Nonhour Burden Cost: None.

III. Comments

On December 19, 2016, we published a **Federal Register** Notice (81 FR 91945) informing the public of our intent to ask OMB to renew approval for this information collection. We solicited comments for a period of 60 days, ending on February 17, 2017. We did not receive any comments in response to this notice.

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. 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 OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Authority: The authorities for this action are the National Park Service Organic Act of

1916 (54 U.S.C. 100101 *et seq.*; P.L. 113-287) and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Timothy Goddard,
 Information Collection Clearance Officer,
 National Park Service.
 [FR Doc. 2017-15227 Filed 7-19-17; 8:45 am]
BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service
[NPS-WASO-NAGPRA-23486;
PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects in the Possession of the U.S. Department of the Interior, National Park Service, Lake Meredith National Recreation Area, Fritch, TX; Correction

AGENCY: National Park Service, Interior.
ACTION: Notice; correction.

SUMMARY: The U.S. Department of the Interior, National Park Service, Lake Meredith National Recreation Area, has corrected an inventory of human remains and associated funerary objects published in a Notice of Inventory Completion in the **Federal Register** on June 18, 2001. This notice corrects the minimum number of individuals and number of associated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to Lake Meredith National

Recreation Area. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Lake Meredith National Recreation Area at the address in this notice by August 21, 2017.

ADDRESSES: Robert Maguire, Superintendent, Lake Meredith National Recreation Area, P.O. Box 1460, Fritch, TX 79036, telephone (806) 857-3151, email *robert_maguire@nps.gov*.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the correction of an inventory of human remains and associated funerary objects under the control of the U.S. Department of the Interior, National Park Service, Lake Meredith National Recreation Area, Fritch, TX. The human remains and associated funerary objects were removed from sites in Potter County, TX.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the Superintendent, Lake Meredith National Recreation Area.

This notice corrects the minimum number of individuals and number of associated funerary objects published in a Notice of Inventory Completion in the **Federal Register** (66 FR 32845–32846, June 18, 2001). A re-evaluation of the inventory resulted in an increase in the minimum number of individuals removed from the Footprint site. The total number of associated funerary objects has been found to be incorrectly calculated, though all funerary objects are accounted for. Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (66 FR 32845, June 18, 2001), column 2, paragraph 2, sentence 1 is corrected by substituting the following sentence:

In 1964, human remains representing a minimum of 43 individuals were recovered during legally-authorized excavation by F.E. Green of Texas Tech University at the Footprint site, then under the management of the U.S. Department of the Interior, Bureau of Reclamation.

In the **Federal Register** (66 FR 32845, June 18, 2001), column 3, paragraph 2, sentences 1 and 2 are corrected by substituting the following sentences:

Based on the above-mentioned information, the superintendent of Lake Meredith National Recreation Area has determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of 49 individuals of Native American ancestry. The superintendent of Lake Meredith National Recreation Area also has determined that, pursuant to 43 CFR 10.2 (d)(2), the 347 objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as a part of a death rite or ceremony.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Robert Maguire, Superintendent, Lake Meredith National Recreation Area, P.O. Box 1460, Fritch, TX 79036, telephone (806) 857-3151, email robert_maguire@nps.gov, by August 21, 2017. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Kiowa Indian Tribe of Oklahoma, and the Wichita & Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma, may proceed.

Lake Meredith National Recreation Area is responsible for notifying the

Caddo Nation of Oklahoma; Cheyenne and Arapaho Tribes, Oklahoma (previously listed as the Cheyenne-Arapaho Tribes of Oklahoma); Comanche Nation, Oklahoma; Kiowa Indian Tribe of Oklahoma; Pawnee Nation of Oklahoma; Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma; and the Cohuhtecan Nation, an Indian group that is not federally recognized, that this notice has been published.

Dated: May 30, 2017.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2017-15217 Filed 7-19-17; 8:45 am]

BILLING CODE 4312-52-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-989]

Certain Automated Teller Machines, ATM Modules, Components Thereof, and Products Containing the Same Commission's Final Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and Cease and Desist Orders; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 in this investigation and has issued a limited exclusion order prohibiting importation of infringing automated teller machines, ATM modules, components thereof, and products containing the same, as well as issued cease and desist orders directed to Diebold Nixdorf, Incorporated and Diebold Self-Service Systems both of North Canton, Ohio. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT:

Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202-205-3042. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<https://www.usitc.gov>). The public record for this investigation

may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on March 14, 2016, based on a complaint filed by Nautilus Hyosung Inc. of Seoul, Republic of Korea and Nautilus Hyosung America Inc. of Irving, Texas (collectively, "Nautilus"). 81 FR 13149 (Mar. 14, 2016). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain automated teller machines, ATM modules, components thereof, and products containing the same by reason of infringement of one or more of claims 1-3 and 5 of U.S. Patent No. 7,891,551 ("the '551 patent"); claims 1 and 6 of U.S. Patent No. 7,950,655 ("the '655 patent"); claims 1-4, 6, and 7 of U.S. Patent No. 8,152,165 ("the '165 patent"); and claims 1-3, 6, 8, and 9 of U.S. Patent No. 8,523,235 ("the '235 patent"). *Id.* The notice of investigation named the following respondents: Diebold, Incorporated of North Canton, Ohio and Diebold Self-Service Systems of North Canton, Ohio (collectively, "Diebold"). *Id.* The Office of Unfair Import Investigations is not a party to the investigation.

On June 30, 2016, the ALJ granted a motion by Nautilus to terminate the investigation as to all asserted claims of the '551 patent and the '165 patent. *See* Order No. 11 (June 30, 2016). The Commission determined not to review Order No. 11. *See* Notice of non-review (July 27, 2016).

On July 21, 2016, the ALJ granted a motion by Nautilus to terminate the investigation as to all asserted claims of the '655 patent. *See* Order No. 17 (July 21, 2016). The Commission determined not to review Order No. 17. *See* Notice of non-review (Aug. 16, 2016).

On February 6, 2017, the ALJ granted a motion to amend the complaint and notice of investigation to reflect a corporate name change of Diebold, Incorporated to Diebold Nixdorf, Incorporated. *See* Order No. 32 (Feb. 6, 2017). The Commission determined not to review Order No. 32.

On March 13, 2017, the ALJ issued his final ID, finding a violation of section 337 by Diebold in connection with claims 1-3, 6, 8, and 9 of the '235 patent. Specifically, the ID finds that the

Commission has subject matter jurisdiction, *in rem* jurisdiction over the accused products, and *in personam* jurisdiction over Diebold. ID at 9, 104–107. The ID finds that Nautilus satisfied the importation requirement of section 337 (19 U.S.C. 1337(a)(1)(B)). *Id.* The ID finds that the accused products directly infringe asserted claims 1–3, 6, 8, and 9 of the '235 patent, and that Diebold contributorily infringes those claims. *See* ID at 111–160, 163–172. The ID, however, finds that Diebold failed to establish that the asserted claims of the '235 patent are invalid for indefiniteness, anticipation, or obviousness. ID at 232–311. Finally, the ID finds that Nautilus established the existence of a domestic industry that practices the asserted patent under 19 U.S.C. 1337(a)(2). *See* ID at 212.

The ALJ's recommended determination on remedy and bonding issued concurrently with the final ID. RD at 330–40. The ALJ recommends that in the event the Commission finds a violation of section 337, the Commission should issue a limited exclusion order prohibiting the importation of Diebold's automated teller machines, ATM modules, components thereof, and products containing the same that infringe the asserted claims of the '235 patent. RD at 335. The ALJ also recommends issuance of cease and desist orders based on the presence of Diebold's commercially significant inventory in the United States. RD at 338. With respect to the amount of bond that should be posted during the period of Presidential review, the ALJ recommends that the Commission set a bond in the amount of zero (*i.e.*, no bond) during the period of Presidential review because Nautilus "did not attempt any type of price comparison." RD at 341.

On March 27, 2017, Diebold filed a petition for review of the ID. On April 4, 2017, Nautilus filed a response to Diebold's petition for review.

On May 15, 2017, the Commission determined to review the final ID in part and requested the parties to brief certain issues. *See* 82 FR 23064–66 (May 19, 2017). On May 25, 2017, the parties filed submissions to the Commission's question and on remedy, the public interest, and bonding. On June 1, 2017, the parties filed reply submissions.

Having examined the record of this investigation, including the final ID, and the parties' submissions, the Commission has determined to (1) affirm the ALJ's finding that the accused products and domestic industry products satisfy the claim limitation "horizontally transfer sheets along the main transfer path" and (2) reverse the

ALJ's finding that certain prior art does not disclose the preamble to claim 1: "Automatic depositing apparatus for automatically depositing a bundle of banknotes including at least one cheque." The Commission adopts the ID's findings to the extent they are not inconsistent with the Commission opinion issued herewith.

Having found a violation of section 337 in this investigation, the Commission has determined that the appropriate form of relief is: (1) A limited exclusion order prohibiting the unlicensed entry of automated teller machines, ATM modules, components thereof, and products containing the same that infringe one or more of claims 1–3, 6, 8, and 9 of the '235 patent that are manufactured on or behalf of, or imported on or behalf of Diebold or any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns, except under license of the patent owner or as provided by law, and except for service or repair articles imported for use in servicing or repairing automated teller machines, ATM modules, components thereof, and products containing the same, for identical articles that were imported as of the date of this Order. This exception does not permit the importation of automated teller machines to replace such articles that were previously imported; and (2) cease and desist orders prohibiting Diebold from conducting any of the following activities in the United States: Importing, selling, marketing, advertising, distributing, transferring (except for exportation), and soliciting U.S. agents or distributors for, automated teller machines, ATM modules, components thereof, and products containing the same covered by one or more of claims 1–3, 6, 8, and 9 of the '235 patent. The proposed cease and desist orders include the following exemptions: if in a written instrument, the owner of the patents authorizes or licenses such specific conduct, such specific conduct is related to the importation or sale of covered products by or for the United States, or such specific conduct is related to service or repair articles imported for use in servicing or repairing automated teller machines, ATM modules, components thereof, and products containing the same, for identical articles that were imported as of the date of this Order. This exception does not permit the importation of automated teller machines to replace such articles that were previously imported.

The Commission has also determined that the public interest factors enumerated in section 337(d) and (f) (19

U.S.C. 1337(d) and (f)) do not preclude issuance of the limited exclusion order or cease and desist orders. Finally, the Commission has determined that a bond in the amount of zero is required to permit temporary importation during the period of Presidential review (19 U.S.C. 1337(j)) of automated teller machines, ATM modules, components thereof, and products containing the same that are subject to the remedial orders. The Commission's orders and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 14, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–15200 Filed 7–19–17; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–17–030]

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: July 27, 2017 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote in Inv. Nos. 701–TA–563 and 731–TA–1331–1332 (Final) (Finished Carbon Steel Flanges from India and Italy). The Commission is currently scheduled to complete and file its determinations and views of the Commission by August 14, 2017.
5. Vote in Inv. No. 731–TA–669 (Fourth Review) (Cased Pencils from China). The Commission is currently scheduled to complete and file its determination and views of the Commission by August 17, 2017.

6. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: July 17, 2017.

William R. Bishop,
*Supervisory Hearings and Information
Officer.*

[FR Doc. 2017-15340 Filed 7-18-17; 11:15 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-583 and 731-TA-1381 (Preliminary)]

Cast Iron Soil Pipe Fittings From China; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International
Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701-TA-583 and 731-TA-1381 (Preliminary) pursuant to the Tariff Act of 1930 (“the Act”) to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of cast iron soil pipe fittings from China, provided for in subheading 7307.11.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of China. Unless the Department of Commerce extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by August 28, 2017. The Commission’s views must be transmitted to Commerce within five business days thereafter, or by September 5, 2017.

DATES: July 13, 2017.

FOR FURTHER INFORMATION CONTACT: Amelia Shister ((202) 205-2047), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission’s TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office

of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to a petition filed on July 13, 2017, by the Cast Iron Soil Pipe Institute, Mundelein, IL.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission’s Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission’s rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission’s rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Commission’s Director of Investigations has scheduled a conference in connection with these investigations for 9:30 a.m. on

Thursday, August 3, 2017, at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Requests to appear at the conference should be emailed to William.bishop@usitc.gov and Sharon.bellamy@usitc.gov (DO NOT FILE ON EDIS) on or before August 1, 2017. Parties in support of the imposition of countervailing and antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission’s deliberations may request permission to present a short statement at the conference.

Written submissions.—As provided in sections 201.8 and 207.15 of the Commission’s rules, any person may submit to the Commission on or before August 8, 2017, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference. All written submissions must conform with the provisions of section 201.8 of the Commission’s rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s Handbook on E-Filing, available on the Commission’s Web site at https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission’s rules with respect to electronic filing.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to section 207.3 of the Commission’s rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter’s knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations,

audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

By order of the Commission.

Issued: July 14, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017-15201 Filed 7-19-17; 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—Cooperative Research Group on Hedge IV

Notice is hereby given that, on June 9, 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 HEDGE IV ("HEDGE IV") 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, Diamond Electric, Ann Arbor, MI, and Honeywell International, Inc., Plymouth, MI, 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 HEDGE IV intends to file additional written notifications disclosing all changes in membership.

On February 14, 2017, HEDGE IV 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 March 27, 2017 (82 FR 15238).

The last notification was filed with the Department on May 10, 2017. A notice was published in the **Federal**

Register pursuant to Section 6(b) of the Act on June 7, 2017 (82 FR 26514).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2017-15238 Filed 7-19-17; 8:45 am]

BILLING CODE P

Department of Justice

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Wireless Industrial Technology Konsortium, Inc.

Notice is hereby given that, on June 20, 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"), Wireless Industrial Technology Konsortium, Inc. ("WITEK") 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, Texas Instruments, Inc., Dallas, TX, 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 WITEK intends to file additional written notifications disclosing all changes in membership.

On August 8, 2008, WITEK 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 September 18, 2008 (73 FR 54170).

The last notification was filed with the Department on June 24, 2015. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 22, 2015 (80 FR 43473).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2017-15240 Filed 7-19-17; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Advanced Media Workflow Association, Inc.

Notice is hereby given that, on June 26, 2017, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, ("the Act"), Advanced Media Workflow Association, 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, Calrec Audio, Inc., West Yorkshire, UNITED KINGDOM; IML Co. Ltd., Seoul, REPUBLIC OF KOREA; and Nextera Video, LLC, El Dorado Hills, CA, have been added as parties to this venture.

Also, Arkena, Paris, FRANCE; Aspera, Inc., Emeryville, CA; TransMedia Dynamics Ltd., Aylesbury, UNITED KINGDOM; and Sebastien Crème (individual member), Paris, FRANCE, 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 Advanced Media Workflow Association, Inc. intends to file additional written notifications disclosing all changes in membership.

On March 28, 2000, Advanced Media Workflow Association, 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 June 29, 2000 (65 FR 40127).

The last notification was filed with the Department on March 24, 2017. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on April 12, 2017 (82 FR 17693).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2017-15236 Filed 7-19-17; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE**Antitrust Division****Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cable Television Laboratories, Inc.**

Notice is hereby given that, on June 28, 2017, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, (“the Act”), Cable Television Laboratories, Inc. (“CableLabs”) 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, Stofa A/S. Horsens, DENMARK; NBN Co. Limited, Melbourne, AUSTRALIA; NOWO Communications, S.A., Lisbon, PORTUGAL; and Guangdong Cable Corporation Limited, Guangzhou, PEOPLE’S REPUBLIC OF CHINA, 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 CableLabs intends to file additional written notifications disclosing all changes in membership.

On August 8, 1988, CableLabs 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 September 7, 1988 (53 FR 34593).

The last notification was filed with the Department on January 30, 2017. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on February 27, 2017 (82 FR 11943).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2017–15237 Filed 7–19–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB Number 1123–0010]

Agency Information Collection Activities; Proposed eCollection; eComments Requested; Request for Registration Under the Gambling Devices Act of 1962

AGENCY: Criminal Division, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: Department of Justice (DOJ), Criminal Division will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** on May 11, 2017 allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 day until August 21, 2017.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to U.S. Department of Justice, Criminal Division, Office of Enforcement Operations, JCK Building, Room 1210, Washington, DC 20530–0001.

The Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- 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 agencies 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.

Overview of this Information Collection

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *Title of the Form/Collection:* Request for Registration Under the Gambling Devices Act of 1962.

(3) Agency form number, if any, and the applicable component of the Department sponsoring the collection: Agency form number: DOJ\CRM\OEO\GDR–1. Sponsoring component: Department of Justice, Criminal Division.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Business or other for-profit. Other: Not-for-profit institutions, individuals or households, and State, Local or Tribal Government. The form can be used by any entity required to register under the Gambling Devices Act of 1962 (15 U.S.C. 1171–1178).

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: It is estimated that 7,800 respondents will complete each form within approximately 5 minutes.

(6) An estimate of the total public burden (in hours) associated with the collection: There are an estimated 650 total annual burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405A, Washington, DC 20530.

Dated: July 17, 2017.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2017–15269 Filed 7–19–17; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE**Notice of Filing of Proposed Settlement Agreement Under the Comprehensive Environmental Response, Compensation, and Liability Act**

On July 14, 2017, a proposed Settlement Agreement among the Governments (United States, five States, seven Tribes, the Debtors (Peabody Energy Corporation and its 152 debtor-affiliates), and the Gold Fields Liquidating Trust was filed with the United States Bankruptcy Court for the Eastern District of Missouri in *In re Peabody Energy Corporation*, No. 16–42529–399 (Bankr. E.D. Mo.).

The proposed Settlement Agreement will resolve certain proofs of claim asserted against Debtors under the Comprehensive Environmental

Response, Compensation and Liability Act ("CERCLA"), 42 U.S.C. 9601–9675, and similar state laws, for costs incurred and to be incurred by the Governments in connection with certain sites, and for natural resource damages and costs of assessment at or in connection with certain sites.

The sites included in the settlement are:

(1) The 5-acre portion of the Former American Zinc, Lead and Smelting Company Site or AZLS in Montgomery County, Kansas also referred to as the "Caney Parcel" or the "Caney Repository" that was previously owned by Gold Fields Mining, LLC.

(2) The Anderson-Calhoun Mine and Mill Superfund Site in Stevens County, Washington.

(3) The ASARCO Taylor Springs Superfund Site in Montgomery County, Illinois.

(4) The Bausch Gray Mine Superfund Site in Jo Daviess County, Illinois.

(5) The Caney Residential Yards Site in Montgomery County, Kansas.

(6) The Carpenter-Snow Creek Mining District Superfund Site in Cascade County, Montana.

(7) The Cherokee County Superfund Site in Cherokee County, Kansas.

(8) The East La Harpe Smelter Site in Allen County, Kansas.

(9) The Grandview Mine and Mill Superfund Site in Pend Oreille County, Washington.

(10) The Jasper County Superfund Site in Jasper County, Missouri, also known as the Oronogo/Duenweg Mining Belt Site.

(11) The Klondyke Tailings Removal Site in Graham County, Arizona.

(12) The Old American Zinc Plant Superfund Site in St. Clair County, Illinois.

(13) The Tar Creek Superfund Site in Ottawa County, Oklahoma.

The Settlement Agreement includes payments for the above Sites as described therein and certain covenants not to sue under Sections 106 and 107 of CERCLA, 42 U.S.C. 9606 or 9607, and Section 70003 of RCRA, 42 U.S.C. 6973 with respect to the above referenced Sites.

The publication of this notice opens a period for public comment on the Settlement Agreement. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *In re Peabody Energy Corporation*, DOJ No. 90–11–3–11582. All comments must be submitted so that they are received by no later than 30 days after the date of publication in the **Federal Register**. Comments may be submitted either by email or by mail:

<i>To submit comments:</i>	<i>Send them to:</i>
By email	<i>pubcomment-ees.enrd@usdoj.gov.</i>

<i>To submit comments:</i>	<i>Send them to:</i>
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Under Section 7003(d) of RCRA, a commenter may request an opportunity for a public meeting in the affected area.

During the public comment period, the Settlement Agreement may be examined and downloaded at this Justice Department Web site: <http://www.justice.gov/enrd/consent-decrees>.

We will provide a paper copy of the Settlement Agreement upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for \$ 7.75 (25 cents per page reproduction cost) payable to the United States Treasury.

Susan M. Akers,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2017–15199 Filed 7–19–17; 8:45 am]

BILLING CODE 4410–15–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2017–055]

Records Management; General Records Schedule (GRS); GRS Transmittal 28

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of new General Records Schedule (GRS) Transmittal 28.

SUMMARY: NARA is issuing a new set of General Records Schedules (GRS) via GRS Transmittal 28. The GRS provides mandatory disposition instructions for administrative records common to several or all Federal agencies. Transmittal 28 announces changes we have made to the GRS since we published Transmittal 27 in January. We are concurrently disseminating Transmittal 28 (the memo and the accompanying records schedules and documents) directly to each agency's records management official and have also posted it on NARA's Web site.

DATES: This transmittal is effective the date it publishes in the **Federal Register**.

ADDRESSES: You can find this transmittal on NARA's Web site at

<http://www.archives.gov/records-mgmt/grs/>. You can download the complete current GRS, in PDF format, from NARA's Web site at <http://www.archives.gov/records-mgmt/grs.html>.

FOR FURTHER INFORMATION CONTACT: For more information about this notice or to obtain paper copies of the GRS, contact Kimberly Keravuori, External Policy Program Manager, by email at regulation_comments@nara.gov or by telephone at 301.837.3151.

Writing and maintaining the GRS is the GRS Team's responsibility. This team is part of Records Management Services in the National Records Management Program, Office of the Chief Records Officer at NARA. You may contact NARA's GRS Team with general questions about the GRS at GRS_Team@nara.gov.

Your agency's records officer may contact the NARA appraiser or records analyst with whom your agency normally works for support in carrying out this transmittal and the revised portions of the GRS. You may access a list of the appraisal and scheduling work group and regional contacts on our Web site at <http://www.archives.gov/records-mgmt/appraisal/index.html>.

SUPPLEMENTARY INFORMATION: GRS Transmittal 28 announces changes to the General Records Schedules (GRS) made since NARA published GRS Transmittal 27 in January 2017. The GRS provide mandatory disposition instructions for records common to several or all Federal agencies. We are nearing the end of our five-year plan to completely rewrite the GRS. With Transmittal 28, 92% of old items are now superseded.

Transmittal 28 includes only schedules newly issued or updated since the last transmittal, those schedules' associated new-to-old crosswalks and FAQs, an update to the FAQs for GRS 6.1 (but not schedule 6.1 itself, which remains unchanged), and an update to the FAQs about Flexible Dispositions. This means that many current GRS schedules are *not* included in this Transmittal.

This means that many current GRS schedules are *not* included in this Transmittal. You can find all schedules (in Word, PDF, and CSV formats), crosswalks and FAQs for all schedules, and FAQs about the whole GRS at <http://www.archives.gov/records-mgmt/grs.html>. At the same location, you can also find the entire GRS (just schedules—no crosswalks or FAQs) in a single document (<https://www.archives.gov/files/records-mgmt/grs/trs28-sch-only.pdf>).

What changes does this transmittal make to the GRS?

GRS Transmittal 28 publishes nine new schedules:

GRS 2.1	Employee Acquisition Records	DAA-GRS-2014-0002
GRS 2.2	Employee Management Records	DAA-GRS-2017-0007
GRS 2.3	Employee Relations Records	DAA-GRS-2015-0007
GRS 2.4	Employee Compensation and Benefits Records	DAA-GRS-2016-0015
GRS 5.1	Common Office Records	DAA-GRS-2016-0016
GRS 5.2	Transitory and Intermediary Records	DAA-GRS-2017-0003
GRS 5.6	Security Records	DAA-GRS-2017-0006
GRS 5.8	Administrative Help Desk Records	DAA-GRS-2017-0001
GRS 6.5	Public Customer Service Records	DAA-GRS-2017-0002

It also publishes a new item in one schedule: GRS 1.1, Financial Management and Reporting Records (see question 3). In addition, it supersedes in its entirety GRS 4.3, Input Records, Output Records, and Electronic Copies (see question 4).

This transmittal also includes an updated table of contents that shows some alterations to the previously published schedule titles. Research led us to conclude that it is not possible at this time to write a GRS for legal records, so the number assigned to that anticipated schedule—GRS 6.3—has been assigned instead to Information Technology Records. A new schedule for rulemaking records is GRS 6.6. Both 6.3 and 6.6 should be published in Transmittal 29.

This transmittal publishes a revised Frequently Asked Questions (FAQs) for GRS 6.1. The revisions include adding new GRS citations where appropriate; removing unnecessary references to

some CFR citations in Q3; clarifying Q4 text; clarifying culling in Q22; and clarifying how to report calendars, appointments, tasks, chat transcripts, and other communications on NA-1005 in Q27. Finally, this transmittal publishes updated FAQs on Flexible Dispositions, adding a new Q6 about batching records for disposal.

How has GRS 1.1 changed? How might these changes affect my agency?

We added one new item (080) to cover administrative claims made by or against the Federal Government. We also added three new questions to the GRS 1.1 FAQs concerning travel receipts scanned into e-systems (question 9), audit records (question 16) and use of item 080 (question 18).

Why did you delete GRS 4.3?

We deleted GRS 4.3, Input Records, Output Records, and Electronic Copies, because we have superseded its seven items with two new items in GRS 5.1

and 5.2. We superseded GRS 4.3, item 040, Non-recordkeeping copies of electronic records, with the closely parallel and identically titled GRS 5.1, item 020. We moved it to 5.1 to place it in context with other common office records. The new item is media-neutral. We superseded GRS 4.3, items 010, 011, 020, 030, 031, and 040 with GRS 5.2, item 020, Intermediary records. We found we could gather records of various formats from various sources into a single unit by recognizing this unifying trait: They are stopping points *en route* to a final record scheduled elsewhere.

What GRS items does GRS Transmittal 28 rescind?

Many old GRS items are superseded by new GRS items. A few old items, however, have outlived their usefulness and cannot be crosswalked to new items. The table below lists old items newly rescinded by GRS Transmittal 28.

GRS	Item	Title	Reason
1	1a	Official Personnel Folders: Transferred employees.	Was simply a filing/handling instruction and never had an associated disposition authority.
1	2a	Service Record Cards	The Service Record Card (SF 7) became obsolete in 1994.
	2b		
1	6	Employee Record Cards	The Employee Record Card (SF 7b) became obsolete in 1993.
1	7a1	Position Classification Standards Files ...	Non-record technical reference in all agencies but OPM, where they are mission records.
1	7a2b	Position Classification Standards Review Files.	No longer exist in the electronic world. If on paper, they are non-record duplicates.
1	7c1	Classification survey reports	OPM believes these records no longer exist.
1	7c2	Inspection, audit, and survey files	
1	11	Position Identification Strips	These records no longer exist.
1	13	Incentive Awards Program Reports	Agencies are no longer required to complete OPM Form 1465. Instead, OPM extracts data from the Enterprise Human Resources Integration-Statistical Data Mart to report Government-wide data on cash and time-off awards.
1	25b	Copies of EEO Complaint Case Files	These are non-record duplicates.
1	25e	Employee Housing Requests	Item does not appear to be in use.
1	33d	Test Material Stock Control	Blank unused forms are not records.
1	33h	Letters to Applicants Denying Transfer of Eligibility.	OPM Form 4896 is obsolete and the entire work process no longer exists.
1	35b1	Health benefits denied, appealed to OPM for reconsideration: Appeal successful—benefits granted.	Replaced by GRS 2.4, item 110. Like the old item, the new item instructs about filing, not disposition. As a result, it cannot be entered into ERA so cannot supersede the old. The old item must therefore be rescinded.
2	1a	Pay record for each employee as maintained in an electronic data base.	Item was not a disposition instruction but rather an instruction to make sure the current record is full and correct.
2	2	Noncurrent Payroll Files	Item authorized periodic disposal of system data after long-term records were downloaded and safeguarded. Such data is now covered under 5.1, item 020.

GRS	Item	Title	Reason
2	14a 14b 14c	Savings Bond Purchase Files	Paper savings bond purchase via payroll deduction was discontinued in 2010. Payroll deductions under the current TreasuryDirect e-system are covered in GRS 2.4, item 010.
2	23b	Payroll Change Files: all other files	Electronic payroll processing means these records no longer exist.
26	1b	Internal agency committees related to an agency's mission.	Item is not a disposition instruction. It tells agencies to submit a schedule for records. Now handled via a note in GRS 5.1, item 030.

Rescinded items are shown in context of their schedules in the old-to-new crosswalk.

How do I cite new GRS items?

When you send records to an FRC for storage, you should cite the records' legal authority—the "DAA" number—in the "Disposition Authority" column of the table. For informational purposes, please include schedule and item number. For example, "DAA-GRS-2013-0001-0004 (GRS 4.3, item 020)."

Do I have to take any action to implement these GRS changes?

NARA regulations (36 CFR 1226.12(a)) require agencies to disseminate GRS changes within six months of receipt.

Per 36 CFR 1227.12(a)(1), you must follow GRS dispositions that state they must be followed without exception.

Per 36 CFR 1227.12(a)(3), if you have an existing schedule that differs from a new GRS item that does *not* require being followed without exception, and you wish to continue using your agency-specific authority rather than the GRS authority, you must notify NARA within 120 days of the date of this transmittal.

If you do not have an already existing agency-specific authority but wish to apply a retention period that differs from that specified in the GRS, you must submit a records schedule to NARA for approval via the Electronic Records Archives.

How do I get copies of the new GRS?

You can download the complete current GRS, in PDF format, from NARA's Web site at <http://www.archives.gov/records-mgmt/grs.html>.

Whom do I contact for further information?

Writing and maintaining the GRS is the responsibility of the GRS Team. You may contact the team with general questions about the GRS at GRS_Team@nara.gov. This team is part of Records Management Services in the National Records Management Program of the Office of the Chief Records Officer at NARA.

Your agency's records officer may contact the NARA appraiser or records

analyst with whom your agency normally works for support in carrying out this transmittal. A list of the appraisal and scheduling work group and regional contacts is on the NARA Web site at <http://www.archives.gov/records-mgmt/appraisal/index.html>.

David S. Ferriero,

Archivist of the United States.

[FR Doc. 2017-15250 Filed 7-19-17; 8:45 am]

BILLING CODE 7515-01-P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA-2017-056]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of proposed extension request.

SUMMARY: NARA proposes to request an extension from the Office of Management and Budget (OMB) of approval to use a voluntary survey of visitors to the Public Vaults located at the National Archives in Washington, DC. We use this information to determine how the various components of the Public Vaults affect visitors' level of satisfaction with the Public Vaults and how effectively the venue communicates to them that records matter. And we use it to make changes that improve the overall visitor experience. We invite you to comment on this proposed information collection.

DATES: We must receive written comments on or before September 18, 2017.

ADDRESSES: Send comments to Paperwork Reduction Act Comments (MP), Room 4100; National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740-6001, fax them to 301-837-0319, or email them to tamee.fechhelm@nara.gov.

FOR FURTHER INFORMATION CONTACT: Contact Tamee Fechhelm by telephone at 301-837-1694 or email at tamee.fechhelm@nara.gov with requests

for additional information or copies of the proposed information collection and supporting statement.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Public Law 104-13), NARA invites the public and other Federal agencies to comment on proposed information collections. The comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for NARA to properly perform its functions; (b) our estimate of the burden of the proposed information collection and its accuracy; (c) ways we could enhance the quality, utility, and clarity of the information we collect; (d) ways we could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether this collection affects small businesses. We will summarize any comments you submit and include the summary in our request for OMB approval. All comments will become a matter of public record. In this notice, we solicit comments concerning the following information collection:

Title: National Archives Public Vaults Survey.

OMB number: 3095-0062.

Agency form number: N/A.

Type of review: Regular.

Affected public: Individuals who visit the National Archives' Public Vaults in Washington, DC.

Estimated number of respondents: 1,050.

Estimated time per response: 10 minutes.

Frequency of response: On occasion (when an individual visits the Public Vaults in Washington, DC).

Estimated total annual burden hours: 175 hours.

Abstract: The information collection is prescribed by EO 12862 issued September 11, 1993, which requires Federal agencies to survey their customers concerning customer service. The general purpose of this voluntary data collection is to measure customer satisfaction with the Public Vaults and

identify additional opportunities for improving customers' experience.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2017-15212 Filed 7-19-17; 8:45 am]

BILLING CODE 7515-01-P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Materials Research; 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: Proposal Review Panel for Materials Research—Partnership for Research and Education in Materials, University of Puerto Rico at Humacao (UPRH) (#1203) Site Visit
Date and Time: August 17, 2017; 8:00 a.m.–6:00 p.m.; August 18, 2017; 8:00 a.m.–12:00 p.m.

Place: University of Puerto Rico at Humacao, PR 908, Humacao, 00792 Puerto Rico.

Type of Meeting: Part-Open.
Contact Person: Dr. Jose Caro, Program Director, Partnership for Research and Education in Materials, PREM, Division of Materials Research, Room 1065, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230; Telephone (703) 292-4914.

Purpose of Meeting: NSF site visit to provide advice and recommendations concerning further NSF support for the Center.

Agenda

Thursday, August 17, 2017

7:15 a.m. Bus leaves Hotel in Palmas del Mar, Humacao to UPRH
7:45 a.m.–8:15 a.m. Continental Breakfast Executive Session for Site Visit Team. (Closed)
8:15 a.m.–8:30 a.m. Break
8:30 a.m.–8:45 a.m. Welcome and Overview by Administration
8:45 a.m.–9:30 a.m. PI's Overview of PREM
9:30 a.m.–9:45 a.m. Q&A for PI's and Administrator's Overviews
9:45 a.m.–10:15 a.m. Partner Institutions Interactions Q&A
10:15 a.m.–10:30 a.m. Break
10:30 a.m.–12:00 a.m. Research Presentations/Q&A
12:00 p.m.–12:15 p.m. Q&A for Science Presentations
12:15 p.m.–1:15 p.m. Lunch with students and post docs (no faculty).
1:15 p.m.–2:15 p.m. Facilities Overview and Visit

2:15 p.m.–2:45 p.m. Visiting Team with University Management (Closed)
2:45 p.m.–4:00 p.m. Poster Session with refreshments
4:00 p.m.–5:00 p.m. Executive session—SV Team only (Closed)
5:00 p.m.–5:45 p.m. SV Team meets with PREM Management Team
5:45 p.m. Adjourn
6:00 p.m. Bus leaves from Natural Sciences Building for dinner
6:30 p.m. Dinner (Panel and Faculty): El Makito Restaurant, Naguabo, PR
9:00 p.m. Bus leaves Restaurant to Hotel (Approximate time)

Friday, August 18, 2017

7:00 a.m. Bus leaves hotel to UPRH
7:30 a.m.–8:00 a.m. Continental Breakfast
8:00 a.m.–9:30 a.m. Education and Outreach Activities
9:30 a.m.–9:45 a.m. Q&A for Educational and Outreach Presentations
9:45 a.m.–10:00 a.m. Break
10:00 a.m.–11:45 a.m. Executive Sessions for Site Visit Team only (Closed)
11:45 a.m.–12:00 p.m. NFS Debriefing with PREM PI
12:00 p.m. End of Site Visit
12:00 p.m. Working Lunch for Site Visit Team
Reason for Closing: The work being reviewed during closed portions of the site visit will include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: July 17, 2017.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2017-15264 Filed 7-19-17; 8:45 am]

BILLING CODE 7555-01-P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting; National Science Board

The National Science Board, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n-5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business, as follows:

TIME AND DATE: Closed teleconference of the Committee on Strategy of the

National Science Board, to be held Tuesday, July 25, 2017 from 10:30 a.m. to 12:00 Noon. EDT.

PLACE: This meeting will be held by teleconference at the National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Committee Chair's opening remarks; Review and discussion of the FY 2019 budget submission to the Office of Management and Budget; Committee Chair's closing remarks.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Kathy Jacquart, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 292-8000.

You may find meeting information and updates (time, place, subject matter or status of meeting) at <http://www.nsf.gov/nsb/notices/>.

Dated: July 17, 2017.

Chris Blair,

Executive Assistant to the NSB Office.

[FR Doc. 2017-15309 Filed 7-18-17; 11:15 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72-1050; NRC-2016-0231]

Waste Control Specialists LLC's Consolidated Interim Spent Fuel Storage Facility Project

AGENCY: Nuclear Regulatory Commission.

ACTION: License application; withdrawal of notice of opportunity to request a hearing.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is withdrawing the notice of opportunity to request a hearing for Waste Control Specialists LLC's application to construct and operate a Consolidated Interim Storage Facility (CISF) for spent nuclear fuel at WCS's facility in Andrews County, Texas.

DATES: July 20, 2017.

ADDRESSES: Please refer to Docket ID NRC-2016-0231 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-2016-0231. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463;

email: Carol.Gallagher@nrc.gov. For technical questions, contact the individual 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. For the convenience of the reader, the ADAMS accession numbers are provided in a table in the "Availability of Documents" Section II of this document.

- *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: John-Chau Nguyen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0262; email: John-Chau.Nguyen@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

By letter dated April 28, 2016, as supplemented on July 20, August 19,

August 31, September 27, October 7, November 16, December 16, December 22, 2016, and March 16, 2017, WCS submitted an application for a specific license pursuant to part 72 of title 10 of the *Code of Federal Regulations* (10 CFR), "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste." In its letter, WCS requested authorization to store up to 5,000 metric tons of uranium for a period of 40 years in a CISF.

In addition, by letter dated July 21, 2016, WCS requested that the NRC initiate its environmental impact statement (EIS) process for the WCS CISF license application as soon as practicable. By letter dated October 7, 2016, the NRC informed WCS of its decision to start the EIS process in advance of making a decision on docketing the application. On November 14, 2016 (81 FR 79531), the NRC published a notice in the **Federal Register** announcing its intent to prepare an EIS and to open the scoping period for the EIS.

By letter dated January 26, 2017, the NRC informed WCS of its decision to accept the application and proceed with the technical review. Subsequently, on January 30, 2017 (82 FR 8773), the NRC published a notice in the **Federal Register** announcing the acceptance for docketing and opportunity to request a hearing and to petition for leave to intervene of the WCS application.

By letter dated March 16, 2017, WCS submitted Revision 1 to its license application. By letter dated April 18, 2017, WCS requested that the NRC temporarily suspend all safety and environmental review activities as well as public participation activities associated with WCS' license application. On April 19, 2017, WCS and the NRC staff jointly requested that the Commission withdraw the hearing notice, explaining that a new **Federal Register** notice to provide a fresh opportunity for interested persons to request a hearing would be issued if review of the application resumes. On May 10, 2017, the NRC staff granted WCS' request to temporarily suspend all safety and environmental review activities as well as public participation activities associated with its license application. On June 22, 2017, the Commission granted WCS's and the NRC staff's request and further directed that the NRC staff to publish a **Federal Register** notice withdrawing the opportunity to request a hearing on this license application and directed the NRC staff to publish a new notice of opportunity to request a hearing in the **Federal Register** if WCS requests that the NRC staff resume its review of WCS's application.

II. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession No.
WCS submittal of CISF license application, with Environmental Report	ML16132A533
WCS letter with schedule for response to NRC request for supplemental information	ML16193A314
WCS initial submittal in response to NRC request for supplemental information	ML16229A537
WCS submittal of supplemental security information	ML16235A467
WCS request for NRC to begin EIS process as soon as practicable	ML16229A340
WCS second submittal in response to NRC request for supplemental information	ML16265A454
WCS submittal of additional supplemental security information	ML16280A300
NRC response to WCS request to begin EIS process as soon as practicable	ML16285A317
WCS third submittal in response to NRC request for supplemental information	ML16287A527
WCS fourth submittal in response to NRC request for supplemental information	ML16330A116
WCS fifth submittal in response to NRC request for supplemental information	ML16356A346
WCS sixth submittal in response to NRC request for supplemental information	ML17018A292
NRC letter accepting application for review	ML17018A168
WCS license application Revision 1 submittal	ML17082A007
WCS request NRC to temporarily suspend all safety and environmental review activities	ML17110A206
NRC granting WCS request to temporarily suspend all safety and environmental review activities	ML17129A314

Dated at Rockville, Maryland, this 13th day of July 2017.

For the Nuclear Regulatory Commission.

John McKirgan,

Chief, Spent Fuel Licensing Branch, Division of Spent Fuel Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2017-15239 Filed 7-19-17; 8:45 am]

BILLING CODE 7590-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81146; File No. SR-NYSEMKT-2017-44]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.38E To Specify the Ranking of an Odd Lot Order That Has a Display Price That Is Better Than Its Working Price

July 14, 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 June 30, 2017, NYSE MKT LLC (the “Exchange” or “NYSE MKT”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.38E (Odd and Mixed Lots) to specify the ranking of an odd lot order that has a display price that is better than its working price. 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.

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 Rule 7.38E (Odd and Mixed Lots) to specify the ranking of an odd lot order that has a display price that is better than its working price.

Rule 7.38E provides that the working price of an odd lot order will be adjusted both on arrival and when resting on the Exchange Book based on the limit price of the order as follows:

- If the limit price of an odd lot order is equal to or worse than the contra-side PBBO, it will have a working price equal to the limit price.
- If the limit price of an odd lot order is better than the contra-side PBBO, it will have a working price equal to the contra-side PBBO.
- If the PBBO is crossed, the odd lot order will have a working price equal to the same-side PBB or PBO.

By moving the working price, an odd lot order to buy (sell) will not trade at a price above (below) the PBO (PBB), or if the PBBO is crossed, above (below) the PBB (PBO). In either case, if the odd lot order is ranked Priority 2—Display Orders,⁴ its display price would not change when its working price is adjusted.

Exchange rules are currently silent regarding how a resting odd lot order that has a display price that is better than its working price would be ranked for trading at that working price.⁵ This scenario would only occur if a resting odd lot order is displayed at a price, and then an Away Market PBBO crosses that display price. In that limited scenario, pursuant to Rule 7.38E(b)(1) described above, the working price of the odd-lot order would be adjusted to a price inferior to the display price, but it would remain displayed at the now crossed price.

The Exchange proposes to specify that in such case, the ranking and priority category applicable to such an order at its display [sic], *i.e.*, the price it is

displayed and Priority 2—Display Orders, would govern its ranking for purposes of a trade at its different, inferior working price.⁶ This ranking would differ from the Exchange’s general rule that an order is ranked based on its working price.⁷ However, the Exchange believes that if the display price of an order is better than its working price, such order has already demonstrated a public willingness to trade at a more aggressive price because it continues to be published in a market data feed at the more aggressive display price.⁸ In such case, the order should receive the benefit of the ranking (both price and priority category) associated with its better display price when determining how that order would be traded at its working price. In other words, an odd-lot order with a better display price than its working price would not be ranked based on its working price, including that it would not be assigned Priority 3—Non-Display Orders at its working price.

The Exchange further believes that if an odd-lot order is assigned a new working price that is worse than its display price, such order should not be assigned a new working time. In other words, when trading at its working price, its time ranking would be based on the working time associated with its display price.⁹ Maintaining the original working time of such order would ensure that it maintains its original ranking, even if it trades at a different price.

To effect this change, the Exchange proposes to amend Rule 7.38E(b)(1) to provide that an odd-lot order ranked Priority 2—Display Orders would not be assigned a new working time if its working price is adjusted under Rule 7.38E(b)(1). In addition, if the display price of an odd lot order to buy (sell) is above (below) its working price, it would be ranked based on its display price.¹⁰

⁶ As described in Rule 7.36E(c), an order is ranked based on price, priority category, and time. Such ranking is only applicable once an order is resting on the Exchange Book.

⁷ Rule 7.36E(d) provides that all orders are ranked based on the working price of the order. Rule 7.36E(e)(3) generally provides that non-marketable orders for which the working price is not displayed have third priority behind Market Orders and non-marketable Limit Orders that are displayed at their working price. This proposed rule change would be an exception to these rules.

⁸ See Rule 7.36E(b)(1) (odd-lot sized orders are considered displayed for ranking purposes).

⁹ Rule 7.36E(f)(2) provides that an order is assigned a new working time any time the working price of the order changes. This proposed rule change would be an exception to this general rule.

¹⁰ For example, assume the PBBO is 10.07 × 10.10 and the Exchange receives orders ranked Priority

Continued

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ As described in Rule 7.36E(e)(2), Priority 2—Display Orders are non-marketable Limit Orders with a displayed working price.

⁵ Pursuant to Rule 7.38E(b)(1), on arrival, an odd lot order’s working price may be adjusted consistent with the terms of the order. However, an arriving odd-lot order would not be assigned a working price that would be inferior to the price at which the arriving odd lot order would be displayed.

Because once on Pillar, the Exchange would trade an odd lot order with a display price better than its working price trades in this manner [sic], these changes will be in effect when the Exchange implements Pillar.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the "Act"),¹¹ in general, and furthers the objectives of Section 6(b)(5),¹² in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

Specifically, the Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system because the Exchange believes that an order that has been displayed should receive the benefit of the ranking of that displayed price if it trades at a less aggressive working price. This scenario would only occur if a resting odd-lot order has been displayed at a price, and then an Away Market PBBO crosses that price and then the working price of that order is adjusted to a price inferior to its display price. In such case, while the odd lot order would be executed at its working price, because it was both willing to trade at a better price and is still displayed at that better price, the Exchange proposes that it would be ranked based on its display price for purposes of its execution at the working price. If the PBBO had not crossed the odd-lot order, such order would have had the benefit of the ranking based on its display price and the Exchange believes it would be consistent with the

2—Display Orders in the following sequence: T1 to buy 25 shares displayed at 10.08, T2 to buy 25 shares displayed at 10.09, T3 to buy 25 shares displayed at 10.08, and T4 to buy 100 shares displayed at 10.07. Assume next that the PBO changes to 10.07. The working price of T1, T2, and T3 will be adjusted to 10.07, but they would keep their original working time. Next, the Exchange receives an incoming order to sell 100 shares at 10.07. The Exchange would trade the incoming order with the resting orders in the following sequence: T2, T1, T3, and then T4 would be allocated the remaining 25 shares. T2 would trade before T1 because it has a better price ranking based on its display price. If the incoming order to sell were for 50 shares, only T2 and T1 would trade.

¹¹ 15 U.S.C. 78f(b).

¹² 15 U.S.C. 78f(b)(5).

protection of investors and the public for the odd-lot order to retain such ranking when its working price is moved to an inferior price. The Exchange further believes that the proposed rule change would promote fair and orderly markets that would protect investors and the public interest because it would to [sic] promote the display of liquidity by ensuring that a displayed odd lot order maintains its ranking even if it trades at a less aggressive price.

The Exchange further believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would promote transparency in Exchange rules and reduce potential confusion regarding how an odd-lot order would be ranked and execute in the limited scenario when the display price of a resting odd lot has been crossed, and it has been assigned a working price inferior to its display price.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change is not designed to address any competitive issues but rather to provide an incentive for market participants to enter aggressively-priced displayed liquidity.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹³ and Rule 19b-4(f)(6) thereunder.¹⁴

¹³ 15 U.S.C. 78s(b)(3)(A).

¹⁴ 17 CFR 240.19b-4(f)(6). The Commission has waived the requirement under Rule 19b-4(f)(6)(iii) that the Exchange provide it with written notice of its intent to file the proposed rule change, along

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act¹⁵ normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)¹⁶ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The Exchange represents that it anticipates beginning the migration of symbols to Pillar on July 24, 2017. Waiver of the 30-day operative delay would allow the Exchange to implement the proposed rule change concurrently with the commencement of its migration of symbols to Pillar, and thus reduce any potential for confusion of how odd-lot orders would be processed on the new trading platform. Accordingly, the Commission finds that waiving the 30-day operative delay is consistent with the protection of investors and the public interest and designates the proposal operative upon filing.¹⁷

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 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-NYSEMKT-2017-44 on the subject line.

with a brief description and the text of the proposed rule change, at least five business days prior to the date of the filing of the proposed rule change, or such shorter time as designated by the Commission.

¹⁵ 17 CFR 240.19b-4(f)(6).

¹⁶ 17 CFR 240.19b-4(f)(6)(iii).

¹⁷ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

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-NYSEMKT-2017-44. 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEMKT-2017-44 and should be submitted on or before August 10, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2017-15191 Filed 7-19-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81152; File No. SR-BatsBZX-2017-45]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to BZX Rule 14.13, Company Listing Fees, To Amend the Fees Applicable to Securities Listed on the Exchange

July 14, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 3, 2017, Bats BZX Exchange, Inc. (the "Exchange" or "BZX") 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 filed a proposed rule change to amend the fees applicable to securities listed on the Exchange, which are set forth in Exchange Rule 14.13. Changes to the Exchange's fees pursuant to this proposal are effective upon filing.

The text of the proposed rule change is available at the Exchange's Web site at www.bats.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 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 30, 2011, the Exchange received approval of rules applicable to the qualification, listing, and delisting of companies on the Exchange,³ which it modified on February 8, 2012 in order to adopt pricing for the listing of exchange traded products ("ETPs")⁴ on the Exchange,⁵ which it subsequently modified again on June 4, 2014.⁶ On October 16, 2014, the Exchange modified Rule 14.13, "Company Listing Fees," to eliminate the annual fees for ETPs not participating in the Exchange's Competitive Liquidity Provider Program pursuant to Rule 11.8, Interpretations and Policies .02 (the "CLP Program").⁷ On May 22, 2015, the Exchange further modified Rule 14.13 to eliminate the application fee for ETPs, effectively eliminating any compulsory fees for both new ETP issues and transfer listings onto the Exchange.⁸ On September 30, 2015, the Exchange began offering an incentive payment to ETPs that are listed on the Exchange based on the consolidated average daily volume (the "CADV") of the ETP (the "Issuer Incentive Program").⁹ The Exchange subsequently made an administrative change to the Issuer Incentive Program that required an issuer to enroll in order to receive payment.¹⁰

The Exchange submits this proposal to decommission the Issuer Incentive Program. Currently, under Exchange Rule 14.13(b)(2)(C), the issuer of each class of securities that is a domestic or foreign issue listed on the Exchange as an ETP is eligible to receive payments from the Exchange on a quarterly basis based on the CADV of the ETP for each trading day of the preceding calendar

³ See Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR-BATS-2011-018).

⁴ As defined in Exchange Rule 11.8(e)(1)(A), the term "ETP" means any security listed pursuant to Exchange Rule 14.11.

⁵ See Securities Exchange Act Release No. 66422 (February 17, 2012), 77 FR 11179 (February 24, 2012) (SR-BATS-2012-010).

⁶ See Securities Exchange Act Release No. 72377 (June 12, 2014), 79 FR 34822 (June 18, 2014) (SR-BATS-2014-024).

⁷ See Securities Exchange Act Release No. 73414 (October 23, 2014), 79 FR 64434 (October 29, 2014) (SR-BATS-2014-050).

⁸ See Securities Exchange Act Release No. 75085 (June 1, 2015), 80 FR 32190 (June 5, 2015) (SR-BATS-2015-39).

⁹ See Securities Exchange Act Release No. 76113 (October 8, 2015), 80 FR 62142 (October 15, 2015) (SR-BATS-2015-80).

¹⁰ See Securities Exchange Act Release No. 77960 (June 1, 2016), 81 FR 36632 (June 7, 2016) (SR-BatsBZX-2016-20).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹⁸ 17 CFR 200.30-3(a)(12).

quarter that the ETP was listed on the Exchange. The annualized payments range from the lowest bracket of \$3,000 for CADV between 1–3 million shares to the highest bracket of \$400,000 for CADV greater than 35 million shares. The Exchange is proposing to eliminate such payments.

Implementation Date

The Exchange proposes to implement the amendments to Rule 14.13(b)(2)(C) effective July 3, 2017.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.¹¹ Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) and 6(b)(5) of the Act,¹² in that it provides for the equitable allocation of reasonable dues, fees and other charges among issuers and is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange is proposing to decommission the Issuer Incentive Program, which established payments from the Exchange to ETP issuers that list on the Exchange and achieve a particular CADV threshold. The Exchange believes that the proposal is equitable, reasonable, and non-discriminatory because decommissioning the Issuer Incentive Program will affect all ETP issuers listing on the Exchange equally. The Exchange also believes that the proposal to eliminate the Issuer Incentive Program is reasonable, fair and equitable, and not an unfairly discriminatory allocation of fees and other charges because it would apply equally to all Issuers and eliminating the payment will allow the Exchange to better allocate its resources in order to make it a more attractive listing venue for ETPs. Additionally, the payments under the Issuer Incentive Program have not had the impact that the Exchange sought when it was implemented.

Based on the foregoing, the Exchange believes that the proposed amendment to Rule 14.13(b)(2)(C) to eliminate the Issuer Incentive Program is a reasonable, equitable, and non-discriminatory allocation of fees and other charges to issuers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange acknowledges that it operates in a highly competitive environment, and that ETP issuers may opt to disfavor listing on the Exchange if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of ETP issuers or competing venues to maintain their competitive standing in the financial markets. The Exchange does not believe that the proposed changes to the Exchange's standard fees, rebates and tiered pricing structure burdens competition, but instead, enhances competition as it is intended to increase the competitiveness of the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

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) of the Act¹³ and paragraph (f) of Rule 19b-4 thereunder.¹⁴ 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.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal 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 No. SR-BatsBZX-2017-45 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 No. SR-BatsBZX-2017-45. 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 will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR-BatsBZX-2017-45 and should be submitted on or before August 10, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2017-15197 Filed 7-19-17; 8:45 am]

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¹¹ 15 U.S.C. 78f.

¹² 15 U.S.C. 78f(b)(4) and (5).

¹³ 15 U.S.C. 78s(b)(3)(A).

¹⁴ 17 CFR 240.19b-4(f).

¹⁵ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81151; File No. SR-MRX-2017-02]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change in Connection With a System Migration to Nasdaq INET Technology

July 14, 2017.

On May 17, 2017, Nasdaq MRX, LLC (“MRX” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)¹ and Rule 19b-4 thereunder,² a proposed rule change to amend various Exchange rules in connection with a system migration to Nasdaq, Inc. supported technology. The proposed rule change was published for comment in the **Federal Register** on June 5, 2017.³ The Commission received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act⁴ provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is July 20, 2017.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the Exchange’s proposal, as described above.

Accordingly, pursuant to Section 19(b)(2) of the Act,⁵ the Commission designates September 3, 2017, as the date by which the Commission should either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File No. SR-MRX-2017-02).

¹ 15 U.S.C. 78s(b)(1).² 17 CFR 240.19b-4.³ See Securities Exchange Act Release No. 80815 (May 30, 2017), 82 FR 25827 (“Notice”).⁴ 15 U.S.C. 78s(b)(2).⁵ 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2017-15196 Filed 7-19-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81144; File No. SR-ISE-2017-69]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees in Connection With the ISE System Migration

July 14, 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 July 3, 2017, Nasdaq ISE, LLC (“ISE” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Schedule of Fees to indicate the treatment of various symbols which are migrating to INET technology in July 2017.

The text of the proposed rule change is available on the Exchange’s Web site at www.ise.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 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 the Schedule of Fees to: (1) Exclude certain Select Symbols³ which will migrate to INET from July 3rd through July 30th 2017 from the Market Maker Plus⁴ Tiers for the month of July 2017; and (2) exclude certain activity for certain Select Symbols which will migrate to INET on July 31, 2017 from the Market Maker Plus Tiers for the month of July 2017. Each rule change will be described in greater detail below.

These rule changes are being made in connection with the migration of the Exchange’s trading system to the Nasdaq INET technology, which began on June 12, 2017.⁵ On June 9, 2017, the Exchange filed a proposed rule change that eliminated fees and rebates for trades in FX Options that began trading on INET with the launch of the re-platformed trading system.⁶ In addition, on June 27, 2017 the Exchange filed another proposed rule change that eliminated fees and rebates for trades in symbol KANG that began trading on INET on that date.⁷ The Exchange recently filed a proposed rule change that eliminated fees and rebates for trades executed on June 30, 2017 in the following symbols: ACN, ACOR, AEO, AFSI, AMJ, AOBC, BKD, BTE, BV, CBI, CCL, CLR, CME, CNQ, ADM, ADSK, AGNC, ASHR, BBT, BK, BSX, CIEN, and

³ “Select Symbols” are options overlying all symbols listed on ISE that are in the Penny Pilot Program.⁴ A Market Maker Plus is a Market Maker who is on the National Best Bid or National Best Offer a specified percentage of the time for series trading between \$0.03 and \$3.00 (for options whose underlying stock’s previous trading day’s last sale price was less than or equal to \$100) and between \$0.10 and \$3.00 (for options whose underlying stock’s previous trading day’s last sale price was greater than \$100) in premium in each of the front two expiration months. The specified percentage is at least 80% but lower than 85% of the time for Tier 1, at least 85% but lower than 95% of the time for Tier 2, and at least 95% of the time for Tier 3. A Market Maker’s single best and single worst quoting days each month based on the front two expiration months, on a per symbol basis, will be excluded in calculating whether a Market Maker qualifies for this rebate, if doing so will qualify a Market Maker for the rebate.⁵ See Securities Exchange Act Release No. 80432 (April 11, 2017), 82 FR 18191 (April 17, 2017) (SR-ISE-2017-03). See also Options Trader Alert 2017-51.⁶ See Securities Exchange Act Release No. 80999 (June 22, 2017) 82 FR 29354 (June 28, 2017) (SR-ISE-2017-59).⁷ See SR-ISE-2017-63 (publication pending).⁶ 17 CFR 200.30-3(a)(31).¹ 15 U.S.C. 78s(b)(1).² 17 CFR 240.19b-4.

IBM.⁸ Additionally, that rule change also proposed that activity in the following Select Symbols will not be counted for purposes of determining Market Maker Plus tiers: ADM, ADSK, AGNC, ASHR, BBT, BK, BSX, CIEN, and IBM.⁹

Current Proposal—Number 1

The Exchange proposes that Select Symbols which will migrate to INET from July 3rd through July 30th 2017, as noticed by the Exchange in Options Trader Alert #2017–51¹⁰ (“Migrated Symbols”) will not be subject to Market Maker Plus Tiers 1–3 for the month of July 2017. These Migrated Symbols will be subject to Market Maker Plus Tiers 1–3 as of August 1, 2017 and thereafter.

During the transition symbols will migrate from the legacy T7 system to the INET system. The two systems utilize different billing systems. For ease of transition and to ensure that Members are not impacted by the transition to a new billing system, the Exchange is proposing to simply not apply the Market Maker Plus Tiers to the symbols which will be transitioning from July 3rd through July 30th 2017 for the month of July 2017. In August 2017, the Migrated Symbols will all be subject to the INET billing system and therefore the Exchange would begin applying the Market Maker Plus Tiers at that time.

Current Proposal—Number 2

The Exchange proposes to exclude Select Symbols which will migrate to INET on July 31, 2017, as noticed by the Exchange at Options Trader Alert #2017–51 (“July 31 Migrated Symbols”) and only include activity from July 3, 2017 through July 30, 2017 for purposes of qualifying for the Market Maker Plus Tiers for the month of July 2017.

As noted above, since the July 31 Migrated Symbols will migrate from the legacy T7 system to the INET system and utilize two different billing systems the Exchange proposes this exclusion. The Exchange believes that the exclusion will provide ease of transition and ensure that Members are not impacted by the transition to a new billing system. In August 2017, the July 31 Migrated Symbols will be subject to the INET billing system and therefore the Exchange would begin applying the Market Maker Plus Tiers at that time for the entire month of August 2017.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with

the provisions of Section 6 of the Act,¹¹ in general, and Section 6(b)(4) of the Act,¹² in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

Current Proposal—Number 1

The Exchange’s proposal that Migrated Symbols will not be subject to Market Maker Plus Tiers 1–3 for the month of July 2017 is reasonable because the Exchange will utilize two billing systems with the migration from legacy T7 to INET. For ease of transition and to ensure that Members are not impacted by the transition to a new billing system, the Exchange believes it is reasonable to not apply the Market Maker Plus Tiers to the symbols which will be transitioning from July 3rd through July 30th 2017 for the month of July 2017. The new INET system would result in higher performance, scalability, and more robust architecture for ISE Members.

The Exchange’s proposal that Migrated Symbols will not be subject to Market Maker Plus Tiers 1–3 for the month of July 2017 is equitable and not unfairly discriminatory as it will apply to all transactions in Migrated Symbols on INET.

Current Proposal—Number 2

The Exchange’s proposal that July 31 Migrated Symbols will only include activity from July 3, 2017 through July 30, 2017 for purposes of qualifying for the Market Maker Plus Tiers for the month of July 2017 is reasonable because the Exchange will utilize two billing systems with the migration from legacy T7 to INET. For ease of transition and to ensure that Members are not impacted by the transition to a new billing system, the Exchange believes it is reasonable to exclude the July 31, 2017 trading activity from the Market Maker Plus Tiers for the July 31 Migrated Symbols and only apply activity from July 3rd through July 30th 2017 for purposes of qualifying for the Market Maker Plus Tiers for the month of July 2017. The new INET system would result in higher performance, scalability, and more robust architecture for ISE Members.

The Exchange’s proposal to exclude activity for July 31, 2017 for the July 31 Migrated Symbols qualification for July 2017 and only include activity from July 3, 2017 through July 30, 2017 for purposes of qualifying for the Market Maker Plus Tiers for the month of July

2017 is equitable and not unfairly discriminatory as it will apply to all transactions in July 31 Migrated Symbols on INET.

B. Self-Regulatory Organization’s Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,¹³ the Exchange does not believe that the proposed rule changes will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes are intended to ease members’ transition to the re-platformed INET trading system and is not designed to have any significant competitive impact. The proposed changes will apply to all transactions in both the Migrated Symbols and the July 31 Migrated Symbols. The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates 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,¹⁴ and Rule 19b–4(f)(2)¹⁵ 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: (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.

¹³ 15 U.S.C. 78f(b)(8).

¹⁴ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁵ 17 CFR 240.19b–4(f)(2).

⁸ See SR–ISE–2017–66 (publication pending).

⁹ *Id.*

¹⁰ This alert contains a link to the specific symbols that migrate on each date.

¹¹ 15 U.S.C. 78f.

¹² 15 U.S.C. 78f(b)(4).

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-ISE-2017-69 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-ISE-2017-69. 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-ISE-2017-69 and should be submitted on or before August 10, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2017-15189 Filed 7-19-17; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81147; File No. SR-GEMX-2017-30]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Remove Outdated Language in the Exchange's Rulebook and Fee Schedule

July 14, 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 July 5, 2017, Nasdaq GEMX, LLC ("GEMX" 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 remove outdated rule text from GEMX's Rulebook and Fee Schedule.

The text of the proposed rule change is available on the Exchange's Web site at www.ise.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 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.

¹⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to remove certain rule text in the GEMX Rulebook and Fee Schedule which reflects certain dates which are no longer applicable. The Exchange proposes to remove the proposed outdated rule text to avoid confusion in the Rulebook and Fee Schedule. Each change is discussed below.

The Exchange proposes to remove text from GEMX Rule 716, entitled "Block Trades." Specifically, the Exchange proposes to remove the following rule text, "The Block Order Mechanism in Rule 716(c) will not be available on a date prior to February 27, 2017, the date to be announced in a separate Market Information Circular. The Exchange will recommence the Block Order Mechanism on Nasdaq GEMX prior to June 1, 2017, the date to be announced in a separate Market Information Circular." This rule text was added at the time the Exchange proposed to delay this functionality.³ The Exchange recommenced the Block Order Mechanism on May 30, 2017.⁴ The text is no longer applicable.

The Exchange proposes to remove the following outdated sentences in Sections I and II of the Fee Schedule:

- There will be no fees or rebates for trades in options overlying Symbol CPN executed on February 27-28, 2017.⁵
- For March 2017 only, all Qualifying Tier Threshold ADV calculations will be based on the better of (1) the member's full month ADV for the period of March 1-31, 2017, or (2) the member's ADV for the period of March 1-24, 2017.⁶
- Volume executed in options overlying Symbol CPN on February 27-28, 2017 will not be counted towards a member's tier for February activity.⁷

The operative dates for the pricing noted above has expired. The Exchange desires to remove the outdated text from its Fee Schedule to avoid confusion.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b)

³ See Securities Exchange Act Release No. 80101 (February 24, 2017), 82 FR 12380 (March 2, 2017) (SR-ISEGemini-2017-05).

⁴ See Options Trader Alert #2017-38.

⁵ This rule text was added to the Fee Schedule in connection with a pricing change. See Securities Exchange Act Release No. 80184 (March 9, 2017), 82 FR 13893 (March 15, 2017) (SR-ISEGemini-2017-09).

⁶ *Id.*

⁷ *Id.*

of the Act,⁸ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁹ in particular, in that it is designed to promote just and equitable principles of trade, 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, by removing outdated text in the Exchange's Rulebook and Fee Schedule which applied at one point in time and is no longer applicable. Removing the outdated text will avoid confusion as to its applicability.

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. The Exchange's proposal to remove the outdated text does not impose an undue burden on competition because the specified text does not apply to any market participant.

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

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁰ and subparagraph (f)(6) of Rule 19b-4 thereunder.¹¹

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 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-GEMX-2017-30 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-GEMX-2017-30. 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-GEMX-2017-30 and should be submitted on or before August 10, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2017-15192 Filed 7-19-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81148; File No. SR-ISE-2017-67]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Re-Letter Rulebook Definition

July 14, 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 July 5, 2017, Nasdaq ISE, LLC ("ISE" 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 correct a lettering issue with the ISE Rulebook.

The text of the proposed rule change is available on the Exchange's Web site at www.ise.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 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.

¹² 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(5).

¹⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

¹¹ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to correct a lettering reference in the ISE Rulebook. The Exchange recently added a new definition to Rule 715. The Exchange filed to add a new definition of Opening Sweep at Rule 715(t).³ The ISE Rulebook already has a definition at Rule 715(t) for QCC with Stock Orders. In light of the QCC with Stock Orders definition, the Exchange proposes re-lettering the Opening Sweep definition as Rule 715(u). The Exchange proposes to re-letter the Opening Sweep definition to avoid confusion in the Rulebook.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁴ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁵ in particular, in that it is designed to promote just and equitable principles of trade, 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, by re-lettering the Opening Sweep definition to avoid confusion in the Rulebook and will also permit market participants to reference the Opening Sweep definition.

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. The Exchange's proposal to re-letter the Opening Sweep definition will avoid confusion in the Rulebook.

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.

³ See Securities Exchange Act Release No. 80225 (March 13, 2017, 82 FR 14243 (March 17, 2017) (SR-ISE-2017-02) (Order Approving Proposed Rule Change, as Modified by Amendment No. 1, To Amend the Exchange Opening Process). The Exchange defined an Opening Sweep as a Market Maker order submitted for execution against eligible interest in the system during the Opening Process pursuant to Rule 701(b)(1).

⁴ 15 U.S.C. 78f(b).

⁵ 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act⁶ and subparagraph (f)(6) of Rule 19b-4 thereunder.⁷

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 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-ISE-2017-67 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-ISE-2017-67. 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/>

⁶ 15 U.S.C. 78s(b)(3)(A)(iii).

⁷ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-ISE-2017-67 and should be submitted on or before August 10, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2017-15193 Filed 7-19-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81149; File No. SR-IEX-2017-23]

Self-Regulatory Organizations: Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make a Clarifying Amendment to IEX Rule 16.135

July 14, 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 July 7, 2017, the Investors Exchange LLC filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to

⁸ 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.

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Securities Exchange Act of 1934 ("Act"),⁴ and Rule 19b-4 thereunder,⁵ Investors Exchange LLC ("IEX" or "Exchange") is filing with the Commission a proposed rule change to amend IEX Rule 16.135(b)(1) to clarify that the description in a proposal under Section 19(b) of the Act to list a series of Managed Fund Shares constitutes continued listing standards for such series of Managed Fund Shares.

The text of the proposed rule change is available at the Exchange's Web site at www.iextrading.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 the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements [sic] may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Overview

The Exchange proposes to amend IEX Rule 16.135(b)(1) to clarify that the description in a proposal under Section 19(b) of the Act to list a series of Managed Fund Shares constitutes continued listing standards for such series of Managed Fund Shares. The proposed rule change is substantially identical to a recent Nasdaq Stock Market ("Nasdaq") rule change.⁶

Specifically, the Exchange proposes to amend the applicability section of IEX Rule 16.135(b)(1) to specify that any of the statements or representations regarding not just the description of the

portfolio, but also of the reference assets, among other things, will constitute continued listing requirements for listing of shares. This revision will conform the language to current criteria in IEX Rule 16.135(d)(2)(C)(iv) with respect to criteria for IEX to consider the suspension of trading and initiation of delisting proceedings of a series of Managed Fund Shares under the IEX Rule Series 14.500.⁷

The Exchange does not currently list any Managed Fund Shares.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with Section 6(b)⁸ of the Act in general, and furthers the objectives of Section 6(b)(5) of the Act,⁹ in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed change to amend the applicability section of IEX Rule 16.135(b)(1) to specify that any of the statements or representations regarding not just the description of the portfolio, but also of the reference assets, among other things, will constitute continued listing requirements for listing of shares will provide clarity and accurately reflect the intent of the rule to the benefit of investors and the public interest.

Accordingly, based on the foregoing, the Exchange believes that the proposed rule change is consistent with Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change may enhance competition since it addresses an inconsistency in the applicability of listing standards applicable to Managed Fund Shares.

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 Exchange has designated this rule filing as non-controversial under Section 19(b)(3)(A)¹⁰ of the Act and Rule 19b-4(f)(6)¹¹ thereunder. Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6) 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 under Section 19(b)(2)(B)¹² 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-IEX-2017-23 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-IEX-2017-23. This file

⁴ 15 U.S.C. 78s(b)(1).

⁵ 17 CFR 240.19b-4.

⁶ See Securities Exchange Act Release No. 80810 (May 30, 2017), 82 FR 26205 (June 6, 2017) (SR-NASDAQ-2017-052).

⁷ See Securities Exchange Act Release No. 80545 (April 27, 2017), 82 FR 20648 (May 3, 2017) (SR-IEX-2017-03).

⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(5).

¹⁰ 15 U.S.C. 78s(b)(3)(A).

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 15 U.S.C. 78s(b)(2)(B).

number should be included in 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 Section, 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 will also be available for inspection and copying at the principal office of the Exchange and on its Internet Web site at www.iextrading.com. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-IEX-2017-23 and should be submitted on or before August 10, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2017-15194 Filed 7-19-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81145; File Nos. SR-BatsBZX-2017-37; SR-BatsEDGX-2017-23; SR-BOX-2017-17; SR-C2-2017-018; SR-CBOE-2017-041; SR-FINRA-2017-013; SR-ISE-2017-46; SR-IEX-2017-18; SR-MIAX-2017-20; SR-PEARL-2017-23; SR-NASDAQ-2017-055; SR-BX-2017-027; SR-PHLX-2017-43; SR-NYSE-2017-23; SR-NYSEArca-2017-57; SR-NYSEArca-2017-59; SR-NYSEMKT-2017-29; SR-NYSEMKT-2017-30]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Bats EDGX Exchange, Inc.; BOX Options Exchange LLC; C2 Options Exchange, Incorporated; Chicago Board Options Exchange, Incorporated; Financial Industry Regulatory Authority, Inc.; International Securities Exchange, LLC; Investors Exchange LLC; Miami International Securities Exchange LLC; MIAX PEARL, LLC; The NASDAQ Stock Market LLC; NASDAQ BX, Inc.; NASDAQ PHLX, Inc.; New York Stock Exchange LLC; NYSE Arca, Inc.; NYSE MKT LLC; Notice of Designation of Longer Period for Commission Action on Proposed Rule Changes To Eliminate Requirements That Will Be Duplicative of CAT

July 14, 2017.

On May 15, 2017, Bats BZX Exchange, Inc. ("Bats BZX"); Bats EDGX Exchange, Inc. ("Bats EDGX"); BOX Options Exchange LLC ("BOX"); C2 Options Exchange, Incorporated ("C2"); Chicago Board Options Exchange, Incorporated ("CBOE"); Financial Industry Regulatory Authority, Inc. ("FINRA"); International Securities Exchange, LLC ("ISE"); Investors Exchange LLC ("IEX"); Miami International Securities Exchange LLC ("MIAX"); MIAX PEARL, LLC ("PEARL"); NYSE Arca, Inc. ("NYSE Arca"); and NYSE MKT LLC ("NYSE MKT") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² proposed rule changes to eliminate or modify certain rules that require the collection or reporting of information that is duplicative of the information that will be collected by the Consolidated Audit Trail ("CAT") established pursuant to the National Market System Plan contemplated by Rule 613 of Regulation NMS.³ On May 22, 2017, the New York Stock Exchange LLC ("NYSE") filed with the Commission a proposed rule change for

the same purpose, and each of NYSE Arca and NYSE MKT filed an additional proposed rule change for the same purpose. On May 26, 2017,⁴ the NASDAQ Stock Market LLC ("NASDAQ") and NASDAQ PHLX LLC ("Phlx") filed with the Commission proposed rule changes for the same purpose. On May 30, 2017,⁵ NASDAQ BX, Inc. ("BX") filed with the Commission a proposed rule change for the same purpose. On June 1, 2017, the proposed rule changes submitted by Bats BZX, Bats EDGX, BOX, C2, CBOE, FINRA, IEX, ISE, MIAX, and PEARL; both proposed rule changes submitted by NYSE MKT; and one of the proposed rule changes submitted by NYSE Arca were published for comment in the **Federal Register**.⁶ On June 2, 2017, the proposed rule change submitted by NYSE and the other proposed rule change submitted by NYSE Arca were published for comment in the **Federal Register**.⁷ On June 5, 2017, the proposed rule changes submitted by NASDAQ, BX, and Phlx were published for comment in the **Federal Register**.⁸ Four

⁴ Nasdaq and Phlx initially filed proposed rule changes on May 15, 2017 (SR-NASDAQ-2017-050 and SR-PHLX-2017-38). On May 26, 2017, Nasdaq and Phlx withdrew these filings and submitted new proposed rule changes (SR-NASDAQ-2017-055 and SR-PHLX-2017-43) that remain pending before the Commission.

⁵ BX initially filed a proposed rule change on May 15, 2017 (SR-BX-2017-025). On May 30, 2017, BX withdrew that initial filing and submitted a new proposed rule change (SR-BX-2017-027) that remains pending before the Commission.

⁶ See Securities Exchange Act Release No. 80796 (May 26, 2017), 82 FR 25374 (SR-BatsBZX-2017-37); Securities Exchange Act Release No. 80795 (May 26, 2017), 82 FR 25358 (SR-BatsEDGX-2017-23); Securities Exchange Act Release No. 80789 (May 26, 2017), 82 FR 25492 (SR-BOX-2017-17); Securities Exchange Act Release No. 80798 (May 26, 2017), 82 FR 25385 (SR-C2-2017-018); Securities Exchange Act Release No. 80797 (May 26, 2017), 82 FR 25429 (SR-CBOE-2017-041); Securities Exchange Act Release No. 80783 (May 26, 2017), 82 FR 25423 (SR-FINRA-2017-013); Securities Exchange Act Release No. 80788 (May 26, 2017), 82 FR 25400 (SR-IEX-2017-18); Securities Exchange Act Release No. 80787 (May 26, 2017), 82 FR 25469 (SR-ISE-2017-46); Securities Exchange Act Release No. 80790 (May 26, 2017), 82 FR 25366 (SR-MIAX-2017-20); Securities Exchange Act Release No. 80792 (May 26, 2017), 82 FR 25436 (SR-PEARL-2017-23); Securities Exchange Act Release No. 80791 (May 26, 2017), 82 FR 25362 (SR-NYSEArca-2017-59); Securities Exchange Act Release No. 80793 (May 26, 2017), 82 FR 25443 (SR-NYSEMKT-2017-29); Securities Exchange Act Release No. 80794 (May 26, 2017), 82 FR 25439 (SR-NYSEMKT-2017-30).

⁷ See Securities Exchange Act Release No. 80799 (May 26, 2017), 82 FR 25635 (SR-NYSE-2017-23); Securities Exchange Act Release No. 80800 (May 26, 2017), 82 FR 25639 (SR-NYSEArca-2017-57).

⁸ See Securities Exchange Act Release No. 80813 (May 30, 2017), 82 FR 25863 (SR-NASDAQ-2017-055); Securities Exchange Act Release No. 80814 (May 30, 2017), 82 FR 25872 (SR-BX-2017-027); Securities Exchange Act Release No. 80811 (May 30, 2017), 82 FR 25863 (SR-PHLX-2017-43).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 17 CFR 242.613.

¹³ 17 CFR 200.30-3(a)(12).

comments were submitted to File No. SR-FINRA-2017-013.⁹ On June 22, 2017, each of NASDAQ, BX, ISE, and Phlx filed a technical amendment to its proposed rule change.¹⁰

Section 19(b)(2) of the Act¹¹ provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for the proposed rule changes published on June 1, 2017, is July 16, 2017. The 45th day for the proposed rule changes published on June 2, 2017, is July 17, 2017. The 45th day for the proposed rule changes published on June 5, 2017, is July 20, 2017.

The Commission is extending the 45-day time period for Commission action on each of the proposed rule changes. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule changes so that it has sufficient time to consider the comments received and any response to the comments that the self-regulatory organizations might provide.

Accordingly, pursuant to Section 19(b)(2)(A)(ii)(I) of the Act¹² and for the reasons stated above, the Commission designates August 30, 2017, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule changes (File Nos. SR-BatsBZX-2017-37; SR-BatsEDGX-2017-23; SR-BOX-2017-17; SR-C2-2017-018; SR-CBOE-2017-041; SR-FINRA-2017-013; SR-ISE-2017-46; SR-IEX-2017-18; SR-MIAX-2017-20; SR-PEARL-2017-23; SR-NASDAQ-2017-055; SR-BX-2017-027; SR-PHLX-2017-43; SR-NYSE-2017-23;

⁹ See letters from William H. Herbert, Managing Director, Financial Information Forum, dated June 22, 2017; Manisha Kimmel, Chief Regulatory Officer, Wealth Management, Thomson Reuters, dated June 22, 2017; Marc R. Bryant, Senior Vice President, Deputy General Counsel, Fidelity Investments, dated June 22, 2017; and Ellen Greene, Managing Director and Theodore R. Lazo, Managing Director and Associate General Counsel, SIFMA, dated June 23, 2017.

¹⁰ These amendments modified Section 2 of the Form 19b-4 submitted by each of NASDAQ, BX, ISE, and Phlx to state that on June 1, 2017, the exchange obtained the necessary approval from its Board of Directors for the proposed rule change.

¹¹ 15 U.S.C. 78s(b)(2).

¹² 15 U.S.C. 78s(b)(2)(A)(ii)(I).

SR-NYSEArca-2017-57; SR-NYSEArca-2017-59; SR-NYSEMKT-2017-29; SR-NYSEMKT-2017-30).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2017-15190 Filed 7-19-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81150; File Nos. SR-NYSE-2016-71 and SR-NYSEMKT 2016-99]

Self-Regulatory Organizations; New York Stock Exchange LLC; NYSE MKT LLC; Order Disapproving Proposed Rule Changes Amending Exchange Rule 104 To Delete Subsection (g)(i)(A)(III), Which Prohibits Designated Market Makers From Engaging in Transactions, During the Last Ten Minutes of Trading Before the Close, That Establish a New High (Low) Price for the Day on the Exchange in an Assigned Security in Which the DMM Has a Long (Short) Position

July 1, 2017.

I. Introduction

On October 27, 2016, New York Stock Exchange LLC (“NYSE”) and NYSE MKT LLC (“NYSE MKT”) (each an “Exchange,” and collectively the “Exchanges”) each filed with the Securities and Exchange Commission (“Commission”) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Exchange Act”) ¹ and Rule 19b-4 thereunder,² a proposed rule change amending its respective Rule 104 to delete subsection (g)(i)(A)(III)—“Prohibited Transactions.”³ Exchange Rule 104(g)(i)(A)(III) prohibits Designated Market Makers (“DMMs”) from engaging in a transaction that establishes, during the last ten minutes of trading before the close, a new high (low) price for the day on the Exchange in an assigned security in which the DMM has a long (short) position (“Prohibited Transactions Rule”). The

¹³ 17 CFR 200.30-3(a)(31).

¹⁴ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ This order refers to both NYSE Rule 104 and NYSE MKT Rule 104—Equities as “Exchange Rule 104.” NYSE MKT Rule 104—Equities is based on and, in relevant part, substantively identical to NYSE Rule 104. See Securities Exchange Act Release Nos. 58705 (Oct. 1, 2008), 73 FR 58995 (Oct. 8, 2008) (SR-Amex-2008-63) and 59022 (Nov. 26, 2008), 73 FR 73683 (Dec. 3, 2008) (amending NYSE MKT equity rules to conform to NYSE New Market Model Pilot rules).

proposed rule changes were published for comment in the **Federal Register** on November 17, 2016.⁴

On December 20, 2016, the Commission extended to February 15, 2017, the time period in which to approve or disapprove the proposed rule changes or to institute proceedings to determine whether to approve or disapprove the proposals.⁵ On February 15, 2017, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule changes.⁶ The Commission then received a comment letter, as well as a combined response letter from NYSE and NYSE MKT.⁷ On April 28, 2017, the Commission designated a longer period for Commission action on proceedings to determine whether to approve or disapprove the proposed rule changes.⁸ This order disapproves the proposed rule changes.

II. Description of the Proposals

Currently, under Exchange Rule 104(g)(i)(A)(III), a DMM with a long (short) position in an assigned security cannot, during the last ten minutes before the close of trading, make a purchase (sale) in that security that results in a new high (low) price on the Exchange for the day.⁹ The Prohibited Transactions Rule provides two exceptions that permit a DMM to: (1) Match another market’s better bid or offer price; or (2) bring the price of a security into parity with an underlying or related security or asset.¹⁰ The Exchanges propose to remove the Prohibited Transactions Rule from their rulebooks.

⁴ See Securities Exchange Act Release Nos. 79284 (Nov. 10, 2016), 81 FR 81222 (Nov. 17, 2016) (“NYSE Notice”) and 79283 (Nov. 10, 2016), 81 FR 81210 (Nov. 17, 2016) (“NYSE MKT Notice”).

⁵ See Securities Exchange Act Release Nos. 79612 (Dec. 20, 2016), 81 FR 95205 (Dec. 27, 2016) and 79611 (Dec. 20, 2016), 81 FR 95205 (Dec. 27, 2016).

⁶ See Securities Exchange Act Release Nos. 80044 (Feb. 15, 2017), 82 FR 11388 (Feb. 22, 2017) (“NYSE Order Instituting Proceedings”) and 80043 (Feb. 15, 2017), 82 FR 11379 (Feb. 22, 2017) (“NYSE MKT Order Instituting Proceedings”) (collectively, the “Orders Instituting Proceedings”).

⁷ See Letter from Stephen John Berger, Managing Director, Government and Regulatory Policy, Citadel Securities, to Brent J. Fields, Secretary, Commission (Mar. 15, 2017) (“Citadel Letter”); Letter from Elizabeth K. King, General Counsel and Corporate Secretary, NYSE, to Brent J. Fields, Secretary, Commission (Mar. 16, 2017) (“NYSE Letter”). The Citadel Letter addressed only the NYSE proposal, which is substantively identical to the NYSE MKT proposal. The NYSE Letter was submitted on behalf of both NYSE and NYSE MKT.

⁸ See Securities Exchange Act Release Nos. 80552 (Apr. 28, 2017), 82 FR 20927 (May 4, 2017) and 80550 (Apr. 28, 2017), 82 FR 20926 (May 4, 2017).

⁹ See Exchange Rule 104(g)(i)(A)(III).

¹⁰ See *id.*; see also Exchange Rule 104(g)(i)(A)(II)(2)(i).

The Exchanges assert that, in light of developments in the equity markets and in their trading model, the Prohibited Transactions Rule has lost its original purpose and utility.¹¹ Specifically, the Exchanges assert that in today's electronic marketplace—where DMMs have replaced specialists and control of pricing decisions has moved away from market participants on the Exchange trading floor—the Prohibited Transactions Rule is no longer necessary.¹² According to the Exchanges, eliminating the Prohibited Transactions Rule would not eliminate other existing safeguards that prevent DMMs from inappropriately influencing or manipulating the close.¹³

The Exchanges assert that the rationale behind the Prohibited Transactions Rule—preventing specialists from setting the price of a security on the Exchange in the final ten minutes of trading—was to prevent a specialist from inappropriately influencing the price of a security at the close to advantage the specialist's proprietary position.¹⁴ According to the Exchanges, in today's fragmented marketplace, a new high (low) price for a security on one of the Exchanges in the last ten minutes of trading does not have a significant effect on the market price for that security, because a new high (low) price on one of the Exchanges may not be the new high (low) market-wide price for a security—prices may be higher (lower) in away markets, where the majority of intra-day trading in Exchange-listed securities takes place—and because any advantage to a DMM from establishing a new high or low on the Exchange during the last ten minutes can rapidly evaporate following trades in away markets.¹⁵ The Exchanges assert that, because DMMs do not have the ability to direct or influence trading or to control intra-day prices that specialists had before the implementation of Regulation NMS, the Prohibited Transactions Rule is anachronistic.¹⁶

III. Summary of Comment Letter and the Exchanges' Response

The Commission received one comment letter in support of the NYSE proposal and a combined response letter

from NYSE and NYSE MKT.¹⁷ The commenter asserts that the Prohibited Transactions Rule is no longer necessary. First, the commenter states that, when the Prohibited Transactions Rule was originally adopted, structural advantages enjoyed by NYSE specialists—including a dominant position in NYSE-listed securities and an advance look at incoming orders—warranted imposing prescriptive limitations on their trading activities, particularly at certain critical pricing points during the day, such as the pre-closing period.¹⁸ The commenter states that, because DMMs no longer have these same structural advantages, and because DMMs do not have the dominant position that NYSE specialists once had in the trading of NYSE-listed securities, DMMs should be able to engage in the sorts of transactions barred under the Prohibited Transactions Rule.¹⁹

Second, the commenter states that the Prohibited Transactions Rule is unnecessary because existing NYSE and Commission rules “prohibit all market participants, including DMMs, from engaging in market manipulation, including around the close.”²⁰ Finally, the commenter states that the Prohibited Transactions Rule is “artificial” and creates an “uneven playing field” in the current market structure because it only prohibits trading activity on a single exchange.²¹ According to the commenter, this restriction affects a DMM's ability to provide competitive quotations during the last ten minutes of trading, thereby hindering price discovery, reducing liquidity at NYSE, and causing trading activity to migrate to venues where participants are not subject to the same artificial restriction.²²

According to NYSE and NYSE MKT, in today's electronic marketplace, where increased automation of trading has decentralized control of pricing decisions away from the DMM and from other market participants on the

Exchanges' trading floor, retaining the Prohibited Transactions Rule is no longer necessary.²³ NYSE and NYSE MKT believe that the Prohibited Transactions Rule is anachronistic because DMMs do not have the same ability to direct or influence trading or control intra-day prices that specialists had before Regulation NMS.²⁴ Further, NYSE and NYSE MKT assert that the proposal does not alter the existing balance of DMM benefits and obligations because, despite the elimination of the Prohibited Transactions Rule, remaining DMM obligations would be sufficient to safeguard against the possibility that DMMs may act to inappropriately influence prices or manipulate the close.²⁵ Finally, NYSE and NYSE MKT state that the Exchanges would use their existing suite of trading surveillances to assess whether a particular transaction was effectuated to manipulate a security's price going into the close to benefit the DMM's position.²⁶

IV. Discussion and Commission Findings

Under Section 19(b)(2)(C) of the Exchange Act,²⁷ the Commission shall approve a proposed rule change by a self-regulatory organization if the Commission finds that the proposed rule change is consistent with the requirements of the Exchange Act and the applicable rules and regulations thereunder.²⁸ The Commission shall disapprove a proposed rule change if it does not make such a finding.²⁹ The Commission's Rules of Practice, under Rule 700(b)(3), state that the “burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization that proposed the rule change” and that a “mere assertion that the proposed rule change is consistent with those requirements . . . is not sufficient.”³⁰

²³ See NYSE Letter, *supra* note 7, at 3.

²⁴ See *id.*

²⁵ See *id.* at 3–6. The Exchanges state that these obligations include the obligations: (1) Not to destabilize the market when buying or selling to increase a position or reaching across the market; (2) to facilitate the close; (3) to effect transactions in a reasonable and orderly manner; and (4) to refrain from causing or exacerbating excessive price movements. See *id.*

²⁶ See *id.* at 5.

²⁷ 15 U.S.C. 78s(b)(2)(C).

²⁸ See 15 U.S.C. 78s(b)(2)(C)(i).

²⁹ See 15 U.S.C. 78s(b)(2)(C)(ii).

³⁰ 17 CFR 201.700(b)(3). The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative

¹¹ See NYSE Notice, *supra* note 4, 81 FR at 81223; NYSE MKT Notice, *supra* note 4, 81 FR at 81211.

¹² See NYSE Notice, *supra* note 4, 81 FR at 81222; NYSE MKT Notice, *supra* note 4, 81 FR at 81212.

¹³ See NYSE Notice, *supra* note 4, 81 FR at 81222–23; NYSE MKT Notice, *supra* note 4, 81 FR at 81212.

¹⁴ See NYSE Notice, *supra* note 4, 81 FR at 81223; NYSE MKT Notice, *supra* note 4, 81 FR at 81211.

¹⁵ See *id.*

¹⁶ See *id.*

¹⁷ See *supra* note 7. While Citadel submitted its letter solely to the NYSE proposal, the Commission will consider the comment letter to be applicable to the NYSE MKT proposal, as both proposals are substantively identical.

¹⁸ See Citadel Letter, *supra* note 7, at 1–3.

¹⁹ See *id.* The commenter states that, for example, in February 2017, NYSE market share for NYSE-listed stocks was approximately 24% including auctions and 19% excluding auctions. See *id.* at 2. The commenter further states that, during the same month, a stock in which NYSE is the primary exchange and the DMM is the commenter, NYSE market share during the last ten minutes was approximately 27% on a share-weighted basis. See *id.*

²⁰ *Id.* at 3.

²¹ See *id.* at 3–4.

²² See *id.*

After careful consideration of the proposals, and for the reasons discussed below, the Commission does not believe that the proposed rule changes are consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.³¹ Specifically, the Commission does not find that the proposals are consistent with Section 6(b)(5) of the Exchange Act, which, among other things, requires that the rules of a national securities exchange not be designed to permit unfair discrimination and that those rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, 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.³²

The Exchanges propose to eliminate the Prohibited Transactions Rule—a negative obligation imposed on DMMs to restrict aggressive trading immediately before the close—and the Commission analyzes the proposed rule changes in the context of the unique role played by DMMs on the Exchanges. Because the Exchanges' proposal would alter the balance of the benefits and obligations of DMMs, and in light of the special responsibilities that DMMs have for the closing auction on the Exchanges, the Commission sought comment in the Orders Instituting Proceedings on these topics. Specifically, the Commission asked for public comment on whether each Exchange's proposal "would maintain an appropriate balance between the benefits and obligations of being a DMM on the Exchange and whether the obligations of DMMs under remaining Exchange rules are reasonably designed to prevent DMMs from inappropriately influencing or manipulating the close in light of DMMs' special responsibility for closing auctions under Exchange rules."³³

Commission finding. *See id.* Any failure of a self-regulatory organization to provide the information elicited by Form 19b-4 may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder that are applicable to the self-regulatory organization. *See id.*

³¹ In disapproving the proposed rule changes, the Commission has considered the proposed rules' impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

³² *See* 15 U.S.C. 78f(b)(5).

³³ NYSE Order Instituting Proceedings, *supra* note 6, 82 FR at 11389; NYSE MKT Order Instituting Proceedings, *supra* note 6, 82 FR at 11380.

The Prohibited Transactions Rule was originally adopted by NYSE in 2006 as NYSE moved to its "hybrid market" model,³⁴ and NYSE retained Prohibited Transactions Rule in 2008, when it adopted its New Market Model, which replaced the specialists on its floor with DMMs.³⁵ NYSE MKT subsequently adopted the NYSE's New Market Model, including the Prohibited Transactions Rule, pursuant to its merger with the NYSE.³⁶

Exchange Rule 104 sets forth the obligations of DMMs on each Exchange, which include the affirmative obligation to engage in a course of dealings for their own account to assist in the maintenance of a fair and orderly market in securities for which they have been assigned responsibility as the DMM, to maintain quotes in their assigned securities at the inside market a specified percentage of time, and to facilitate certain transactions in their assigned securities, most notably the opening and closing auctions.³⁷ Under Exchange rules, DMMs have significant responsibilities to "facilitate the close of trading" in their assigned securities.³⁸ The closing price for a security on its listing exchange is widely used as a reference price (e.g., by mutual funds calculating their net asset value), and the listing exchange tends to have a dominant market share at the close.³⁹

Supporting these general obligations, Exchange Rules 104(g) and 104(h) regulate specific types of DMM transactions: Neutral Transactions, Non-Conditional Transactions, Conditional Transactions, and Prohibited Transactions.⁴⁰ DMMs may engage in

³⁴ *See* Securities Exchange Act Release No. 54860 (Dec. 1, 2006), 71 FR 71221 (Dec. 8, 2006) (SR-NYSE-2006-76) (order approving amendments to Rule 104 that included Prohibited Transactions in Supplementary Material .10 of Rule 104).

³⁵ *See* Securities Exchange Act Release No. 58845 (Oct. 24, 2008), 73 FR 64379 (Oct. 29, 2008) (SR-NYSE-2008-46) (order approving New Market Model pilot program).

³⁶ *See* Securities Exchange Act Release No. 75952 (Sept. 18, 2015), 80 FR 57645, 57646 & n.6 (Sept. 24, 2015) (describing filings by which NYSE MKT adopted NYSE equity trading rules).

³⁷ *See* Exchange Rule 104.

³⁸ *See* Exchange Rule 104; NYSE Rule 123C; NYSE MKT Rule 123C—Equities.

³⁹ *See, e.g.,* NYSE Opening and Closing Auctions Fact Sheet (stating that NYSE has a 100% market share in the closing auction for Tape A securities), https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Opening_and_Closing_Auctions_Fact_Sheet.pdf.

⁴⁰ *See* Exchange Rule 104(g)(i)(A)(I)–(III) (defining Neutral Transactions, Non-Conditional Transactions, and Prohibited Transactions); Exchange Rule 104(h)(i) (defining Conditional Transaction). A Neutral Transaction is a purchase or sale by which a DMM liquidates or decreases a position and may be made without regard to price, but the DMM's "obligation to maintain a fair and orderly market may require re-entry on the opposite

side of the market trend . . . in accordance with the immediate and anticipated needs of the market." *See* Exchange Rule 104(g)(i)(A)(I). A Non-Conditional Transaction is a DMM's bid or purchase and offer or sale that establishes or increases a position, other than a transaction that reaches across the market to trade with the Exchange best bid or offer, and may be made without regard to price in order to match another market's better bid or offer price; to bring the price of a security into parity with an underlying or related security or asset; to add size to an independently established bid or offer on the Exchange; to purchase at the published bid price on the Exchange; to sell at the published offer price on the Exchange; to purchase or sell at a price between the Exchange BBO; or to purchase below the published bid or sell above the published offer on the Exchange. *See* Exchange Rule 104(g)(i)(A)(II). Following a Non-Conditional Transaction, a DMM's obligation to maintain a fair and orderly market "may require re-entry on the opposite side of the market trend . . . commensurate with the size of the Non-Conditional Transactions and the immediate and anticipated needs of the market." *Id.*

Conditional Transactions throughout the trading day—generally, crossing the market to take liquidity by buying (selling) at an increasing (decreasing) price—if those transactions are followed by "appropriate" re-entry on the opposite side of the market "commensurate with the size of the DMM's transaction."⁴¹ During the last ten minutes of the day, however, DMMs are subject to the Prohibited Transactions Rule at issue here—a bright-line rule against aggressively taking liquidity and moving prices on the exchange immediately before the closing auction.⁴²

In return for their obligations and responsibilities, DMMs have significant priority and informational advantages in trading on the Exchanges, both during continuous trading and during the closing auction. During continuous trading, DMMs trade on parity with the entire order book and with floor brokers, which "provides DMMs with a substantial advantage over off-Floor orders" sent to the NYSE order book.⁴³ Moreover, during the trading day, including the ten minutes before the close, DMMs have unique access to aggregated information about closing auction interest at each price level, and, during the auction itself, DMMs are

⁴¹ *See* Exchange Rule 104(h)(i)–(iv). According to their rules, the Exchanges periodically issue guidelines, called "price participation points" that "identify the price at or before which a DMM is expended to re-enter the market after effecting a Conditional Transaction." *See* Exchange Rule 104(h)(iii)(A).

⁴² *See* Exchange Rule 104(g)(i)(A)(III).

⁴³ *See* Securities Exchange Act Release No. 58845 (Oct. 24, 2008), 73 FR 64379, 64389 (Oct. 29, 2008) (Order approving SR-NYSE-2008-46). *See also* NYSE Rule 72(c)(ii) and NYSE MKT Rule 72(c)(ii)—Equities (stating that, for the purpose of share allocation in an execution, each single floor broker, the DMM, and orders on the Exchange book shall constitute individual participants and that the orders on the Exchange book shall constitute a single participant).

aware of interest represented by floor brokers, which is not publicly disseminated.⁴⁴ When offsetting an imbalance during the closing auction, DMM interest trades at parity with limit orders on the Exchange order book, and DMM interest takes priority over limit-on-close orders with a price equal to the closing price and over closing-offset orders.⁴⁵ In approving the entire set of advantages given to DMMs in 2008 through the New Market Model, the Commission specifically assessed “whether the rewards granted to DMMs . . . are commensurate with their obligations” and found that the proposed New Market Model pilot reflected “an appropriate balance of DMM obligations against the benefits provided to DMMs.”⁴⁶

In proposing to remove the Prohibited Transactions Rule, however, NYSE and NYSE MKT have failed to adequately explain or justify how the proposed alteration to the balance of benefits and obligations of a DMM previously approved by the Commission is consistent with Section 6(b)(5) of the Exchange Act, or how allowing DMMs to aggressively take liquidity in the last ten minutes of trading is both consistent with a DMM’s obligation to maintain a fair and orderly market in its assigned securities and designed to prevent fraudulent or manipulative acts and practices regarding the closing auction, for which a DMM has crucial responsibilities.

The Exchanges and Citadel in their comment letters argue that changes in market structure such as the inability of DMMs, compared to specialists, to “set prices” in their assigned securities, and the movement of trading volume in NYSE-listed securities away from the NYSE, support the elimination of the Prohibited Transactions Rule. But, as noted above, the Prohibited Transactions Rule was included in the New Market Model rule filing that established the role of DMMs, and the market-share statistics offered by Citadel—which purportedly establish the relatively weak pricing power of a DMM⁴⁷—fail to acknowledge that the Exchanges have a dominant market share in the closing auction,⁴⁸ and that a DMM has discretion and informational advantages that place the DMM in a unique position to choose its own level

of participation in the auction and to influence the closing price.⁴⁹ Additionally, the argument by Citadel that the current prohibition creates an uneven playing field, and that it limits DMMs’ “ability to provide competitive quotations,”⁵⁰ fails to address that DMMs have unique privileges on NYSE and NYSE MKT and that the proposed rule change is not limited to circumstances in which DMMs would be allowed to quote competitively and provide liquidity, but would also allow them to aggressively take liquidity.

Additionally, while NYSE and NYSE MKT have argued that the proposal is consistent with the Exchange Act because remaining exchange rules address the possibility of disruptive or improper DMM trading during the last ten minutes of the day, the Commission does not believe that NYSE and NYSE MKT have met their burden to demonstrate that these other rules—which require the exercise of judgment as to what is “reasonable,” “excessive,” “appropriate,” or “commensurate”⁵¹—are adequate substitutes for a clear, meaningful, and enforceable bright-line rule that limits aggressive DMM trading at a particularly sensitive and important time of the trading day and that addresses the risk of destabilizing or even manipulative activity. Additionally, the Commission believes that NYSE and NYSE MKT have merely asserted that, but not explained how, existing surveillances can act as an adequate substitute for this bright-line rule.

Thus, because the Exchanges’ arguments in favor of the proposed rule changes do not adequately address significant issues raised by the proposals, the Commission does not find that the proposed rule changes are consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, with Section 6(b)(5) of the Exchange Act.

V. Conclusion

It is therefore ordered that, pursuant to Section 19(b)(2) of the Exchange Act,⁵² the proposed rule changes (SR–NYSE–2016–71 and SR–NYSEMKT–2016–99) be, and hereby are, *disapproved*.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵³

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2017–15195 Filed 7–19–17; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Delegation of Authority: 437]

Delegation of Authority to the Director of the Office of U.S. Foreign Assistance Resources To Concur in Assistance Programs

By virtue of the authority vested in the Secretary of State, including section 1 of the State Department Basic Authorities Act (22 U.S.C. 2651a) and 10 U.S.C. 333, I hereby delegate to the Director the Office of U.S. Foreign Assistance Resources, to the extent authorized by law, the authority to concur in programs authorized by section 333 of title 10 of the U.S. Code.

Notwithstanding this delegation of authority, any function or authority delegated herein may be exercised by the Secretary or a Deputy Secretary. Any reference in this delegation of authority to any statute or delegation of authority shall be deemed to be a reference to such statute or delegation of authority as amended from time to time.

This delegation of authority shall be published in the **Federal Register**.

Dated: May 1, 2017.

Rex W. Tillerson,

Secretary of State.

[FR Doc. 2017–15226 Filed 7–19–17; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF STATE

[Public Notice: 10062]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition Determinations: “Delirious: Art at the Limits of Reason, 1950–1980” Exhibition

Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No.

⁵³ 17 CFR 200.30–3(a)(12).

⁴⁴ See Exchange Rule 104(j); see also NYSE Rule 123C and NYSE MKT Rule 123C—Equities.

⁴⁵ See NYSE Rule 123C(7)(b); NYSE MKT Rule 123C(7)(b)—Equities.

⁴⁶ Securities Exchange Act Release No. 58845 (Oct. 24, 2008), 73 FR 64379, 64388–89 (Oct. 29, 2008) (SR–NYSE–2008–46).

⁴⁷ See Citadel Letter, *supra* note 7, at 2.

⁴⁸ See *supra* note 39 and accompanying text.

⁴⁹ See *supra* notes 42–44 and accompanying text.

⁵⁰ Citadel Letter, *supra* note 7, at 2–3.

⁵¹ See *supra* notes 25 & 40 and accompanying text.

⁵² 15 U.S.C. 78s(b)(2).

257–1 of December 11, 2015), I hereby determine that certain objects to be included in the exhibition “Delirious: Art at the Limits of Reason, 1950–1980,” imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art, New York, New York, from on or about September 12, 2017, until on or about January 14, 2018, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Alyson Grunder,

Deputy Assistant Secretary for Policy, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2017–15214 Filed 7–19–17; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 33 (Sub-No. 333X)]

Union Pacific Railroad Company— Discontinuance Exemption—in Grundy County, IL

Union Pacific Railroad Company (UP) has filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue service over a 2.85-mile portion of the Pequot Subdivision from milepost 56.85, along BNSF’s Transcon Line, to Reed Road at milepost 59.70 (the Line). The Line traverses United States Postal Service Zip Codes 60416 and 60407.

UP has certified that: (1) No local or overhead traffic has moved over the Line for at least two years; (2) there is no need to reroute any traffic over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line is pending either with the Surface Transportation Board (Board) or with

any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) to subsidize continued rail service has been received, this exemption will be effective on August 19, 2017, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2)¹ must be filed by July 28, 2017.² Petitions for reconsideration must be filed by August 9, 2017, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to Mack H. Shumate, Jr., Union Pacific Railroad Company, 101 North Wacker Drive, Room 1920, Chicago, IL 60606.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available on our Web site at WWW.STB.GOV.

Decided: July 14, 2017.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Rena Laws-Byrum,

Clearance Clerk.

[FR Doc. 2017–15115 Filed 7–19–17; 8:45 am]

BILLING CODE 4915–01–P

¹ Each OFA must be accompanied by the filing fee, which is currently set at \$1,700. See 49 CFR 1002.2(f)(25).

² Because this is a discontinuance proceeding and not an abandonment, interim trail use/rail banking and public use conditions are not appropriate. Because there will be an environmental review during abandonment, this discontinuance does not require an environmental review.

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2017–0027]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: FHWA invites public comments about our intention to request the Office of Management and Budget’s (OMB) approval for a new information collection, which is summarized below under **SUPPLEMENTARY INFORMATION**. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on June 19, 2017. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by August 21, 2017.

ADDRESSES: You may send comments within 30 days to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention DOT Desk Officer. All comments should include the Docket number FHWA–2017–0027.

FOR FURTHER INFORMATION CONTACT:

Bruce Bradley, 202–493–0564, Department of Transportation, Federal Highway Administration, Office of Real Estate Services, 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 8 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA’s performance; (2) the accuracy of the estimated burden; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information.

Title: FHWA Excellence in Right-of-Way Awards and Utility Relocation and Accommodation Awards.

Background: In 1995, the Federal Highway Administration established the biennial Excellence in Right-of-Way Awards Program to recognize partners, projects, and processes that use FHWA funding sources to go beyond regulatory compliance and achieve right-of-way

excellence. Excellence in Right-of-Way awardees have contributed to outstanding innovations that enhance the right-of-way professional's ability to meet the challenges associated with acquiring real property for Federal-aid projects.

Similarly, FHWA established the Excellence in Utility Relocation and Accommodation Awards Program to honor the use of innovative practices and outstanding achievements in reducing the cost or shortening the time required to accommodate or relocate utilities associated with highway improvement projects. The goal of the program is to showcase exemplary and innovative projects, programs, initiatives, and practices that successfully integrate the consideration of utilities in the planning, design, construction, and maintenance of transportation facilities.

Award: Anyone can nominate a project, process, person or group that has used Federal Highway Administration funding sources to make an outstanding contribution to transportation and the right-of-way or utility fields. The nominator is responsible for submitting via email, fax, or mail an application form that summarizes the outstanding accomplishments of the entry. FHWA will use the collected information to evaluate, showcase, and enhance the public's knowledge on addressing right-of-way challenges on transportation projects and on relocating and accommodating utilities associated with highway improvement projects. Nominations will be reviewed by an independent panel of judges from varying backgrounds. It is anticipated that awards will be given every two years. The winners are presented plaques at an awards ceremony.

Respondents: Anyone who has used Federal Highway funding sources in the fifty states, the District of Columbia and Puerto Rico.

Frequency: The information will be collected biennially.

Estimated Average Burden per Response: 6 hours per respondent per application.

Estimated Total Annual Burden

Hours: It is expected that the respondents will complete approximately 50 applications for an estimated total of 600 annual burden hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to

enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued on: June 11, 2017.

Michael Howell,

Information Collection Officer.

[FR Doc. 2017-15186 Filed 7-19-17; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by the California Department of Transportation (Caltrans), pursuant to 23 U.S.C. 327.

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final. The actions relate to a proposed highway project, State Route 242/Clayton Road Ramps Project, on State Route 242, in the City of Concord, in the County of Contra Costa, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(J)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before December 18, 2017. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: California Department of Transportation, Attn: Cristin Hallissy, Environmental Branch, Chief Office of Environmental Analysis, MS-8B, 111 Grand Avenue, Oakland, CA 94612, (510) 622-8717, cristin.hallissy@dot.ca.gov, Normal Office Hours: 9-5, M-F.

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and

the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that the Caltrans has taken final agency actions subject to 23 U.S.C. 139(J)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: State Route (SR) 242/Clayton Road Ramps Project: Caltrans proposes to modify the existing partial interchanges at SR 242 at Clayton Road and Concord Avenue, in the City of Concord. The SR 242/Clayton Road interchange would be reconfigured from a partial interchange to provide new northbound and southbound SR 242 on- and off-ramps. Proposed local roadway improvements include a combination of additional travel lanes and the extension of left-turn pockets on Willow Pass Road, Concord Avenue, Franquette Avenue, Clayton Road, Market Street, and Commerce Avenue, in the City of Concord. The project will relieve local street congestion. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Initial Study with Negative Declaration/Environmental Assessment with Finding of No Significant Impact (IS-ND/EA-FONSI) for the project, approved on December 27, 2016, in the Caltrans Finding of No Significant Impact (FONSI) also issued on December 27, 2016, and in other documents in the Caltrans project records. The IS-ND/EA-FONSI and other project records are available by contacting Caltrans at the addresses provided above. The Caltrans IS-ND/EA-FONSI can be viewed and downloaded from the project Web site at <http://www.dot.ca.gov/dist4/envdocs.htm>, or viewed at public libraries in the project area.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) (42 U.S.C. 4321-4351 *et seq.*).
2. Council on Environmental Quality Regulations.
3. Federal-Aid Highway Act of 1970, 23 U.S.C. 109.
4. Clean Air Act (42 U.S.C. 7401-7671(q)).
5. Migratory Bird Treaty Act (16 U.S.C. 703-712).
6. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended, (16 U.S.C. 470(f) *et seq.*).
7. Clean Water Act (Section 401) (33 U.S.C. 1251-1377) of 1977 and 1987

(Federal Water Pollution Control Act of 1972).

8. Federal Endangered Species Act of 1973 (16 U.S.C. 1531–1543).

9. Noise Control Act of 1972.

10. Executive Order 12898, Federal Actions to Address Environmental Justice and Low-Income Populations.

11. Title VI of the Civil Rights Act of 1964, as amended.

12. Fair Housing Law (Title VIII of the Civil Right Act of 1968).

13. Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970.

14. Department of Transportation Act of 1966, Section 4(f) (49 U.S.C. 303).

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: July 14, 2017.

Larry Vinzant,

*Senior Environmental Protection Specialist,
Federal Highway Administration,
Sacramento, California.*

[FR Doc. 2017–15221 Filed 7–19–17; 8:45 am]

BILLING CODE 4910-RY-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2017–0128]

Agency Information Collection

Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below under **SUPPLEMENTARY INFORMATION**. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on June 19, 2017. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by August 21, 2017.

ADDRESSES: You may send comments within 30 days to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention DOT Desk Officer. All

comments should include the Docket number FHWA–2017–0128.

FOR FURTHER INFORMATION CONTACT: John Moulden, 202–493–3470, Turner-Fairbank Highway Research Center, Office of Corporate Research, Technology, and Innovation Management, Federal Highway Administration, Department of Transportation, 6300 Georgetown Pike, McLean, VA 22101. Office hours are from 8 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burden; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information.

Title: Federal Highway Administration Research, Development and Technology Agenda Web site.

Background: Title 23, United States Code, Section 502(a)(5) requires that Federal surface transportation research and development activities address the needs of stakeholders, including “States, metropolitan planning organizations, local governments, the private sector, researchers, research sponsors, and other affected parties, including public interest groups.” As part of its effort to ensure that Federal research, development and technology (RD&T) activities are addressing the most critical national challenges, the Federal Highway Administration (FHWA) is developing the RD&T Agenda Web site. This Web site will communicate FHWA's RD&T goals, objectives and strategies to its stakeholders and highlight notable initiatives or projects that illustrate FHWA's RD&T approach. The Web site will include an electronic mechanism for stakeholders to provide feedback on the overall RD&T Agenda, FHWA's approach to addressing national transportation challenges, and potential opportunities for FHWA to collaborate with stakeholders to address them.

Respondents: Approximately 1,000 annual respondents.

Frequency: Annually.

Estimated Average Burden per Response: Approximately 10 minutes per respondent per year.

Estimated Total Annual Burden Hours: Approximately 167 hours per year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued on: June 11, 2017.

Michael Howell,

Information Collection Officer.

[FR Doc. 2017–15184 Filed 7–19–17; 8:45 am]

BILLING CODE 4910–22-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2017–0029]

Agency Information Collection

Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below under **SUPPLEMENTARY INFORMATION**. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on June 19, 2017. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by August 21, 2017.

ADDRESSES: You may send comments within 30 days to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention DOT Desk Officer. All comments should include the Docket number FHWA–2017–0029.

FOR FURTHER INFORMATION CONTACT: Mark Ferroni, 202–366–3233, Office of Planning, Environment, and Realty, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 6:00 a.m. to 3:30 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burden; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information.

Title: Noise Barrier Inventory.

Background: The basis of the Federal-aid highway program is a strong federal-state partnership. At the core of that partnership is a philosophy of trust and flexibility, and a belief that the states are in the best position to make investment decisions and that states base these decisions on the needs and priorities of their citizens. The FHWA noise regulation (23 CFR 772) gives each state department of transportation (SDOT) flexibility to determine the feasibility and reasonableness of noise abatement by balancing of the benefits of noise abatement against the overall adverse social, economic, and environmental effects and costs of the noise abatement measures. The SDOT must base its determination on the interest of the overall public good, keeping in mind all the elements of the highway program (need, funding, environmental impacts, public involvement, etc.).

Reduction of highway traffic noise should occur through a program of shared responsibility with the most effective strategy being implementation of noise compatible planning and land use control strategies by state and local governments. Local governments can use their power to regulate land development to prohibit noise-sensitive land use development adjacent to a highway, or to require that developers plan, design, and construct development in ways that minimize noise impacts. The FHWA noise regulations limit Federal participation in the construction of noise barriers along existing highways to those projects proposed along lands where land development or substantial construction predated the existence of any highway.

The data reflects the flexibility in noise abatement decision-making. Some states have built many noise barriers while a few have built none. Through the end of 2010, 47 SDOTs and the Commonwealth of Puerto Rico have constructed over 2,748 linear miles of barriers at a cost of over \$4.05 billion (\$5.44 billion in 2010 dollars). Three states and the District of Columbia have not constructed noise barriers. Ten SDOTs account for approximately sixty-two percent (62%) of total barrier length and sixty-nine percent (69%) of total barrier cost. The type of information requested can be found in 23CFR772.13(f).

The previously distributed listing can be found at http://www.fhwa.dot.gov/environment/noise/noise_barriers/inventory/summary/sintro7.cfm.

This listing continues to be extremely useful in the management of the highway traffic noise program, in our

technical assistance efforts for State highway agencies, and in responding to inquiries from congressional sources, Federal, State, and local agencies, and the general public. An updated listing of noise barriers will be distributed nationally for use in the highway traffic noise program. It is anticipated that this information will be requested in 2014 (for noise barriers constructed in 2011, 2012 and 2013) and then again in 2017 (for noise barriers constructed in 2014, 2015 and 2016). After review of the "Summary of Noise Barriers Constructed by December 31, 2004" document, a SDOT may request to delete, modify or add information to any calendar year.

Respondents: Each of the 50 SDOTs, the District of Columbia, and the Commonwealth of Puerto Rico.

Frequency: Every 3 years.

Estimated Average Burden per Response: It is estimated that on average it would take 8 hours to respond to this request.

Estimated Total Annual Burden Hours: It is estimated that the estimated total annual burden is 139 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49CFR 1.48.

Issued on: July 11, 2017.

Michael Howell,

Information Collection Officer.

[FR Doc. 2017-15183 Filed 7-19-17; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA-2017-0026]

Agency Information Collection Activities: Notice of Request for Extension of Currently Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that FHWA will submit the collection of information described below to the Office of Management and Budget (OMB) for review and comment. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 19, 2017. The PRA submission describes the nature of the information collection and its expected cost and burden.

DATES: Please submit comments by August 21, 2017.

ADDRESSES: You may submit comments identified by DOT Docket ID 2017-0026 by any of the following methods:

Web site: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Fax: 1-202-493-2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Michael Dougherty, 202-366-9234, Department of Transportation, Federal Highway Administration, Office of Highway Policy Information, 1200 New Jersey Avenue SE., Washington, DC 20590, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Certification of Enforcement of the Heavy Vehicle Use Tax.

OMB Control #: 2125-0541.

Background: Title 23 United States Code, Section 141(c), provides that a State's apportionment of funds under 23 U.S.C. 104(b)(1) shall be reduced in an amount up to 8 percent of the amount to be apportioned during any fiscal year beginning after September 30, 1984, if vehicles subject to the Federal heavy vehicle use tax are lawfully registered in the State without having presented proof of payment of the tax. The annual certification by the State Governor or designated official regarding the collection of the heavy vehicle use tax serves as the FHWA's primary means of

determining State compliance. The FHWA has determined that an annual certification of compliance by each State is the least obtrusive means of administering the provisions of the legislative mandate. In addition, States are required to retain for 1 year a Schedule 1, IRS Form 2290, Heavy Vehicle Use Tax Return (or other suitable alternative provided by regulation). The FHWA conducts compliance reviews at least once every 3 years to determine if the annual certification is adequate to ensure effective administration of 23 U.S.C. 141(c).

The estimated annual reporting burden is 102 hours; the estimated recordkeeping burden is 510 hours for a total of 612 hours. The 50 States and the District of Columbia share this burden. Preparing and processing the annual certification is estimated to require 2 hours per State. Recordkeeping is estimated to require an average of 10 hours per State.

Respondents: 50 State Transportation Departments, and the District of Columbia for a total of 51 respondents.

Frequency: Annually.

Estimated Average Annual Burden per Response: The average burden to submit the certification and to retain required records is 12 hours per respondent.

Estimated Total Annual Burden Hours: Total estimated average annual burden is 612 hours.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued on: July 11, 2017.

Michael Howell,

Information Collection Officer.

[FR Doc. 2017-15185 Filed 7-19-17; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2005-20027; FMCSA-2005-20560; FMCSA-2006-26653; FMCSA-2007-27333; FMCSA-2008-0021; FMCSA-2008-0398; FMCSA-2009-0054; FMCSA-2009-0121; FMCSA-2010-0327; FMCSA-2010-0413; FMCSA-2011-0024; FMCSA-2011-0092; FMCSA-2011-0102; FMCSA-2012-0338; FMCSA-2013-0022; FMCSA-2013-0027; FMCSA-2013-0328; FMCSA-2014-0302; FMCSA-2014-0304; FMCSA-2014-0305; FMCSA-2014-0048; FMCSA-2015-0049; FMCSA-2015-0052]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 88 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: Each group of renewed exemptions was applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below. Comments must be received on or before August 21, 2017.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202-366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA-2005-20027; FMCSA-2005-20560; FMCSA-2006-26653; FMCSA-2007-27333; FMCSA-2008-0021; FMCSA-2008-0398; FMCSA-2009-0054; FMCSA-2009-0121; FMCSA-2010-0327; FMCSA-2010-0413; FMCSA-2011-0024; FMCSA-2011-0092; FMCSA-2011-0102; FMCSA-2012-0338; FMCSA-2013-0022; FMCSA-2013-0027; FMCSA-2013-0028; FMCSA-2014-0302; FMCSA-2014-0304; FMCSA-2014-0305; FMCSA-2014-0048; FMCSA-2015-0049; FMCSA-2015-0052 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.
 - *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.
 - *Hand Delivery:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.
 - *Fax:* 1-202-493-2251.
- Instructions:* Each submission must include the Agency name and the

docket number(s) for this notice. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments online.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for two years if it finds “such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.” The statute also allows the Agency to renew exemptions at the end of the two-year period.

The physical qualification standard for drivers regarding vision found in 49 CFR 391.41(b)(10) states that a person is physically qualified to driver a CMV if that person:

Has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

The 88 individuals listed in this notice have requested renewal of their exemptions from the vision standard in 49 CFR 391.41(b)(10), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits

and decided to extend each exemption for a renewable two-year period.

II. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

III. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 88 applicants has satisfied the renewal conditions for obtaining an exemption from the vision requirement (70 FR 2701; 70 FR 16887; 70 FR 17504; 70 FR 30997; 72 FR 8417; 72 FR 12666; 72 FR 25831; 72 FR 27624; 72 FR 36099; 73 FR 15567; 73 FR 27015; 74 FR 7097; 74 FR 11988; 74 FR 15584; 74 FR 19270; 74 FR 21427; 74 FR 21796; 74 FR 26461; 74 FR 26466; 74 FR 34630; 75 FR 19674; 75 FR 65057; 75 FR 79081; 76 FR 1493; 76 FR 12408; 76 FR 17481; 76 FR 25762; 76 FR 25766; 76 FR 28125; 76 FR 29022; 76 FR 34135; 76 FR 37168; 76 FR 37173; 76 FR 37885; 76 FR 44082; 77 FR 23797; 77 FR 74731; 78 FR 800; 78 FR 12811; 78 FR 12815; 78 FR 22596; 78 FR 22602; 78 FR 24300; 78 FR 24798; 78 FR 26106; 78 FR 27281; 78 FR 34140; 78 FR 37270; 78 FR 41188; 78 FR 46407; 78 FR 51268; 78 FR 51269; 78 FR 57679; 79 FR 23797; 80 FR 603; 80 FR 12248; 80 FR 14220; 80 FR 14223; 80 FR 16502; 80 FR 18696; 80 FR 22773; 80 FR 25766; 80 FR 26139; 80 FR 26320; 80 FR 29152; 80 FR 31640; 80 FR 31636; 80 FR 31640; 80 FR 31957; 80 FR 33007; 80 FR 33011; 80 FR 35699; 80 FR 36395; 80 FR 36398; 80 FR 45573; 80 FR 48404; 80 FR 48409; 80 FR 48413). They have submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that

extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315, the following groups of drivers received renewed exemptions in the month of July and are discussed below:

As of July 2, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 32 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (70 FR 2701; 70 FR 16887; 70 FR 17504; 70 FR 30997; 72 FR 8417; 72 FR 27624; 72 FR 36099; 73 FR 15567; 73 FR 27015; 74 FR 7097; 74 FR 11988; 74 FR 15584; 74 FR 19270; 74 FR 21427; 74 FR 21796; 74 FR 26466; 75 FR 19674; 75 FR 65057; 76 FR 17481; 76 FR 25762; 76 FR 25766; 76 FR 28125; 76 FR 37173; 76 FR 37885; 77 FR 23797; 77 FR 74731; 78 FR 800; 78 FR 12811; 78 FR 12815; 78 FR 22596; 78 FR 22602; 78 FR 24300; 78 FR 26106; 78 FR 37270; 78 FR 57679; 79 FR 23797; 80 FR 603; 80 FR 12248; 80 FR 14220; 80 FR 14223; 80 FR 16502; 80 FR 18696; 80 FR 22773; 80 FR 25766; 80 FR 26139; 80 FR 26320; 80 FR 29152; 80 FR 31640; 80 FR 31957; 80 FR 33011; 80 FR 45573; 80 FR 48409):

Michael W. Anderson (NM)
 Michael R. Bradford (MD)
 Ralph H. Bushman (IL)
 William D. Cardiff (IL)
 John J. Caricola, Jr. (NC)
 Adan Cortes-Juarez (WA)
 David L. Ellis (OK)
 Denise M. Engle (GA)
 Robert A. Goerl, Jr. (PA)
 Wade M. Hillmer (MN)
 Paul M. Hinkson (TN)
 Michael W. Jensen (CA)
 Clifford D. Johnson (VA)
 Michael Lafferty (ID)
 Mark L. LeBlanc (MN)
 Michael J. McGregor (FL)
 Felix L. McLean (NM)
 Anthony R. Miles (NV)
 Jerry D. Paul (OK)
 John P. Perez (FL)
 Raymond W. Pitts (FL)
 William A. Ramirez Vasquez (CA)
 Donald W. Randall (OR)
 Raymond Sherrill (PA)
 Kyle C. Shover (NJ)
 Charles H. Smith (IN)
 George Stapleton (GA)
 David B. Stone (OK)
 David M. Stout (OR)
 James K. Waites (AR)
 John E. Westbrook (LA)
 Jason R. White (OH)

The drivers were included in one of the following docket Nos: FMCSA–2005–20027; FMCSA–2005–20560;

FMCSA–2006–26653; FMCSA–2008–0021; FMCSA–2008–0398; FMCSA–2009–0054; FMCSA–2010–0327; FMCSA–2011–0024; FMCSA–2011–0092; FMCSA–2012–0338; FMCSA–2013–0022; FMCSA–2014–0302; FMCSA–2014–0304; FMCSA–2014–0305; FMCSA–2015–0048. Their exemptions are applicable as of July 2, 2017, and will expire on July 2, 2019.

As of July 7, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 8 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (80 FR 31636; 80 FR 48413):

Robert A. Buckley (IN)
 Jose J. Guzman-Olguin (IL)
 Stephen T. Hines (NJ)
 James J. Keranen (MI)
 Herbert S. Lear (PA)
 Nathan C. Nissen (IA)
 Gregory S. Richter (PA)
 George Tomecek (PA)

The drivers were included in docket No. FMCSA–2015–0049. Their exemptions are applicable as of July 7, 2017, and will expire on July 7, 2019.

As of July 9, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 5 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (78 FR 41188; 78 FR 27281; 78 FR 41188; 80 FR 33007):

Brian G. Dvorak (IL)
 Charles T. Spears (VA)
 Brian E. Tessman (WI)
 Gregory J. Thurston (PA)
 Donald Torbett (IA)

The drivers were included in docket No. FMCSA–2013–0028. Their exemptions are applicable as of July 9, 2017, and will expire on July 9, 2019.

As of July 16, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 7 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (74 FR 26461; 74 FR 34630; 76 FR 1493; 76 FR 12408; 76 FR 37168; 78 FR 51269):

Steven L. Forristall (WI)
 Rocky D. Gysberg (MN)
 Charles H. Lefew (VA)
 Joseph B. Peacock (NC)
 James M. Tennyson (MD)
 Steven L. Thomas (IN)
 Daniel A. Wescott (CO)

The drivers were included in one of the following docket Nos: FMCSA–2009–0413; FMCSA–2009–0121. Their exemptions are applicable as of July 16, 2017, and will expire on July 16, 2019.

As of July 22, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 12 individuals have satisfied

the conditions for obtaining a renewed exemption from the vision requirements (72 FR 72666; 72 FR 25831; 74 FR 19270; 76 FR 29022; 76 FR 34135; 76 FR 44082; 78 FR 34140; 78 FR 51268; 80 FR 36398):

Stanley C. Anders (SD)
Joel A. Cabrera (FL)
Sherman W. Clapper (ID)
Eric Esplin (UT)
Ronald R. Fournier (NY)
Ronald D. Jackman II (NV)
Thomas W. Kent (IN)
Robert J. MacInnis (MA)
Steven A. Proctor (TX)
Rodney W. Sukalski (MN)
Larry D. Warneke (WA)
Lonnie Wendinger (MN)

The drivers were included in one of the following docket Nos: FMCSA–2007–27333; FMCSA–2011–0102. Their exemptions are applicable as of July 22, 2017, and will expire on July 22, 2019.

As of July 23, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 19 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (80 FR 35699; 80 FR 48404):

Robert J. Bickel (MI)
Steven R. Brinegar (TX)
Garry D. Burkholder (PA)
Dennis W. Cosens (NM)
William J. Garigulo (OH)
Wladyslaw Gogola (IL)
Antonio Gomez (PA)
Mark A. Grenier (CT)
Acquillious Jackson III (SC)
Jimmy D. Johnson, II (TN)
Bradley J. Kearn (UT)
Larry G. Kreke (IL)
Christopher P. Mrockza (MD)
Gary A. Oster (OR)
Mark A. Pleskovitch (IL)
Edward J. Puto (CT)
Andrew P. Risner (OH)
Kyle B. Sharp (MI)
Francis A. St. Pierre (NH)

The drivers were included docket No. FMCSA–2015–0052. Their exemptions are applicable as of July 23, 2017, and will expire on July 23, 2019.

As of July 31, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 5 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (76 FR 25766; 76 FR 37885; 78 FR 37270; 80 FR 31640):

Anthony Luciano (CT)
David McKinney (OR)
Frank L. O'Rourke (NY)
Larry F. Reber (OH)
Edward Swaggerty, Jr. (OH)

The drivers were included in docket No. FMCSA–2011–0092. Their exemptions are applicable as of July 31, 2017, and will expire on July 31, 2019.

Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must undergo an annual physical examination (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a certified Medical Examiner, as defined by 49 CFR 390.5, who attests that the driver is otherwise physically qualified under 49 CFR 391.41; (2) each driver must provide a copy of the ophthalmologist's or optometrist's report to the Medical Examiner at the time of the annual medical examination; and (3) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

IV. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VI. Conclusion

Based upon its evaluation of the 88 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)). In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years unless revoked earlier by FMCSA.

Issued on: June 8, 2017.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2017–14919 Filed 7–19–17; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2006–24016; FMCSA–2009–0067; FMCSA–2011–0040; FMCSA–2011–0058; FMCSA–2013–0012; FMCSA–2013–0014; FMCSA–2014–0315; FMCSA–2015–0057]

Qualification of Drivers; Exemption Applications; Diabetes

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions of 132 individuals from its prohibition in the Federal Motor Carrier Safety Regulations (FMCSRs) against persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. The exemptions enable these individuals with ITDM to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions was applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202–366–4001, fmcamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8 a.m. to 5:30 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: <http://www.regulations.gov>.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter

provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

II. Background

On April 17, 2017, FMCSA published a notice announcing its decision to renew exemptions for 132 individuals from the insulin-treated diabetes mellitus prohibition in 49 CFR 391.41(b)(3) to operate a CMV in interstate commerce and requested comments from the public (82 FR 18206). The public comment period ended on May 17, 2017, and no comments were received.

As stated in the previous notice, FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(3).

The physical qualification standard for drivers regarding diabetes found in 49 CFR 391.41(b)(3) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control.

III. Discussion of Comments

FMCSA received no comments in this preceding.

IV. Conclusion

Based upon its evaluation of the 132 renewal exemption applications and that no comments were received, FMCSA confirms its decision to exempt the following drivers from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce in 49 CFR 391.41(b)(3):

As of May 3, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following nine individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (78 FR 16032; 78 FR 26107):

Maryland A. Chandler (KY)
 Ronald D. Clark (AR)
 Larry L. Eberly (PA)
 Steven J. Fessler (IL)
 Patrick L. Morningstar (MD)
 Russell L. Stiley (CO)
 Gary T. Stoutamyer (VA)
 Jack K. Webster (KY)
 Harry V. Wilhite, Jr. (AL)

The drivers were included in docket No. FMCSA-2013-0014. Their exemptions are applicable as of May 3, 2017, and will expire on May 3, 2019.

As of May 6, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following nine individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (78 FR 16758; 78 FR 26422):

Victor L. Daniels (DE)
 Kenneth T. Faborito (HI)
 Kevin P. Lee (MN)
 Duane W. Mansur (NH)
 Fritz R. McBride (WI)
 Arthur H. Olsen (AZ)
 Jacob D. Parnaby (OH)
 Brandon P. Wilson (NC)
 Peter S. Zipperer (LA)

The drivers were included in docket No. FMCSA-2013-0012. Their exemptions are applicable as of May 6, 2017, and will expire on May 6, 2019.

As of May 8, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 50 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (80 FR 18681; 80 FR 37716):

Rafael M. Alvarado (TX)
 Mark J. Avedisian (NY)
 Timothy J. Burke (MA)
 Roger D. Cassada (VA)
 Leonard W. Cleaves (MA)
 Larry A. Cramer (SD)
 Bradford A. Davies (ME)
 Larry A. DeSanno (OR)
 Robert S. Doering (IL)
 Michael L. Domarus (MN)
 Adan A. Espinoza (CA)
 Howard E. Fruehling (IA)
 Michael F. Gabbianelli (NJ)
 James E. Goins (NJ)
 Gregory J. Goodenbour (IA)
 Michael D. Howell (NC)
 Mayer Indorsky (NY)
 Raymond J. Jacobs (NY)
 Lyle J. Kaehler (WI)
 Charles F. Kennedy (PA)
 Curtis G. Krichbaum (PA)
 Walter P. Leck (PA)
 John R. Mauney (NC)
 Derrell R. McCaskill (MD)
 Eric O. McLamb (NC)
 Michael S. Murray (IA)
 Benjamin M. Naastad (ND)
 Richard G. Niemi (WI)
 Kenthia E. Norfleet (AL)
 Donald M. Oakes (NH)
 Robert E. Piernik (FL)
 Harold E. Pratt (MO)
 Jack C. Reed (NE)
 Fernando Rivera (IL)
 William J. Schmidt (MN)
 Todd J. Schoeller (WI)
 Gary H. Schrot (WI)
 Ryan A. Snow (PA)
 Kevin L. Sundh (UT)

William H. Terry (IN)
 Duane K. Torlish, Jr. (NY)
 Ronald W. Truitt (PA)
 Timothy E. Vanderwiele (NY)
 Leo D. Vermeire (WA)
 Brian W. Walls (PA)
 Gary L. Webster (VT)
 Lance A. Wendinger (MN)
 Allan W. Widener (GA)
 Shane D. Wildoner (PA)
 Kyle A. Wright (WA)

The drivers were included in docket No. FMCSA-2014-0315. Their exemptions are applicable as of May 8, 2017, and will expire on May 8, 2019.

As of May 9, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 38 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (76 FR 17475; 76 FR 26792; 80 FR 18928; 80 FR 37726):

James R. Bledsoe (FL)
 Sammy W. Bowlin (KS)
 Durwin A. Brannon (NC)
 Larry J. Carril (IL)
 Jimmy E. Cole (TN)
 Robert S. Colosimo (ND)
 Joel F. Cook (NY)
 James N. Coombs (NJ)
 David A. Daniels (ME)
 John A. DelGiudice (RI)
 Mark J. Dias (MA)
 Brian A. Foss (WY)
 William A.H. Gardner (CA)
 Steven M. Gilmour (MA)
 Ismael Gonzalez (IN)
 Charles A. Gudaitis (PA)
 Cory A. Harker (UT)
 Clark D. Holdeman (TX)
 David A. Holwenger (WA)
 Conrad J. Janik (NY)
 David F. Kenny (NY)
 George W. Key, Jr. (AL)
 Michael O. Lancial (MI)
 Robert E. McKenna (NY)
 Gregory O. Morton (AL)
 Frank A. Mowers (IL)
 Charles H. Nichols (MI)
 Robert L. Rush (PA)
 Derek J. Scougal (VA)
 Roy Silva (IL)
 James L. Skinner (IA)
 Crispin Tabangcura Jr. (HI)
 Robert L. Terry (TN)
 Rafael Torres, Jr. (FL)
 Harold E. Watters (IN)
 Joseph E. Weitzel (PA)
 John B. Wojcicki (OH)
 Steven L. Wolvers (IA)

The drivers were included in one of the following docket Nos: FMCSA-2011-0058; FMCSA-2015-0057. Their exemptions are applicable as of May 9, 2017, and will expire on May 9, 2019.

As of May 11, 2017, and in accordance with 49 U.S.C. 31136(e) and

31315, the following 8 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (76 FR 17478; 76 FR 27376):

Peter N. Amendola (MA)
 Steven V. Callison (LA)
 Douglas A. Carroll (IN)
 Tamara D. Folsom (SD)
 Ernest Martinelli, III (RI)
 Johnathon C. Morgan (TN)
 David R. Smith (ME)
 Adam J. Stegenga (MI)

The drivers were included in docket No. FMCSA–2011–0040. Their exemptions are applicable as of May 11, 2017, and will expire on May 11, 2019.

As of May 18, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, Thomas G. Deke (MO) has satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce. (71 FR 17558; 71 FR 28913).

This driver was included in docket No. FMCSA–2006–24016. The exemption is applicable as of May 18, 2017, and will expire on May 18, 2019.

As of May 22, 2017, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 17 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (74 FR 15578; 74 FR 24072):

William C. Arrington (MD)
 Raymond Barajas (KS)
 William N. Carpenter (KY)
 Darin L. Carpenter (MT)
 Jeffery W. Cotner (OR)
 Juan A. Hartwell (CT)
 David A. Holzbach (SC)
 Joseph T. Jackson (CT)
 Donald A. Lambrecht (NC)
 William M. Liebert (NV)
 Curtis J. Panther (MN)
 Eric S. Ritter (CA)
 Gary L. Robinson (TN)
 Kevin J. Sears (IL)
 Peter A. Storm (LA)
 Don A. Wisnosky (WI)
 Patrick D. Yosten (NE)

The drivers were included in docket No. FMCSA–2009–0067. Their exemptions are applicable as of May 22, 2017, and will expire on May 22, 2019.

In accordance with 49 U.S.C. 31315, each exemption will be valid for two years from the applicable date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than

was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

Issued on: June 8, 2017.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2017–14917 Filed 7–19–17; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2017–0016; Notice 1]

Mack Trucks, Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Mack Trucks, Inc. (MTI), has determined that certain model year (MY) 2017 Mack heavy duty trucks do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 120, *Tire selection and rims and motor home/recreation vehicle trailer load carrying capacity information for motor vehicles with a GVWR of more than 4,536 kilograms (10,000 pounds)*. MTI filed a noncompliance information report dated February 9, 2017. MTI also petitioned NHTSA on February 28, 2017, and revised its petition on April 29, 2017, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety.

DATES: The closing date for comments on the petition is August 21, 2017.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and submitted by any of the following methods:

- **Mail:** Send comments by mail addressed to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- **Hand Delivery:** Deliver comments by hand to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.

- **Electronically:** Submit comments electronically by logging onto the Federal Docket Management System (FDMS) Web site at <https://www.regulations.gov/>. Follow the online instructions for submitting comments.

- Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to https://www.regulations.gov, including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at https://www.regulations.gov by following the online instructions for accessing the dockets. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000, (65 FR 19477–78).

SUPPLEMENTARY INFORMATION:

I. Overview: Mack Trucks, Inc. (MTI), has determined that certain model year (MY) 2017 Mack heavy duty trucks do not fully comply with paragraph S5.2(b) of Federal Motor Vehicle Safety Standard (FMVSS) No. 120, *Tire selection and rims and motor home/recreation vehicle trailer load carrying capacity information for motor vehicles with a GVWR of more than 4,536 kilograms (10,000 pounds)*. MTI filed a noncompliance report dated February 9, 2017, pursuant to 49 CFR part 573, *Defect and Noncompliance*

Responsibility and Reports. MTI also petitioned NHTSA on February 28, 2017, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, and revised its petition on April 29, 2017, to obtain an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety.

This notice of receipt of MTI's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

II. Vehicles Involved: Approximately 226 MY 2017 Mack Pinnacle, Granite, TerraPro and LR heavy duty trucks, manufactured between August 15, 2016, and December 12, 2016, are potentially involved.

III. Noncompliance: MTI explains that the noncompliance is that the wheels on the subject vehicles incorrectly identify the rim size as 24.5" x 8.25" instead of 22.5" x 8.25", and therefore do not meet the requirements of paragraph S5.2(b) of FMVSS No. 120. Specifically, the marking error overstates the wheel diameter by 2".

IV. Rule Text: Paragraph S5.2 of FMVSS No. 120 states:

S5.2 *Rim marking.* Each rim or, at the option of the manufacturer in the case of a single-piece wheel, wheel disc shall be marked with the information listed in paragraphs (a) through (e) of this paragraph, in lettering not less than 3 millimeters high, impressed to a depth or, at the option of the manufacturer, embossed to a height of not less than 0.125 millimeters. . . .

(b) The rim size designation, and in case of multipiece rims, the rim type designation. For example: 20 x 5.50, or 20 x 5.5.

V. Summary of MTI's Petition: MTI described the subject noncompliance and stated its belief that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, MTI referenced a letter to NHTSA, dated December 5, 2016, from Arconic Wheel and Transportation Products (Arconic), which is the rim manufacturer, and provided the following:

1. A 24.5" tire will not seat on the rim; therefore, if someone tries to mount a 24.5" tire to the rim, it will not hold air and therefore cannot be inflated.

2. When tires are replaced, the technician will select the tire based on the size and rating of the tire being replaced. When Mack manufactured the vehicle, the tire used was a 22.5" (*i.e.*, the correct size for the rim). Therefore, the tires installed by Mack have the correct size on the sidewall of the tire.

3. Mack is required to list the tires size and inflation pressures on the

certification label as required by 49 CFR 567. The information printed on the label is the correct size, a 22.5" tire and reflects the tires that were installed when manufactured. The certification label is located inside the driver's door and can be easily accessed by the tire installer.

MTI concluded by expressing the belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

To view MTI's petition analyses in its entirety you can visit <https://www.regulations.gov> by following the online instructions for accessing the dockets and by using the docket ID number for this petition shown in the heading of this notice.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject vehicles that MTI no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after MTI notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2017-15254 Filed 7-19-17; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2016-0109; Notice 2]

Mercedes-Benz USA, LLC, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: Mercedes-Benz USA, LLC (MBUSA), has determined that certain model year (MY) 2015-2016 Mercedes-Benz CLS-Class motor vehicles do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 110, *Tire Selection and Rims and Motor Home/Recreation Vehicle Trailer Load Carrying Capacity Information for Motor Vehicles with a GVWR of 4,536 kilograms (10,000 pounds) or Less*. MBUSA filed a Safety Recall Report dated September 12, 2016. MBUSA also petitioned NHTSA on October 4, 2016, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety.

ADDRESSES: For further information on this decision contact Kerrin Bressant, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366-1110, facsimile (202) 366-5930.

SUPPLEMENTARY INFORMATION:

I. Overview

Mercedes-Benz USA, LLC (MBUSA), has determined that certain model year (MY) 2015-2016 Mercedes-Benz CLS-Class motor vehicles do not fully comply with paragraph S4.3(a) of Federal Motor Vehicle Safety Standard (FMVSS) No. 110, *Tire Selection and Rims and Motor Home/Recreation Vehicle Trailer Load Carrying Capacity Information for Motor Vehicles with a GVWR of 4,536 kilograms (10,000 pounds) or Less*. MBUSA filed a report dated September 12, 2016, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. MBUSA also petitioned NHTSA on October 4, 2016, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety.

Notice of receipt of the petition was published, with a 30-day public comment period on December 20, 2016,

in the **Federal Register** (81 FR 92964). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) Web page at: <http://www.regulations.gov/>. Then follow the online search instruction to locate docket number “NHTSA–2016–0109.”

II. Vehicles Involved

Approximately 6,773 MY 2015–2016 Mercedes-Benz CLS 400 and Mercedes-Benz CLS 400 4MATIC motor vehicles manufactured between May 23, 2014 and April 21, 2016, are potentially involved.

III. Noncompliance

MBUSA explains that the noncompliance is that the subject vehicles have tire and loading information placards affixed to their B-pillars that incorrectly identify the maximum combined weight of occupants and cargo. Specifically, the

Mercedes CLS 400 was manufactured with a tire and loading information placard that identifies a maximum combined weight of 420 kilograms (926 pounds) and the Mercedes CLS 400 4MATIC was manufactured with a tire and loading information placard that identifies a maximum combined weight of 355 kilograms (783 pounds). However, the maximum combined weight of occupants and cargo should be 315 kilograms (694 pounds) for the Mercedes CLS 400 and 325 kg (717 pounds) for the CLS 400 4MATIC. Therefore, the vehicles do not comply with paragraph S4.3 of FMVSS No. 110.

IV. Rule Text

Paragraph S4.3 of FMVSS No. 110 states:

S4.3 Placard. Each vehicle, except for a trailer or incomplete vehicle, shall show the information specified in S4.3 (a) through (g), and may show, at the manufacturer’s option, the information specified in S4.3 (h) and (i),

on a placard permanently affixed to the driver’s side B-pillar. . . .

(a) Vehicle capacity weight expressed as “The combined weight of occupants and cargo should never exceed XXX kilograms or XXX pounds

V. Summary of MBUSA’s Petition

MBUSA described the subject noncompliance and stated its belief that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, MBUSA submitted the following reasoning:

(a) The tires originally equipped on the subject vehicles are able to carry the additional weight indicated on the tire and loading information placard. Further, the tire pressure detailed on the placard is sufficient to carry those weights. The maximum tire and vehicle load information detailed in the table below demonstrates that the tire is designed to carry a higher load than that which was incorrectly set out on the tire label:

Tire dimension	Maximum tire load (lbs)	Maximum vehicle load (per tire)	
		CLS 400 (lbs)	CLS 400 4MATIC (lbs)
18" front	1708	1243	1289
18" rear	1609	1256	1278
19" front	1565	1243	1289
19" rear	1653	1256	1278

(b) Should the driver follow the maximum combined weight of occupants and cargo displayed on the tire and information placard, motor vehicle safety is not negatively impacted. The vehicle platform (including chassis and axles) serves other CLS vehicle lines and is designed for vehicles with a higher gross vehicle weight rating (“GVWR”). The platform therefore can handle the potential additional weight.

(c) Subject vehicles are equipped with the B-pillar certification information label in accordance with 49 CFR part 567 indicating a GVWR of 2260 kilograms (4982 pounds) for vehicle type 218.365, the CLS 400, and a GVWR of 2330 kg (5137 pounds) for vehicle type 218.367, the CLS 400 4MATIC. The GVWR information detailed on the B-pillar certification information label is correct. Therefore, the driver can refer to this alternative source of information in order to determine the correct maximum load weight of the vehicle.

(d) After identifying the potentially incorrect values in the tire label, Daimler AG (DAG) analyzed potential technical implications, specifically with

respect to the requirements of FMVSS No. 110, including potential effects on axles, suspension, brakes, driving dynamic, and crashworthiness. Based on this analysis, an impact on steering, braking or other vehicle dynamics as a result of the tire label weight discrepancy can be excluded.

(e) Moreover, MBUSA is not aware of any customer complaints, accidents or injuries alleged to have occurred as a result of this non-compliance. Hence, field data supports the assertion that the issue described above will have an inconsequential impact on safety.

MBUSA concluded by expressing the belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

NHTSA’S Decision

NHTSA’s Analysis: FMVSS No. 110 specifies requirements for tire selection to prevent tire overload. The intent of the standard is to ensure that vehicles

are equipped with tires appropriate to handle the vehicle manufacturer’s designed maximum vehicle weight.

The maximum weight of a vehicle is determined by adding to the vehicle the manufacturer specified maximum weight of occupants and cargo. FMVSS No. 110, paragraph 4.3(a) requires that vehicles be labeled with a “Vehicle Capacity Weight (VCW)” value which is the specified maximum occupant and cargo weight that can be loaded into a vehicle. This value is equal to 68 kgs times the vehicle’s designated seating capacity plus the rated cargo/payload of the vehicle. FMVSS No. 110, (S4.2.1.1 and S4.3.4(b)), requires that the vehicle maximum load on the tire shall not be greater than the applicable maximum load rating as marked on the sidewall of the tire or greater than the load rating of the tire at the manufacturer specified cold inflation pressure listed on the tire and loading information placard.

For the subject vehicles, MBUSA noted that the VCW values on the placards are incorrect. The tire and information placard on the CLS 400 model vehicle specifies a 420 kg VCW which should have been 315 kg, an

increase of 105 kg. The label on the CLS 400 4MATIC model vehicle specifies a 355 kg VCW which should have been 325 kg, an increase of 30 kg. These errors could cause a consumer to load the subject vehicles beyond their original design specifications.

In its petition, MBUSA provided an analysis indicating the mounted tires on the subject vehicles are sufficient for carrying the maximum vehicle loads derived from the higher, incorrect, VCW values. For the CLS 400 vehicles the analysis indicates the tire load carrying capabilities exceed the maximum tire load by at least 147 kg (710 kg tire load rating minus 563 kg maximum tire load). For the CLS 400 4MATIC vehicles the analysis indicates the tire load carrying capabilities exceed the maximum tire load by at least 125 kg (709 kg tire load rating minus 584 kg maximum tire load). NHTSA verified the tire load ratings specified by MBUSA in accordance with the European Tyre and Rim Technical Organisation (ETRTO) manual. As shown by MBUSA, the tire capacities are more than adequate to handle the additional weight of the higher VCW values. MBUSA's analysis shows that the tires mounted on the subject vehicles exceed the load requirements of FMVSS No. 110.

MBUSA also mentioned that the certification labels affixed to the subject vehicles provide the vehicle's gross axle weight ratings (GAWRs) and the gross vehicle weight rating (GVWR) in accordance with 49 CFR 567, *Certification*. MBUSA stated that the GAWRs and GVWR values provided on the subject vehicles are correct as labeled. These ratings are established by the vehicle manufacturer and provided as an alternative source of information consumers can use to ensure a vehicle and its axles are not overloaded. Vehicle manufacturers specify that these ratings should not be exceeded when loading any vehicle. The agency reviewed the maximum loads on the axles and vehicles, using the higher labeled VCW values, against the certified GAWRs and GVWR of the subject vehicles. For the CLS 400 4MATIC vehicles, maximum loads were well below the GAWR and GVWR values. For the CLS 400 vehicles, the maximum loads are essentially at the certified GAWRs and GVWR values. MBUSA also stated in its petition that the platform (chassis and axles) utilized on the subject vehicles is used with other CLS vehicle lines and is designed for vehicles with higher GVWRs. It appears from this analysis the subject vehicles can safely accommodate the

higher VCW loads without overload concerns.

No comments were received during the receipt notice comment period.

NHTSA Decision: In consideration of the foregoing, NHTSA finds that MBUSA has met its burden of persuasion that the FMVSS No. 110 noncompliance is inconsequential as it relates to motor vehicle safety. Accordingly, MBUSA's petition is hereby granted and MBUSA is exempted from the obligation to provide notification of, and a remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject vehicles that MBUSA no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after MBUSA notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,
Director, Office of Vehicle Safety Compliance.
[FR Doc. 2017-15255 Filed 7-19-17; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2017-0015; Notice 1]

Volvo Trucks North America, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Volvo Trucks North America (VTNA), has determined that certain model year (MY) 2017 Volvo VNL and 2017 Volvo VNM heavy duty trucks do not fully comply with Federal Motor

Vehicle Safety Standard (FMVSS) No. 120, *Tire selection and rims and motor home/recreation vehicle trailer load carrying capacity information for motor vehicles with a GVWR of more than 4,536 kilograms (10,000 pounds)*. VTNA filed a noncompliance information report dated February 9, 2017. VTNA also petitioned NHTSA on February 28, 2017, and revised its petition on April 29, 2017, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety.

DATES: The closing date for comments on the petition is August 21, 2017.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and submitted by any of the following methods:

- **Mail:** Send comments by mail addressed to U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- **Hand Delivery:** Deliver comments by hand to U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal holidays.

- **Electronically:** Submit comments electronically by logging onto the Federal Docket Management System (FDMS) Web site at <https://www.regulations.gov/>. Follow the online instructions for submitting comments.

- Comments may also be faxed to (202) 493-2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to <https://www.regulations.gov/>, including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at <https://www.regulations.gov> by following the online instructions for accessing the dockets. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000, (65 FR 19477-78).

SUPPLEMENTARY INFORMATION:

I. Overview: Volvo Trucks North America (VTNA), has determined that certain model year (MY) 2017 Volvo VNL and 2017 Volvo VNM heavy duty trucks do not fully comply with paragraph S5.2(b) of Federal Motor Vehicle Safety Standard (FMVSS) No. 120, *Tire selection and rims and motor home/recreation vehicle trailer load carrying capacity information for motor vehicles with a GVWR of more than 4,536 kilograms (10,000 pounds)*. VTNA filed a noncompliance report dated February 9, 2017, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. VTNA also petitioned NHTSA on February 28, 2017, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, and revised its petition on April 29, 2017, to obtain an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety.

This notice of receipt of VTNA's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

II. Vehicles Involved: Approximately 862 MY 2017 Volvo VNL and 2017 Volvo VNM heavy duty trucks, manufactured between August 15, 2016, and November 10, 2016, are potentially involved.

III. Noncompliance: VTNA explains that the noncompliance is that the wheels on the subject vehicles incorrectly identify the rim size as 24.5" x 8.25" instead of 22.5" x 8.25", and therefore do not meet the requirements of paragraph S5.2(b) of FMVSS No. 120. Specifically, the marking error overstates the wheel diameter by 2".

IV. Rule Text: paragraph S5.2 of FMVSS No. 120 states:

S5.2 *Rim marking.* Each rim or, at the option of the manufacturer in the case of a single-piece wheel, wheel disc shall be marked with the information listed in paragraphs (a) through (e) of this paragraph, in lettering not less than 3 millimeters high, impressed to a depth or, at the option of the manufacturer, embossed to a height of not less than 0.125 millimeters. . . .

(b) The rim size designation, and in case of multipiece rims, the rim type designation. For example: 20 x 5.50, or 20 x 5.5.

V. Summary of VTNA's Petition: VTNA described the subject noncompliance and stated its belief that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, VTNA referenced a letter to NHTSA, dated December 5, 2016, from Arconic Wheel and Transportation Products (Arconic), which is the rim manufacturer, and provided the following:

1. A 24.5" inch tire will not seat on the rim; therefore, if someone tries to mount a 24.5" tire to the rim, it will not hold air and therefore cannot be inflated.

2. When tires are replaced, the technician will select the tire based on the size and rating of the tire being replaced. When Volvo manufactured the vehicle, the tire used was a 22.5" (*i.e.*, the correct size for the rim). Therefore, the tires installed by Volvo have the correct size on the sidewall of the tire.

3. Volvo is required to list the tires size and inflation pressures on the certification label as required by 49 CFR 567. The information printed on the label is the correct size, a 22.5" inch tire and reflects the tires that were installed when manufactured. The certification label is located inside the driver's door and can be easily accessed by the tire installer.

Volvo concluded by expressing the belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

To view VTNA's petition analyses in its entirety you can visit <https://www.regulations.gov> by following the online instructions for accessing the dockets and by using the docket ID number for this petition shown in the heading of this notice.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and

30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject vehicles that VTNA no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after VTNA notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120; Delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2017-15253 Filed 7-19-17; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Reports, Forms and Record Keeping Requirements; Agency Information Collection Activity Under OMB Review

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collections and their expected burden. The **Federal Register** Notice with a 60-day comment period was published on January 4, 2017.

DATES: Comments must be submitted on or before August 21, 2017.

FOR FURTHER INFORMATION CONTACT: Coleman Sachs, Office of Vehicle Safety Compliance (NEF-230), National Highway Traffic Safety Administration, West Building, 4th Floor, Room W43-481, 1200 New Jersey Avenue SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: National Highway Traffic Safety Administration.

Title: 49 CFR part 566 *Manufacturer Identification.*

OMB Number: 2127-0043.

Type of Request: Extension of a Currently Approved Collection.

Abstract: The National Highway Traffic Safety Administration (NHTSA) has requested OMB to extend that agency's approval of the information collection that is incident to NHTSA's administration of the regulations at 49 CFR part 566 *Manufacturer identification*. Those regulations require manufacturers of motor vehicles or motor vehicle equipment, other than tires, to which a Federal motor vehicle safety standard (FMVSS) applies, to submit to NHTSA, on a one-time basis, identifying information on themselves and a description of the products that they manufacture to those standards. The information that must be submitted includes: (a) The full individual, partnership, or corporate name of the manufacturer; (b) the residence address of the manufacturer and State of incorporation, if applicable; and (c) a description of each type of motor vehicle or of covered equipment manufactured by the manufacturer, including, for motor vehicles, the approximate ranges of gross vehicle weight ratings (GVWR) for each type. The information must be submitted no later than 30 days after the manufacturer begins to manufacture motor vehicles or motor vehicle equipment subject to the FMVSS. No specific form need be used for the submission of this information. NHTSA provides an online portal with a fillable web-based format for use in submitting the required information. This is described in a handbook entitled *Requirements for Manufacturers of Motor Vehicles and Motor Vehicle Equipment* that can be accessed on the agency's Web site at <https://vpic.nhtsa.dot.gov>. A description of the reporting requirement is included on pages 8 and 9 of the handbook. With changes implemented in 2015, manufacturers have been able to make these submissions using an online portal on the above agency Web site. Manufacturers who have previously submitted identifying information must ensure that the information on file is accurate and complete by submitting revised information no later than 30 days after a change in the business that affects the validity of that information has occurred.

This information collection is necessary to ensure that manufacturers of motor vehicles and motor vehicle equipment subject to the Federal motor vehicle safety standards identify themselves and their products to NHTSA so that NHTSA may contact them in the event that one of their products is suspected or found to contain a defect related to motor vehicle safety or fails to comply with an

applicable FMVSS. Manufacturers of defective or noncompliant motor vehicles or replacement motor vehicle equipment are required under 49 U.S.C. 30118 to furnish notification of the defect or noncompliance to the Secretary of Transportation, and as well as to owners, purchasers, and dealers of the motor vehicle or replacement equipment, and to remedy the defect or noncompliance without charge to the owner.

Affected Public: New manufacturers of motor vehicles and motor vehicle equipment, other than tires, subject to the Federal motor vehicle safety standards.

Estimated Total Annual Burden: 131 hours; \$3,930.

ADDRESSES: Send comments, within 30 days, to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention NHTSA Desk Officer.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

A Comment to OMB is most effective if OMB receives it within 30 days of publication.

Jeffrey M. Giuseppe,

Acting Associate Administrator, Enforcement.

[FR Doc. 2017-15252 Filed 7-19-17; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2017-0011; Notice 2]

Daimler Trucks North America, LLC, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: Daimler Trucks North America, LLC (DTNA), has determined that certain model year (MY) 2016-2017 Freightliner trucks do not fully comply

with Federal Motor Vehicle Safety Standard (FMVSS) No. 101, *Controls and Displays*. DTNA filed a noncompliance report dated January 19, 2017, and amended it on January 25, 2017. DTNA also petitioned NHTSA on January 20, 2017, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety.

ADDRESSES: For further information on this decision contact Stu Seigel, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366-5287, facsimile (202) 366-3081.

SUPPLEMENTARY INFORMATION:

I. Overview: Daimler Trucks North America (DTNA), has determined that certain model year (MY) 2016-2017 Freightliner trucks do not fully comply with Table 2 of Federal Motor Vehicle Safety Standard (FMVSS) No. 101, *Controls and Displays*. DTNA filed a noncompliance report dated January 19, 2017, and amended it on January 25, 2017, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. DTNA also petitioned NHTSA on January 20, 2017, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety.

Notice of receipt of the petition was published with a 30-day public comment period, on April 7, 2017, in the **Federal Register** (82 FR 17069). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: <https://www.regulations.gov/>. Then follow the online search instructions to locate docket number "NHTSA-2017-0011."

II. Vehicles Involved: Affected are approximately 81,641 MY 2016-2017 versions of the following trucks, manufactured between March 2, 2015 and September 8, 2016:

- Freightliner 108SD
- Freightliner Business Class M2
- Freightliner Cascadia
- Freightliner 114SD

III. Noncompliance: DTNA explains that the noncompliance is that the Low Brake Air Pressure telltale for air brake systems displays the word "BRAKE" and a message on an adjacent display screen says "LOW AIR", rather than the words "BRAKE AIR," as specified in Table 2 of FMVSS No. 101. DTNA states

that the telltale is accompanied by an audible alert and pressure gauges.

IV. Rule Text: Paragraph S5 of FMVSS No. 101 provides: "Each passenger car, multipurpose passenger vehicle, truck and bus that is fitted with a control, a telltale, or an indicator listed in Table




1 or Table 2 must meet the requirements of this standard for the location, identification, color, and illumination of that control, telltale or indicator."

Paragraph S5.2.1 of FMVSS No. 101 provides, in pertinent part: ". . . each control, telltale and indicator that is

listed in column 1 of Table 1 or Table 2 must be identified by the symbol specified for it in column 2 or the word or abbreviation specified for it in column 3 of Table 1 or Table 2."

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Table 2
Identifiers for
Controls, Telltales and Indicators with
No Color or Illumination Requirements

Column 1 ITEM	Column 2 SYMBOL	Column 3 WORD(S) OR ABBREVIATION
Hand Throttle Control	—	Throttle
Engine Start Control	—	Engine Start ₁
Manual Choke Control	—	Choke
Odometer	—	Kilometers or km, if kilometers are shown. Otherwise, no identifier is required. ₂
Horn		Horn
Master Lighting Switch		Lights
Headlamps and Taillamps Control	—	— _{4,5}
Low Brake Air Pressure Telltale (for vehicles subject to FMVSS 121)	—	Brake Air
Seat Belt Unfastened Telltale		Fasten Belts or Fasten Seat Belts

Notes:

1. Use when engine control is separate from the key locking system.
2. Any combination of upper- or lowercase letters may be used.
3. Framed areas may be filled.
4. If a line appears in Column 2 and Column 3, the Control, Telltale or Indicator is required to be identified, however the form of the identification is the manufacturer's option.
5. Separate identification not required if function is combined with Master Lighting Switch.

BILLING CODE 4910-59-C

V. Summary of DTNA's Petition: DTNA described the subject noncompliance and stated its belief that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, DTNA submitted the following reasoning:

(a) DTNA notes that the purpose of the low brake air pressure telltale is to alert the driver to a low air condition, consistent with the requirements of FMVSS No. 121, S5.1.5 (warning signal). The word "BRAKE" instead of

"BRAKE AIR," together with a message on the display screen saying "LOW AIR!" and an audible alert that occurs in the subject vehicles would alert the driver to an air issue with the brake system. Once alerted, the driver can check the actual air pressure by reading the primary and secondary air gauges and seeing the contrasting color on the gauges indicating low pressure.

(b) NHTSA stated in a 2005 FMVSS No. 101 rulemaking that the reason for including vehicles over 10,000 pounds in the requirements of FMVSS No. 101

is that there is a need for drivers of heavier vehicles to see and identify their displays, just as there is for drivers of lighter vehicles. See 70 FR 48295, 48298 (Aug. 17, 2005). The telltale in the subject vehicles saying "BRAKE" and the message on the display screen that says "LOW AIR!" would allow the driver to see and identify the improper functioning system as was the intent of the rule, thus serving the purpose of the FMVSS No. 101 requirement.

(c) Drivers of commercial vehicles would conduct daily pre-trip

inspections of their vehicles paying particular attention to the warning signs and gauges to ensure correct functionality of their vehicles braking system, before driving the vehicle. Drivers therefore would be very familiar with the telltales and other warnings, and their meaning, in the event a low air warning was to occur while the vehicle was driven.

(d) There are two scenarios when a low brake air pressure condition would exist: A parked vehicle and a moving vehicle. Each of these are discussed separately below; in each scenario, there is ample warning provided to the driver of low brake air pressure.

1. Parked Vehicle

The driver of an air-braked vehicle must ensure that the vehicle has enough brake air pressure to operate safely. At startup, the vehicle will likely be in a low air condition. When in a low air condition the following warnings would occur, conditioning the driver over time as to the purpose of the telltale, message and audible alerts and under what conditions they are activated.

- Red contrasting color of the telltale saying “BRAKE”
- Message on the display screen that says “LOW AIR!”
- Audible alert to the driver as long as the vehicle has low air
- Air gauges for the primary and secondary air tanks clearly showing the air pressure in the system
- Red contrasting color on the air gauges indicating when the pressure is low
- Difficulty/inability of releasing the parking brakes with low air
- Reduced drivability if the driver attempts to drive with the parking brakes applied

2. Moving Vehicle

If a low brake air pressure situation occurs while driving, the function of the service brakes may be reduced or lost and, eventually if the pressure gets low enough, the parking brakes will engage. The driver must pull to the side of the road and apply the parking brakes as soon as possible. A loss of brake air pressure while driving represents a malfunctioning brake system and requires immediate action from the driver. Drivers recognize that a telltale illuminated in red represents a malfunction which needs to be remedied.

The following warning would occur if a low air condition occurred while driving.

- Red contrasting color of the telltale saying “BRAKE”

- Message on the display screen that says “LOW AIR!”
- Audible alert to the driver as long as the vehicle has low air
- Air gauges for the primary and secondary air tanks clearly showing the air pressure in the system
- Red contrasting color on the air gauges indicating when the pressure is low.

(e) The functionality of both the parking brake system and the service brake system remains unaffected by the “BRAKE” telltale used in the subject vehicles.

(f) NHTSA Precedents—DTNA notes that NHTSA has previously granted petitions for decisions of inconsequential noncompliance for similar brake telltale issues. See Docket No. NHTSA–2012–0004, 78 FR 69931 (November 21, 2013) (grant of petition for Ford Motor Company) and Docket No. NHTSA–2014–0046, 79 FR 78559 (December 30, 2014) (grant of petition for Chrysler Group, LLC). In both of these instances, the vehicles at issue did not have the exact wording as required under FMVSS No. 101. The available warnings were deemed sufficient to provide the necessary driver warning. DTNA respectfully suggest that the same is true for the subject vehicles: The red “BRAKE” telltale and the “LOW AIR!” pop-up message, together with other warnings and alerts, are fully sufficient to warn the driver of a low brake air pressure situation.

DTNA concluded by expressing the belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

NHTSA’S Decision

NHTSA’s Analysis: NHTSA has reviewed DTNA’s analyses that the subject noncompliance is inconsequential to motor vehicle safety. Specifically, the telltale marking for low brake air pressure says “Brake” instead of “Brake Air” as required in table 2 of FMVSS No. 101 and FMVSS No. 121. We believe that this incomplete labeling poses no risk to motor vehicle safety because multiple sources of information, as discussed below, are simultaneously activated to properly warn the driver of the low air condition.

1. When a low air pressure situation exists, for both a parked or moving vehicle, the “Brake” telltale will activate in red letters with a black background. There are no requirements in FMVSS No. 101 or 121 for the color

of the telltale, but DTNA’s use of red, which is an accepted color representing an urgent condition, provides a definitive indication of a situation that needs attention.

2. Activation of the “Brake” telltale is accompanied by illumination on the instrument cluster message display screen with the words “LOW AIR!” in white, upper case lettering with a green background. The height of the lettering appears greater than that of the surrounding telltales and is followed by an exclamation point for increased importance. In a follow-up telephone conversation with DTNA after notice of receipt of petition was published, DTNA confirmed that the lettering height was one quarter inch. Although there is no lettering height requirement for “Brake Air,” and the specification is only that the warning be visible, for reference, a common minimum height for many FMVSS visual indicators is one-eighth inch. This combined with the green rectangular background, which also is comparatively large, is readily visible to the operator and is unlikely to be overlooked. Both the “BRAKE” telltale and the “LOW AIR!” message are in clear view of the driver and when activated will alert the driver of a brake system malfunction.

3. Simultaneous to illumination of both the “Brake” telltale and “LOW AIR!” in the message center, is activation of an audible alert, further notifying the operator that a malfunction exists requiring corrective action. Although the alert would not in and of itself identify the problem, a driver would be prompted by the warning tone to heed the telltales and warning messages activated in the instrument cluster (*i.e.*, “Brake” and “LOW AIR!”).

4. In a low pressure situation, the operator is provided additional feedback by the primary and secondary instrument cluster air gauges which are marked with PSI numerical values along with red-delineated ranges where the needle pointers would be positioned during a low pressure condition.

5. NHTSA agrees with DTNA that for a vehicle that is parked, if a low air condition were present, along with the operator feedback described above, there would be difficulty or an inability to release the parking brake and/or reduced drivability, as sufficient air in the system is required to release the parking brake.

6. Further, NHTSA agrees with DTNA’s contention that the functionality of the parking brake system and the braking performance of the service brake system remains unaffected by use of the telltale word

“Brake” instead of “Brake Air” on the subject vehicles.

7. Lastly, NHTSA believes that, as these affected trucks are predominately used as commercial vehicles with professional drivers, operators will monitor their vehicle’s condition and take note of any warning signs and gauge readings to ensure proper functionality of all systems. As DTNA states, and we agree, drivers will be familiar with the meaning of telltales and other warnings and the feedback provided to the driver in these vehicles if a low brake pressure condition exists would be well understood.

NHTSA concludes that simultaneous activation of red “Brake” telltale with a black contrasting background, message center wording “LOW AIR!” in large white letters on a substantially sized green contrasting background, and an audible alert for a low air pressure condition, along with the primary and secondary air gauge indicators, and the reduced drivability of the vehicles under a low air pressure condition, provides adequate notification to the operator that a brake malfunction exists. NHTSA further concludes that the discrepancy with the labeling requirement is unlikely to lead to any misunderstanding since other sources of correct information beyond the “Brake” telltale, are always provided.

NHTSA’s Decision: In consideration of the foregoing, NHTSA finds that DTNA has met its burden of persuasion that the FMVSS No. 101 noncompliance is inconsequential as it relates to motor vehicle safety. Accordingly, DTNA’s petition is hereby granted and DTNA is consequently exempted from the obligation to provide notification of, and remedy for, the subject noncompliance in the affected vehicles under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject vehicles that DTNA no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their

control after DTNA notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,
Director, Office of Vehicle Safety Compliance.

[FR Doc. 2017-15256 Filed 7-19-17; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA-2017-0051]

Reports, Forms, and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. This document describes the collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before September 18, 2017.

ADDRESSES: You may submit comments identified by DOT Docket Number NHTSA-2017-0051 using any of the following methods:

Electronic submissions: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Mail: Docket Management Facility, M-30, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590.

Hand Delivery: West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: 1-202-493-2251.

Each submission must include the agency name and the docket number for this notice. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Kathy J. Sifrit, Contracting Officer’s

Representative, Office of Behavioral Safety Research (NPD-320), National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, W46-466, Washington, DC 20590. Dr. Sifrit’s phone number is 202-366-0868, and her email address is kathy.sifrit@dot.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB’s regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) How to enhance the quality, utility, and clarity of the information to be collected; and

(iv) How 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, *e.g.*, permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

Title: Older Driver Rearview Video Systems.

Type of Request: New information collection.

OMB Clearance Number: None.

Form Number: NHTSA Forms 1398 and 1399.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: The National Highway Traffic Safety Administration (NHTSA) proposes to collect information from older licensed drivers about their driving performance, driving habits, and levels of familiarity with rearview video systems (RVSS), and to measure their ability to avoid obstacles while backing using an RVS as compared to using only mirrors and shoulder checks. Following

initial data collection, the research team will develop a training protocol based on common errors participants made during the first study segment. During the training segment of the study, a new sample of participants will complete backing tasks similar to those in the first segment. Then participants will be randomly assigned to either a training group or a placebo group. Following training all participants will again complete a series of backing tasks. Analyses will test whether the training improved drivers' ability to use the RVS appropriately. This research would give the traffic safety community greater insight into the extent to which older drivers are able to use RVSs effectively and whether training in proper use of the devices improves their ability to use the systems to back safely.

Study participation will be voluntary and will be solicited among residents of residential communities, senior centers, and/or service- or faith-based organizations in the southeastern Pennsylvania area through community newsletters and other community media. Interested older adults will attend a public meeting to learn about the research opportunity including inclusion and exclusion criteria. Following the meeting, interested older adults will provide their name and telephone number on a signup sheet. A project assistant will then call individuals on the signup sheet and conduct a brief telephone pre-screening to ensure that all participants meet inclusion and exclusion criteria; the project assistant will also answer questions about study participation. For interested candidate participants who meet inclusion criteria, the project assistant will make appointments to conduct either a controlled, off-road backing performance evaluation or a training protocol evaluation, at a mutually convenient time. At the beginning of the appointment, the project assistant will obtain a signature from each participant on an informed consent. A driving rehabilitation specialist (DRS) will then conduct the off-road backing performance evaluation or training protocol evaluation. Participants will then receive compensation of \$100 for study participation.

Throughout the project, the privacy of all participants would be protected. Access to the participants' data would be controlled using password-protection for both the computer and the files. Personally-identifiable information, such as participants' postal addresses, would be kept separate from the data collected and would be stored in a wall safe in password-protected folders on an external hard drive that is only accessible to study staff who need to access such information. In addition, all participant data would be reported in aggregate, and identifying information would not be used in any reports resulting from this data collection effort. Rigorous de-identification procedures would be used to prevent participants from being identified through reconstructive means.

Description of the Need for the Information and Proposed Use of the Information—NHTSA was established by the Highway Safety Act of 1970 (23 U.S.C. 101) to carry out a Congressional mandate to reduce deaths, injuries, and economic losses resulting from motor vehicle crashes on the Nation's highways. As part of this mandate, NHTSA is authorized to conduct research as a foundation for the development of traffic safety programs.

A 2014 final rule issued by NHTSA (Federal Motor Vehicle Safety Standard No. 111, "Rear visibility") requires rear visibility technology in all new vehicles with a Gross Vehicle Weight Rating (GVWR) under 10,000 pounds by May 2018, but the anticipated safety gains depend in part on the extent to which drivers understand and use the technology as intended. This study has two purposes. The first purpose is to assess the driving performance of adults 50 and older using mirrors and an RVS while operating a motor vehicle in reverse. The second purpose is to develop, implement, and assess the effectiveness of an RVS training protocol. Findings will provide information about whether people ages 50 and older differ in backing performance when using RVS versus only mirrors, whether elements of RVS use are particularly difficult for this cohort, and whether RVS training improves older drivers' ability to avoid obstacles while backing. NHTSA will

use the information to inform recommendations to the driving public regarding safe backing practices.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information)— Respondents will include independently living licensed drivers, age 50 and older, in the southeastern Pennsylvania area. It is estimated that 300 one-time telephone conversations will be conducted with those who sign up after the public meeting, to yield 200 participants. Of the 200 participants, 120 will complete a one-time controlled, off-road backing performance evaluation that will inform the development of the training. The remaining 80 will complete the one-time training protocol evaluation.

Estimate of the Total Annual Reporting and Record Keeping Burden Resulting from the Collection of Information—The total estimated burden for this information collection is 365 hours. The 300 telephone pre-screening will average 15 minutes in length including introduction, qualifying questions, potential participant questions, logistical questions, and conclusion for an estimated total burden of 75 hours. For the 120 participants who complete the controlled, off-road backing performance evaluation, the estimated average burden is 75 minutes (15 minutes for the informed consent form plus 60 minutes for the backing evaluation) for a total estimate of 150 hours. For the 80 participants who complete the training protocol evaluation, the estimated average burden is 105 minutes because of the additional 30 minutes for training (or placebo) for a total estimate of 140 hours. Participants will incur no costs from the data collection and participants will incur no record keeping burden and no record keeping cost from the information collection.

Authority: 44 U.S.C. Section 3506(c)(2)(A).

Issued in Washington, DC on July 17, 2017.

Jeff Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2017-15219 Filed 7-19-17; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

[CMS–1678–P]

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: Proposed rule.

SUMMARY: This proposed rule would revise 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 and certain provisions under the 21st Century Cures Act (Pub. L. 114–255). In this proposed rule, we describe the proposed 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 proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

DATES: *Comment period:* To be assured consideration, comments on this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on September 11, 2017.

ADDRESSES: In commenting, please refer to file code CMS–1678–P 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–P, 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–P, 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 at 410–786–0237 or via email Elisabeth.Daniel1@cms.hhs.gov.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia at 410–786–7236 or via email Anita.Bhatia@cms.hhs.gov.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Vinitha Meyyur at 410–786–8819 or via email Vinitha.Meyyur@cms.hhs.gov.

Blood and Blood Products, contact Josh McFeeters at 410–786–9732 or via email Joshua.McFeeters@cms.hhs.gov.

Cancer Hospital Payments, contact Scott Talaga at 410–786–4142 or via email Scott.Talaga@cms.hhs.gov.

Care Management Services, contact Scott Talaga at 410–786–4142 or via email Scott.Talaga@cms.hhs.gov.

CPT Codes, contact Marjorie Baldo at 410–786–4617 or via email Marjorie.Baldo@cms.hhs.gov.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver at 410–786–6719 or via email Chuck.Braver@cms.hhs.gov.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Twi Jackson at 410–786–1159 or via email Twi.Jackson@cms.hhs.gov.

Comprehensive APCs (C–APCs), contact Lela Strong at 410–786–3213 or via email Lela.Strong@cms.hhs.gov.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia at 410–786–7236 or via email Anita.Bhatia@cms.hhs.gov.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur at 410–786–8819 or via email Vinitha.Meyyur@cms.hhs.gov.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson at 410–786–1159 or via email Twi.Jackson@cms.hhs.gov.

Inpatient Only (IPO) Procedures List, contact Lela Strong at 410–786–3213 or via email Lela.Strong@cms.hhs.gov.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga at 410–786–4142 or via email Scott.Talaga@cms.hhs.gov.

No Cost/Full Credit and Partial Credit Devices, contact Twi Jackson at 410–786–1159 or via email Twi.Jackson@cms.hhs.gov.

OPPS Brachytherapy, contact Scott Talaga at 410–786–4142 or via email Scott.Talaga@cms.hhs.gov.

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

at 410-786-1816 or via email Erick.Chuang@cms.hhs.gov or contact Elisabeth Daniel at 410-786-0237 or via email Elisabeth.Daniel1@cms.hhs.gov.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Elisabeth Daniel at 410-786-0237 or via email Elisabeth.Daniel1@cms.hhs.gov.

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 at 410-786-4617 or via email Marjorie.Baldo@cms.hhs.gov.

OPPS Packaged Items/Services, contact Elisabeth Daniel at 410-786-0237 or via email Elisabeth.Daniel1@cms.hhs.gov.

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 at 410-786-2682 or via email Marina.Kushnirova@cms.hhs.gov.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at PHPPaymentPolicy@cms.hhs.gov.

Potential Revisions to the Laboratory Date of Service Policy, contact Rasheeda Johnson at 410-786-3434 or via email Rasheeda.Johnson1@cms.hhs.gov or Susan Janeczko at 410-786-4529 or via email Susan.Janeczko@cms.hhs.gov.

Rural Hospital Payments, contact Josh McFeeters at 410-786-9732 or via email Joshua.McFeeters@cms.hhs.gov.

Skin Substitutes, contact Josh McFeeters at 410-786-9732 or via email Joshua.McFeeters@cms.hhs.gov.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Lela Strong at 410-786-3213 or via email Lela.Strong@cms.hhs.gov.

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 4:00 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the Internet at <https://www.gpo.gov/fdsys/>.

Addenda Available Only Through the Internet on the CMS Web Site

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
 ESRD QIP 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	MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173	SCH Sole community hospital
HCP Health care personnel	MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309	SCOD Specified covered outpatient drugs
HCPCS Healthcare Common Procedure Coding System	MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173	SES Socioeconomic status
HCRIS Healthcare Cost Report Information System	MPFS Medicare Physician Fee Schedule	SI Status indicator
HCUP Healthcare Cost and Utilization Project	MR Medical review	SIA Systems Improvement Agreement
HEU Highly enriched uranium	MRA Magnetic resonance angiography	SIR Standardized infection ratio
HH QRP Home Health Quality Reporting Program	MRgFUS Magnetic Resonance Image Guided Focused Ultrasound	SNF Skilled nursing facility
HHS Department of Health and Human Services	MRI Magnetic resonance imaging	SRS Stereotactic radiosurgery
HIE Health information exchange	MRSA Methicillin-Resistant Staphylococcus Aureus	SRTR Scientific Registry of Transplant Recipients
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191	MS–DRG Medicare severity diagnosis-related group	SSA Social Security Administration
HOP Hospital Outpatient Payment [Panel]	MSIS Medicaid Statistical Information System	SSI Surgical site infection
HOPD Hospital outpatient department	MUC Measure under consideration	TEP Technical Expert Panel
HOP QDRP Hospital Outpatient Quality Data Reporting Program	NCCI National Correct Coding Initiative	TOPs Transitional Outpatient Payments
HPMS Health Plan Management System	NEMA National Electrical Manufacturers Association	USPSTF United States Preventive Services Task Force
IBD Inflammatory bowel disease	NHSN National Healthcare Safety Network	VBP Value-based purchasing
ICC Interclass correlation coefficient	NOTA National Organ and Transplantation Act	WAC Wholesale acquisition cost
ICD Implantable cardioverter defibrillator	NOS Not otherwise specified	
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification	NPI National Provider Identifier	
ICD–10 International Classification of Diseases, Tenth Revision	NQF National Quality Forum	
ICH In-center hemodialysis	NQS National Quality Strategy	
ICR Information collection requirement	NTIOL New technology intraocular lens	
IDTF Independent diagnostic testing facility	NUBC National Uniform Billing Committee	
IGI IHS Global Insight, Inc.	OACT [CMS] Office of the Actuary	
IHS Indian Health Service	OBRA Omnibus Budget Reconciliation Act of 1996, Public Law 99–509	
I/OCE Integrated Outpatient Code Editor	O/E Observed to expected event	
IOL Intraocular lens	OIG [HHS] Office of the Inspector General	
IORT Intraoperative radiation treatment	OMB Office of Management and Budget	
IPFQR Inpatient Psychiatric Facility Quality Reporting	ONC Office of the National Coordinator for Health Information Technology	
IPPS [Hospital] Inpatient Prospective Payment System	OPD [Hospital] Outpatient Department	
IQR [Hospital] Inpatient Quality Reporting	OPPS [Hospital] Outpatient Prospective Payment System	
IRF Inpatient rehabilitation facility	OPSF Outpatient Provider-Specific File	
IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program	OQR [Hospital] Outpatient Quality Reporting	
IT Information technology	OT Occupational therapy	
LCD Local coverage determination	PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93	
LDR Low dose rate	PCHQR PPS-Exempt Cancer Hospital Quality Reporting	
LTCH Long-term care hospital	PCR Payment-to-cost ratio	
LTCHQR Long-Term Care Hospital Quality Reporting	PDC Per day cost	
MAC Medicare Administrative Contractor	PDE Prescription Drug Event	
MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114–10	PE Practice expense	
MAP Measure Application Partnership	PEPPER Program Evaluation Payment Patterns Electronic Report	
MDH Medicare-dependent, small rural hospital	PHP Partial hospitalization program	
MedPAC Medicare Payment Advisory Commission	PHSA Public Health Service Act, Public Law 96–88	
MEG Magnetoencephalography	PN Pneumonia	
MFP Multifactor productivity	POS Place of service	
MGCRB Medicare Geographic Classification Review Board	PPI Producer Price Index	
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	PPS Prospective payment system	
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275	PQRI Physician Quality Reporting Initiative	
MLR Medical loss ratio	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	

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I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we are proposing to update 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 proposed rule. In addition, this proposed rule would update and refine 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 proposing to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.75 percent. This proposed increase factor is based on the proposed hospital inpatient market basket percentage increase of 2.9 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.4 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act. Based on this proposed update, we estimate that proposed total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2018 would be approximately \$70 billion, an increase of approximately \$5.7 billion compared to estimated CY 2017 OPPS payments.

We are proposing to continue 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 proposed reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

- **Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes:** As we did for CY 2017, we are proposing to assign 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 proposing 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, will be assigned to the high cost group for CY 2018. The goal of our proposal 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 rule and final rule 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 proposed rule, we are proposing to reinstate the nonenforcement of direct supervision enforcement instruction for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for CY 2018 and CY 2019.

- **340B Drug Pricing:** We are proposing 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 share in some of the savings realized by hospitals participating in the 340B program. For CY 2018, we are proposing to exercise the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through and vaccines) acquired under the 340B program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. In addition, in this proposed rule, we state our intent to establish a modifier to identify whether a drug billed under the OPPS was purchased under the 340B Drug Discount Program.

- **Device Pass-Through Applications:** For CY 2018, we evaluate five devices for eligibility to receive pass through payments and are seeking comments on whether each of these items meet the criteria for device pass-through status.

- **Rural Adjustment:** We are proposing to continue the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This proposed adjustment would 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 proposing to continue 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 this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, a proposed target PCR of 0.89 would be used to determine the CY 2018 cancer hospital payment adjustment to be paid at cost report settlement. That is, the proposed payment adjustments would be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

- **Changes to the Inpatient Only List:** In CY 2017 OPPS/ASC rulemaking, we solicited comment from the public on whether total knee arthroplasty should be removed from the inpatient only list. Several commenters to the CY 2017 OPPS/ASC proposed rule were supportive of the removal. In addition, the Advisory Panel on Hospital Outpatient Payment recommended at its Summer 2016 meeting that this procedure be removed from the inpatient only list. After evaluating the procedure, for CY 2018, we are proposing to remove total knee arthroplasty from the inpatient-only list. In addition, we are soliciting comment on whether partial and total hip should also be removed from the inpatient only list and added to the ASC Covered Surgical Procedures List.

- **Comprehensive APCs:** For CY 2018, we are not proposing to create any new C-APCs or 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. We note that for CY 2018, for the C-APC for Stereotactic Radio Surgery (SRS), specifically, C-APC 5627 (Level 7 Radiation Therapy), we are proposing 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 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 proposing to remove the exception for certain drug administration services and conditionally package payment for low-cost drug administration services. We are not proposing to package drug administration add-on codes for CY 2018, but are soliciting comments on this policy. In addition, we are broadly soliciting 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.

- *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 would 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, would be reported with the applicable HCPCS code to describe imaging services that are taken using computed radiography technology/cassette-based imaging beginning January 1, 2018.

- *ASC Payment Update*: For CY 2018, we are proposing to increase payment rates under the ASC payment system by 1.9 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed increase is based on a projected CPI-U update of 2.3 percent minus a multifactor productivity adjustment required by the Affordable Care Act of 0.4 percentage point. Based on this proposed update, we estimate that proposed total payments to ASCs (including beneficiary cost sharing and

estimated changes in enrollment, utilization, and case-mix), for CY 2018 would be approximately \$4.68 billion, an increase of approximately \$155 million compared to estimated CY 2017 Medicare payments. In addition, we are soliciting comment on payment reform for ASCs, including the collection of cost data which may support a rate update other than CPI-U.

- *Comment Solicitation on ASC Payment Reform*: We are 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.

- *Changes to the List of ASC Covered Surgical Procedures*: For CY 2018, we are proposing to add three procedures to the ASC Covered Procedures List. In addition, we are soliciting comment on whether total knee arthroplasty, partial hip arthroplasty and total hip arthroplasty meet the criteria to be added to the ASC-CPL. We also are soliciting 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.

- *Potential 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 advance diagnostic laboratory tests (ADLTs) under the new private payor rate-based Clinical Laboratory Fee Schedule (CLFS), we are soliciting public comments on billing for molecular pathology tests and ADLTs ordered less than 14 days of a hospital outpatient discharge.

- *Hospital Outpatient Quality Reporting (OQR) Program*: For the Hospital OQR Program, we are proposing to remove and delay certain measures for the CY 2020 payment determination and the CY 2021 payment determination and subsequent years. For the CY 2020 payment determination and subsequent years, we are proposing to remove OP–21: Median Time to Pain Management for Long Bone Fracture and OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures. We are also proposing to delay the OAS CAHPS Survey measures (OP–37–a–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 to note that the 50 poorest performing outlier hospitals will be targeted for validation; (2) proposing to formalize the validation educational review process, update it to allow corrections of incorrect validation results for chart-abstracted measures, and modify the CFR accordingly; (3) proposing to change the Notice of Participation (NOP) deadline and make corresponding changes to the CFR; (4) proposing to align 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; (5) proposing to publicly report OP–18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients; and (6) proposing to 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. For the CY 2021 payment determination and subsequent years, we are proposing 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 Use.

- *Ambulatory Surgical Center Quality Reporting (ASCQR) Program*: For the ASCQR Program, we are proposing to adopt measures and policies for the CY 2019 payment determination, 2021 payment determination, and CY 2022 payment determination and subsequent years. Specifically, we are proposing, beginning with the CY 2019 payment determination, to 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 proposing 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 and beyond, we are proposing 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 also proposing, beginning with the CY 2021 payment determination, to adopt one new measure, ASC-16: Toxic Anterior Segment Syndrome. In addition, we are proposing, 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.

3. Summary of Costs and Benefits

In sections XIX. and XX. of this proposed rule, we set forth a detailed analysis of the regulatory and Federalism impacts that the proposed changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of the Proposed OPSS Update

(1) Impacts of All OPSS Proposed Changes

Table 38 in section XIX. of this proposed rule displays the distributional impact of all the proposed OPSS changes on various groups of hospitals and CMHCs for CY 2018 compared to all estimated OPSS payments in CY 2017. We estimate that the proposed policies in this proposed rule would result in a 1.9 percent overall increase in OPSS payments to providers. We estimate that proposed total OPSS payments for CY 2018, including beneficiary cost-sharing, to the approximate 3,900 facilities paid under the OPSS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately \$897 million compared to CY 2017 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our proposed OPSS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPSS. Continuing the provider-specific structure that we adopted beginning in CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate a 2.1 percent increase in CY 2018 payments to CMHCs relative to their CY 2017 payments.

(2) Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY

2018 IPPS proposed rule wage indexes results in no change for urban and rural hospitals under the OPSS. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data.

(3) Impacts of the Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our proposed CY 2018 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural hospital payment adjustments. While we are implementing the required reduction to the cancer hospital payment adjustment in Section 16002 of the 21st Century Cures Act for CY 2018, the adjustment amounts do not significantly impact the budget neutrality adjustments for these policies.

(4) Impacts of the Proposed OPD Fee Schedule Increase Factor

We estimate that, for most hospitals, the application of the proposed OPD fee schedule increase factor of 1.75 percent to the conversion factor for CY 2018 would mitigate the impacts of the budget neutrality adjustments. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that rural and urban hospitals would experience increases of approximately 2.0 percent for urban hospitals and 2.0 percent for rural hospitals. Classifying hospitals by teaching status or type of ownership suggests that these hospitals would receive similar increases.

b. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The proposed percentage change in estimated total payments by specialty groups under the proposed CY 2018 payment rates compared to estimated CY 2017 payment rates ranges between 5 percent for integumentary system procedures and 1 percent for genitourinary system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our proposed CY 2018 policies to significantly affect the number of hospitals that do not receive a full annual payment update.

d. Impacts of the ASCQR Program

We do not expect our proposed CY 2018 policies to significantly affect the number of ASCs that do not receive a full annual payment update.

B. Legislative and Regulatory Authority for the Hospital OPSS

When Title XVIII of the Social Security Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) added section 1833(t) to the Act authorizing implementation of a PPS for hospital outpatient services. The OPSS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPSS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) made major changes in the hospital OPSS. The following Acts made additional changes to the OPSS: The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA) (Pub. L. 109-432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110-173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111-309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112-78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012

(MCTR)CA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, and the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016.

Under the OPPS, we pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

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. 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 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 HOP 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 panel 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 22, 2016. 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 that the public should be aware of. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). Further information on this summer's 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).

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 are the Data Subcommittee, the Visits and Observation Subcommittee, and the Subcommittee for APC Groups and Status Indicator (SI) Assignments. The Data Subcommittee is responsible for studying the data issues confronting the Panel and for recommending options for resolving them. The Visits and Observation Subcommittee reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPSS (for example, APC configurations and APC relative payment weights). The Subcommittee for APC Groups and SI Assignments advises the Panel on the following issues: 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; and the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made. The Panel recommended at the August 22, 2016 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the August 22, 2016 Panel meeting, namely conditional packaging, allogeneic hematopoietic stem cell transplantation, and outpatient total knee arthroplasty, were discussed in the CY 2017 OPSS/ASC final rule with comment period (81 FR 79562), the CY 2017 OPSS/ASC correction notice (82 FR 24), or are included in the sections

of this proposed rule that are specific to each recommendation. For discussions of past Panel meetings and recommendations, we refer readers to previously published OPSS/ASC proposed and final rules, the CMS Advisory Panel on Hospital Outpatient Payment Web site mentioned earlier in this section, and the FACA database at: <http://facadatabase.gov/>.

F. Public Comments Received on the CY 2017 OPSS/ASC Final Rule With Comment Period

We received 39 timely pieces of correspondence on the CY 2017 OPSS/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 OPSS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule), the potential limitation on clinical service line expansion or volume of services 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 this proposed rule under the appropriate subject matter headings. Summaries of public comments on the MPFS payment rates for nonexcepted items and services will be set forth in the CY 2018 MPFS final rule with comment period.

II. Proposed Updates Affecting OPSS Payments

A. Proposed 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 OPSS 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 this CY 2018 OPSS/ASC proposed rule, for CY 2018, we are proposing 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 OPPTS/ASC final rule with comment period (81 FR 79574 through 79595). That is, we are proposing to 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 proposed 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 proposed CY 2018 OPPTS 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 OPPTS/ASC proposed rule on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

Addendum N to this proposed rule includes the proposed list of bypass codes for CY 2018. The proposed 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 proposed 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 proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we are proposing to add 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 proposing to remove from the CY 2018 bypass list.

TABLE 1—PROPOSED HCPCS CODES TO BE 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.
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.
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. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2018, in this CY 2018 OPPTS/ASC proposed rule, we are proposing to continue 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 proposed 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 proposed CY 2018 OPPTS 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](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 proposed CY 2018 OPPTS 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 OPPTS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPTS) 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 OPPTS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of this proposed rule.

In the CY 2014 OPPTS/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 OPPTS/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 OPPTS 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 would estimate the imaging APC relative payment weight using cost data from all providers, regardless of the cost allocation statistic employed.

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	–4.3
5522	Level 2 Imaging without Contrast	6.1
5523	Level 3 Imaging without Contrast	1.1
5524	Level 4 Imaging without Contrast	7.3
5525	Level 5 Imaging without Contrast	4.5
5571	Level 1 Imaging with Contrast	10.1
5572	Level 2 Imaging with Contrast	9.4
5573	Level 3 Imaging with Contrast	6.0
8005	CT and CTA without Contrast Composite	13.5
8006	CT and CTA with Contrast Composite	10.5
8007	MRI and MRA without Contrast Composite	6.8
8008	MRI and MRA with Contrast Composite	7.2

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	0.0397	0.0559	0.0828	0.1072
Square Feet Only	0.0332	0.0493	0.0726	0.0972
Direct Assign	0.0591	0.0680	0.1039	0.1247
Dollar Value	0.0485	0.0644	0.0941	0.1203
Direct Assign and Dollar Value	0.0485	0.0644	0.0949	0.1200

Our analysis shows that since the CY 2014 OPSS in which we established the transition policy, the number of valid MRI CCRs has increased by 15.6 percent to 2,142 providers and the number of valid CT CCRs has increased by 13.4 percent to 2,219 providers. However, we note 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 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 are proposing to extend the transition policy an additional year, for the CY 2018 OPSS.

For the CY 2018 OPSS, we are proposing 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.

2. Proposed Data Development Process and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the proposed OPSS payment rates for CY 2018. The Hospital OPSS page on the CMS Web site on which this proposed rule 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 proposed 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 “OPSS Limited Data Set,” which now includes the additional variables previously available only in the OPSS 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 proposed payment rates for the CY 2018 OPSS.

In the history of the OPSS, 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 proposed rule, we are proposing to continue to use geometric mean costs to calculate the proposed 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 proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the proposed OPPS payment rates for CY 2018 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

For details of the claims process used in this proposed rule, we refer readers to the claims accounting narrative under supporting documentation for this CY 2018 OPPS/ASC proposed rule on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

a. Proposed 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.

For CY 2018, in this CY 2018 OPPS/ASC proposed rule, we are proposing 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 are proposing 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 are proposing 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 are proposing 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. We are proposing 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 are proposing 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 refer readers to Addendum B to this 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 are inviting public comments on our proposals.

(b) Pathogen-Reduced Platelets and Rapid Bacterial Testing for Platelets

In March 2016, the Food and Drug Administration (FDA) issued draft guidance for the health care industry 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/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>). This draft guidance recommended the use of rapid bacterial testing devices secondary to testing using a culture-based bacterial detection device or 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).

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) shall be used to report the use of pathogen-reduction technology and HCPCS code Q9987 (Pathogen(s) test for platelets) shall be 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 on the charges and costs for this blood product upon which to apply our blood-specific CCR methodology. Therefore, we established an interim payment rate 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.

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, we are proposing 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 this CY 2018 OPPS/ASC proposed rule, we are soliciting 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 can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

(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 OPSS. We refer readers to the CY 2016 OPSS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPSS payment for brachytherapy sources.

In this CY 2018 OPSS/ASC proposed rule, for CY 2018, we are proposing 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 are proposing to use to set the proposed payment rates for most other items and services that would be paid under the CY 2018 OPSS. We are proposing to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we are proposing for other items and services paid under the OPSS, as discussed in section II.A.2. of this proposed rule. We also are proposing to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPSS/ASC final rule with comment period (74 FR 60537). We are proposing 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 OPSS/ASC final rule with comment period (72 FR 66785). For CY 2018 and subsequent years, we also are proposing to continue the policy we first implemented in the CY 2010 OPSS/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 OPSS/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 are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) and are identified with status indicator "U". For CY 2018, we are proposing to assign status indicator "E2" (Items and Services for Which Pricing Information and Claims Data Are Not Available) to HCPCS code C2645 (Brachytherapy planar, p-103) because this code was not reported on CY 2016 claims. Therefore, we are unable to calculate a proposed payment rate based on the general OPSS 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 are no CY 2016 claims reporting this code. In addition, unlike new brachytherapy sources HCPCS codes, we will not consider external data to determine a proposed payment rate for HCPCS code C2645 for CY 2018. Therefore, we are proposing to assign status indicator "E2" to HCPCS code C2645.

In addition, we assigned status indicator "E2" to HCPCS code C2644 (Brachytherapy cesium-131 chloride) 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 are proposing to assign status indicator "U" to HCPCS code 2644, and our payment rates for HCPCS code C2644 will be based on this information.

We are inviting public comments on our proposals.

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. Proposed Comprehensive APCs (C-APCs) for CY 2018

(1) Background

In the CY 2014 OPSS/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 OPSS 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 OPSS payment and implemented 25 C-APCs beginning in CY 2015 (79 FR 66809 through 66810). In the CY 2016 OPSS/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. In the CY 2017 OPSS/ASC final rule with comment period (81 FR 79584 through 79585), we finalized another 25 C-APCs.

Under this policy, we designated a service described by a HCPCS code assigned to a C-APC as the primary service when the service is identified by OPSS 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 OPSS include services that are not covered OPD services, services that cannot by statute be paid for under the OPSS, 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 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 proposed rule (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 to be not 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). We sum all line item charges for services included on the C-APC claim, convert the charges to costs, and calculate the comprehensive geometric mean cost of one unit of each service assigned to status indicator “J1”. (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 their 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 reported 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 OPPI/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 OPPI/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 this CY 2018 OPPI/ASC proposed rule, we are proposing 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 list 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 this proposed rule (which is available via the Internet on the CMS Web site).

Addendum J to this proposed rule includes 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 this proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and are 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 are 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), includes all paired

code combinations that are proposed to be reassigned to C-APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this proposed rule allows 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.

(2) Proposed Additional C-APCs for CY 2018

For CY 2018 and subsequent years, in this CY 2018 OPPI/ASC proposed rule, we are proposing 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 OPPI, we are not proposing any additional C-APCs to be paid under the existing C-APC payment policy beginning in CY 2018. Table 4 below lists the proposed C-APCs for CY 2018, all of which were established in past rules. All C-APCs are displayed in Addendum J to this proposed rule. Addendum J to this proposed rule (which is available via the Internet on the CMS Web site) also contains all of the data related to the C-APC payment policy methodology, including the list of proposed complexity adjustments and other information.

TABLE 4—PROPOSED 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
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

TABLE 4—PROPOSED CY 2018 C-APCs—Continued

C-APC	CY 2018 APC title	Clinical family
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 (namely CPT codes 57155 (Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy); 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)); 31643 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application); 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); 43241 (Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube catheter); 55920 (Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application); and 58346 (Insertion of Heyman capsules for clinical brachytherapy)) often did not also contain a brachytherapy treatment delivery code (CPT codes 77750 through 77799). 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. 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. 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.

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 are 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 this proposed rule, we also are proposing 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 are proposing to package payments for all adjunctive services reported on the claim into the payment for HCPCS code 55875. We are proposing 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). The brachytherapy insertion codes that will be required to be billed with a brachytherapy treatment code are listed in Table 5 listed below.

TABLE 5—PROPOSED BRACHYTHERAPY INSERTION PROCEDURES ASSIGNED TO STATUS INDICATOR “J1”

HCPCS code	Long descriptor
19296	Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy.
19298	Placement of radiotherapy after loading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance.
19499	Unlisted procedure, breast.
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).
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application.
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.
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube catheter.
55875	Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy.
55920	Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application.
57155	Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy.
58346	Insertion of Heyman capsules for clinical 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 OPPTS/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 OPPTS 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 OPPTS/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 OPPTS/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.

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 are proposing 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 OPPTS/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 are inviting public comments on these proposals.

(5) Proposed Complexity Adjustment for Blue Light Cystoscopy Procedures

As discussed in prior OPPTS/ASC final rules with comment period, and most recently in the CY 2017 OPPTS/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 this proposed rule, drugs that are not eligible for pass-through payment are always packaged when billed with a comprehensive service. To maintain the integrity of a prospective payment system, 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 are not proposing 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 access reasonable and necessary care for which there may not be a clinically comparable alternative. Therefore, we are revisiting 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 procedures, which require additional resources compared to white light cystoscopy alone.

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, we are proposing to create a new HCPCS C-code to describe blue light cystoscopy (HCPCS code C97XX (Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure)) 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). Specifically, to determine which code pair combinations of proposed new HCPCS code C97XX and cystoscopy procedure would qualify for a complexity adjustment, we first crosswalked the costs of HCPCS code C9275 (Hexaminolevulinate hcl) to the proposed new HCPCS code C97XX 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 were eligible for a complexity adjustment. We modeled the data to determine which code pair combinations exceeded the claim frequency and cost threshold in APC 5373, APC 5374, and APC 5375, which are all C-APCs. Results of our analysis indicate that the code pair combination of proposed new HCPCS code C97XX 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 indicate that the combination of proposed new HCPCS code C97XX 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.

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 C97XX 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 C97XX 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 plan to track the utilization and the costs associated with white light/blue light cystoscopy procedure combinations that will receive a complexity adjustment.

We are inviting public comments on our CY 2018 proposal to allow for a complexity adjustment when a white light followed by blue light cystoscopy procedure is performed. In addition, we are seeking public comments on whether alternative procedures, such as narrow band imaging, may be disadvantaged by this proposed policy.

(6) Analysis of C-APC Packaging under the OPSS

In the CY 2017 OPSS/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.

Specifically, using OPSS claims data from the CY 2016 final rule, the CY 2017 final rule, 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 OPSS 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 OPSS payment between CYs 2014 and 2016 for each HCPCS 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 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.

c. Proposed Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPSS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPSS 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 OPSS 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 OPSS, 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 OPSS/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 OPSS/ASC final rule with comment period (76 FR 74163) for more recent background.

In this CY 2018 OPSS/ASC proposed rule, for CY 2018 and subsequent years, we are proposing 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 this proposed rule, we are proposing 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 are proposing to delete the low dose rate (LDR) prostate brachytherapy composite APC for CY 2018 and subsequent years.

(1) Mental Health Services Composite APC

In this CY 2018 OPSS/ASC proposed rule, we are proposing 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 OPSS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPSS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2017 OPPTS/ASC final rule (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 new APC 5863 (Partial Hospitalization (3 or more services per day)). For CY 2018, and subsequent years, we are proposing 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 are proposing to set the payment rate for composite APC 8010 for CY 2018 at the same payment rate that we are proposing 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 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 OPPTS than the highest partial hospitalization per diem payment rate for hospitals.

(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 OPPTS/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 OPPTS 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 OPPTS/ASC final rule with comment period (73 FR 68559 through 68569).

In this CY 2018 OPPTS/ASC proposed rule, we are proposing, 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 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) are based on proposed geometric mean costs calculated from a partial year of CY 2016 claims available for this CY 2018 OPPTS/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 OPPTS/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 OPPTS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this CY 2018 OPPTS/ASC proposed rule (which is available via the Internet on the CMS Web site) and are discussed in more detail in section II.A.1.b. of this CY 2018 OPPTS/ASC proposed rule.

For this CY 2018 OPPTS/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 this CY 2018 OPPTS/ASC proposed rule lists 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.

TABLE 6—PROPOSED OPPTS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs

Family 1—Ultrasound	
Proposed CY 2018 APC 8004 (Ultrasound Composite)	
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.
Family 2—CT and CTA with and without Contrast	
Proposed CY 2018 APC 8005 (CT and CTA without Contrast Composite)*	Proposed CY 2018 Approximate APC Geometric Mean Cost = \$280
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.
Proposed CY 2018 APC 8006 (CT and CTA with Contrast Composite)	Proposed CY 2018 Approximate APC Geometric Mean Cost = \$503
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.
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.

TABLE 6—PROPOSED OPPTS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs—Continued

Family 3—MRI and MRA with and without Contrast	
Proposed CY 2018 APC 8007 (MRI and MRA without Contrast Composite)*	Proposed CY 2018 Approximate APC Geometric Mean Cost = \$571
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.
Proposed CY 2018 APC 8008 (MRI and MRA with Contrast Composite)	Proposed CY 2018 Approximate APC Geometric Mean Cost = \$888
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.
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.

TABLE 6—PROPOSED OPPTS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs—Continued

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. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPTS

Like other prospective payment systems, the OPPTS 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 OPPTS packages payment 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 OPPTS 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 payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPTS since its implementation in August 2000. For an extensive discussion of the history and background of the OPPTS packaging policy, we refer readers to the CY 2000 OPPTS final rule (65 FR 18434), the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPPTS/ASC final rule with comment period (78 FR 74925), the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66817), the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70343), and the CY 2017 OPPTS/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 OPPTS packaging policies. Most, but not necessarily all, items and services currently packaged in the OPPTS are listed in 42 CFR 419.2(b). Our overarching goal is to make OPPTS payments for all services paid under the OPPTS 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 OPPTS to determine which OPPTS services can be packaged to further achieve the objective of advancing the OPPTS toward a more prospective payment system.

For CY 2018, we examined the items and services currently provided under the OPPTS, 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 OPPTS packaging policies or a logical expansion of those existing OPPTS packaging policies. In this proposed rule, for CY 2018, we are proposing to conditionally package the costs of selected newly identified ancillary services into payment with a primary service where we believe that the proposed 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 are proposing to package beginning in CY 2018.

b. CY 2018 Drug Administration Packaging Proposal

(1) Background of Drug Administration Packaging Policy

In the CY 2014 OPPTS/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 OPPTS 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) Proposed 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, 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 this 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 OPPS/ASC 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 services, 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 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 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, hospitals receive a higher payment than a physician office for furnishing the same drug administration service. 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 are proposing 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 are proposing to continue to pay separately for Medicare Part B vaccine administration services. In addition, at this time, we are not proposing to package any drug administration services in APC 5693 (Level 3 Drug Administration) or APC 5694 (Level 4 Drug Administration), but are interested in public comments pertaining to whether services in these APCs may be appropriate for packaging. The proposed status indicators for drug administration services in APC 5691 and APC 5692 are listed in Table 7 below.

TABLE 7—PROPOSED CY 2018 STATUS INDICATORS FOR DRUG ADMINISTRATION SERVICES IN LEVEL 1 AND LEVEL 2 DRUG ADMINISTRATION APCs

HCPCS code	Short descriptor	Proposed CY 2018 status indicator
APC 5691—Level 1 Drug Administration		
95115	Immunotherapy one injection	Q1
95117	Immunotherapy injections	Q1
95144	Antigen therapy services	Q1

TABLE 7—PROPOSED CY 2018 STATUS INDICATORS FOR DRUG ADMINISTRATION SERVICES IN LEVEL 1 AND LEVEL 2—
Continued
DRUG ADMINISTRATION APCs

HCPs code	Short descriptor	Proposed CY 2018 status indicator
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 add-on	S
96370	Sc ther infusion addl hr	S
96375	Tx/pro/dx inj new drug add-on	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
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) 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.

We are not proposing to package drug administration add-on codes for CY 2018 in this proposed rule because we want 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 are soliciting public comment on whether conditionally or unconditionally packaging such codes would create access to care issues or have other unintended consequences. Specifically, we are requesting 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 setting.

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 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 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 this CY 2018 OPPTS/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 is displayed in Table 8 below.

TABLE 8—DISTRIBUTION OF PATHOLOGY ONLY OPPTS CLAIMS

Claim subset	Number of claims	Percent of claims
Claims having 1 pathology code	464,039	74.29
Claims having 2 pathology codes	101,954	16.32
Claims having 3 pathology codes	38,163	6.11
Claims having 4 or more pathology codes	20,435	3.27

Based on our claims analysis, the majority of pathology-only OPPTS claims are reported with one pathology code. Therefore, we believe that it is neither a frequent occurrence nor a common occurrence for a provider to submit a claim for payment under the OPPTS 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 OPPTS/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 88312–88314);
- *Hypothetical Composite APC B:* Claims that contain 5 or more pathology units (CPT codes 88302 through 88309) with or without special stains (CPT codes 88312–88314);
- *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, we evaluated the volume of services and costs for each hypothetical composite. Results from modeling the four composite scenarios show low claim volume, which indicates that the suggested pathology code combinations are infrequently billed by hospital outpatient departments, which may mean that these are not likely clinical scenarios in hospital outpatient departments. A summary of the results from our composite analysis are presented in Table 9 below. We refer readers to Addendum B to the CY 2018 OPPTS/ASC proposed rule (which is available via the Internet on the CMS Web site) for the CPT code descriptors.

TABLE 9—COST AND UTILIZATION STATISTICS OF FOUR HYPOTHETICAL COMPOSITE APCS

Hypothetical composite APC	Number of claims	Geometric mean unit cost	Mean pathology units per claim	Mean special stains units per claim	Mean immunostain units per claim
A	139,238	\$95.82	2.42	0.19	0.02
B	14,388	265.36	6.78	0.24	0.03
C	877	544.71	2.46	0.14	3.98
D	214	1,531.87	6.56	0.12	4.28

As we move toward larger payment bundles under the OPPTS, the necessity of composite APCs diminishes. For example, in this CY 2018 OPPTS/ASC proposed rule, we are proposing 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 are not proposing 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 are soliciting public comments on our packaging policies below.

d. Comment Solicitation on 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 payment for multiple interrelated services into a single payment creates 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 towards a 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 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 outpatient services, it is unclear what, if any, adverse effect packaging has on beneficiary access to care. Specifically, within the framework of existing packaging categories, such as drugs that function as supplies in a surgical procedure or diagnostic test or

procedure, we are interested 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 are interested in stakeholder feedback on common clinical scenarios involving separately payable HCPCS codes for which payment would be most appropriately packaged under the OPPS. We are soliciting public comments from a broad cross-section of stakeholders, including beneficiaries, patient advocates, hospital providers, clinicians, manufacturers, and other interested parties.

4. Proposed 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 are proposing 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.

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). For CY 2018, as we did for CY 2017, we are proposing to continue to standardize all of the relative payment weights to APC 5012. 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 are proposing 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.

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, we are proposing 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 are proposing to apply the same process using the estimated CY 2018 unscaled relative payment weights rather than scaled relative payment weights. We are proposing 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 proposed rule link and open the claims accounting document link at the bottom of the page.

We are proposing 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 are proposing to adjust the calculated CY 2018 unscaled relative payment weights for purposes of budget neutrality. We are proposing to adjust the estimated CY 2018 unscaled relative payment weights by multiplying them by a proposed weight scaler 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 this proposed rule (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 proposed rule.

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.3. of this proposed rule) is included in the proposed budget neutrality calculations for the CY 2018 OPPS.

B. Proposed 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. In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19931), consistent with current law, based on IHS Global Insight, Inc.'s

fourth quarter 2016 forecast of the FY 2018 market basket increase, the proposed FY 2018 IPPS market basket update is 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), we discussed the calculation of the proposed MFP adjustment for FY 2018, which is -0.4 percentage point.

We are proposing that if more recent data become subsequently available after the publication of this 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 the CY 2018 OPPS/ASC final rule with comment period.

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, we are proposing 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 proposing to apply an OPD fee schedule increase factor of 1.75 percent for the CY 2018 OPPS (which is 2.9 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.4 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 proposed rule.

In this CY 2018 OPPS/ASC proposed rule, we are proposing 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.

To set the OPPS conversion factor for this CY 2018 proposed rule, we are proposing to increase the CY 2017 conversion factor of \$75.001 by 1.75 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing further to adjust the conversion factor for CY 2018 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We are proposing to calculate an overall proposed 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 OPSS.

For CY 2018, we are proposing to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment would be 1.0000.

For CY 2018, we are proposing 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 proposed rule. We are proposing 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 are less than estimated payments applying the CY 2017 final cancer hospital payment adjustment. Therefore, we are proposing 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 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 in section II.F. of this proposed rule.

For this proposed rule, we estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2018 would equal approximately \$26.2 million, which represents 0.04 percent of total projected CY 2018 OPSS 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 OPSS payments for CY 2018. We estimate for this proposed rule that outlier payments would be 1.04 percent of total OPSS 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 this proposed rule, we also are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 OPSS spending for the difference in the pass-through spending and outlier payments that result in a proposed conversion factor for CY 2018 of \$76.483.

C. Proposed 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 OPSS payment rate is called the OPSS labor-related share. Budget neutrality is

discussed in section II.B. of this proposed rule.

The OPSS labor-related share is 60 percent of the national OPSS 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 OPSS 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 OPSS final rule with comment period (70 FR 68553). We are proposing to continue this policy for the CY 2018 OPSS. We refer readers to section II.H. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting documentation for this proposed rule (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 proposed 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 OPSS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPSS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPSS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPSS 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 OPSS. As initially explained in the September 8, 1998 OPSS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPSS 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 OPSS/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 (c)(3) of our regulations. For the CY 2018 OPPS, we are proposing to implement this provision in the same manner as we have since CY 2011. 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, we are proposing not to extend the imputed floor under the OPPS for CY 2018 and subsequent years). Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the following sections in 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: For FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; and for FY 2017, 81 FR 56922. We are inviting public comments on this proposal.

In addition to the changes required by the Affordable Care Act, we note that the proposed 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). 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. We refer 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 (including our proposal not to extend 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.

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) discusses 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. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, we are proposing to discontinue the use of SSA county codes and begin using only the FIPS county codes. We are inviting public comments on this proposal.

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, we proposed to update the FIPS codes used for crosswalking counties to CBSAs for the IPPS wage index to incorporate changes to the counties or county equivalent entities included in the Census Bureau’s most recent list. 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 proposed rule (82 FR 19898 through 19899), for the IPPS, we proposed to implement these FIPS code updates, effective October 1, 2017, beginning with the FY 2018 wage indexes. We proposed to include these updates to calculate 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. We noted 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 would be no impact or change to hospitals in these counties; they would continue to be considered rural for the IPPS wage index under these changes. Consistent with the FY 2018 IPPS/LTCH PPS proposed rule, for purposes of the OPSS, we are proposing to implement these revisions effective January 1, 2018, beginning with the CY 2018 OPSS wage indexes. 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 OPSS wage index. In addition, 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. Tables 2 and 3 for the FY 2018 IPPS/LTCH PPS proposed 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. We are inviting public comments on our proposals.

For this CY 2018 OPSS/ASC proposed rule, we are proposing to use the FY 2018 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPSS to determine the wage adjustments for both the OPSS payment rate and the copayment standardized amount for CY 2018. Therefore, any adjustments for the FY 2018 IPPS post-reclassified wage index would be reflected in the final CY 2018 OPSS wage index. (We refer readers to the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19898 through 19915) and the proposed FY 2018 hospital wage index files posted on the CMS Web site). We are inviting public comments on this proposal.

Hospitals that are paid under the OPSS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPSS, 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. We are proposing to continue this policy for CY 2018. The following is a brief summary of the major proposed FY 2018 IPPS wage index policies and adjustments that we are proposing to apply to these hospitals under the OPSS for CY 2018. We are inviting public comments on these proposals. We

further refer readers to the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19898 through 19915) for a detailed discussion of the proposed changes to the FY 2018 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPSS 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 OPSS. We note that, because non-IPPS hospitals cannot reclassify, they would be 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 would apply if the hospital were paid under the IPPS. For CY 2018, we are proposing to continue our policy of allowing non-IPPS hospitals paid under the OPSS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA).

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 OPSS 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 in CY 2017, it will no longer be applied in CY 2018.

In addition, under the IPPS, the imputed floor policy is set to expire effective October 1, 2017, and in the IPPS/LTCH PPS proposed rule, we proposed not to extend the imputed floor policy for FY 2018 and subsequent fiscal years (82 FR 19904 through 19905). For purposes of the CY 2018 OPSS, the imputed floor policy is set to expire effective December 31, 2017, and consistent with the IPPS, we are

proposing not to extend the imputed floor policy beyond this date.

For CMHCs, for CY 2018, we are proposing 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 OPSS 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 in CY 2017, it will not be applied in CY 2018. Consistent with our current policy, the wage index that applies to CMHCs would include the rural floor adjustment, but would not include the imputed floor adjustment because as discussed above, we are proposing to not extend the imputed floor policy beyond December 31, 2017. The wage index that applies to CMHCs also would not include the out-migration adjustment because that adjustment only applies to hospitals.

Table 2 associated with the FY 2018 IPPS/LTCH PPS proposed 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 would 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 proposed rule as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under the CY 2018 OPSS. Addendum L is available via the Internet on the CMS Web site. We refer readers to the CMS Web site for the OPSS at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. At this link, readers will find a link to the proposed FY 2018 IPPS wage index tables and Addendum L.

D. Proposed 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 OPSS 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 this proposed rule, we are proposing 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 OPSS/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 refer readers to the CY 2018 OPSS proposed rule Claims Accounting Narrative that is posted on the CMS Web site. Table 10 below lists the proposed statewide average default CCRs for OPSS services furnished on or after January 1, 2018, based on proposed rule data.

TABLE 10—PROPOSED CY 2018 STATEWIDE AVERAGE CCRS

State	Urban/rural	Proposed CY 2018 default CCR	Previous default CCR (CY 2017 OPSS Final rule)
ALASKA	RURAL	0.582	0.449
ALASKA	URBAN	0.238	0.237
ALABAMA	RURAL	0.191	0.196
ALABAMA	URBAN	0.158	0.158
ARKANSAS	RURAL	0.192	0.196
ARKANSAS	URBAN	0.201	0.205
ARIZONA	RURAL	0.237	0.238
ARIZONA	URBAN	0.171	0.176
CALIFORNIA	RURAL	0.176	0.179
CALIFORNIA	URBAN	0.190	0.188
COLORADO	RURAL	0.351	0.354
COLORADO	URBAN	0.204	0.208
CONNECTICUT	RURAL	0.402	0.402
CONNECTICUT	URBAN	0.253	0.253
DISTRICT OF COLUMBIA	URBAN	0.279	0.286
DELAWARE	URBAN	0.296	0.288
FLORIDA	RURAL	0.170	0.169
FLORIDA	URBAN	0.141	0.143
GEORGIA	RURAL	0.226	0.230
GEORGIA	URBAN	0.187	0.196
HAWAII	RURAL	0.333	0.338
HAWAII	URBAN	0.314	0.319
IOWA	RURAL	0.297	0.291
IOWA	URBAN	0.247	0.252
IDAHO	RURAL	0.341	0.341
IDAHO	URBAN	0.404	0.401
ILLINOIS	RURAL	0.232	0.241
ILLINOIS	URBAN	0.216	0.209
INDIANA	RURAL	0.305	0.272
INDIANA	URBAN	0.217	0.218
KANSAS	RURAL	0.272	0.269
KANSAS	URBAN	0.202	0.194
KENTUCKY	RURAL	0.192	0.194
KENTUCKY	URBAN	0.188	0.189
LOUISIANA	RURAL	0.273	0.217
LOUISIANA	URBAN	0.200	0.201
MASSACHUSETTS	RURAL	0.315	0.316
MASSACHUSETTS	URBAN	0.349	0.345
MAINE	RURAL	0.419	0.425
MAINE	URBAN	0.412	0.413
MARYLAND	RURAL	0.263	0.264
MARYLAND	URBAN	0.228	0.229
MICHIGAN	RURAL	0.308	0.295
MICHIGAN	URBAN	0.323	0.324
MINNESOTA	RURAL	0.374	0.398
MINNESOTA	URBAN	0.304	0.319
MISSOURI	RURAL	0.226	0.222
MISSOURI	URBAN	0.243	0.261
MISSISSIPPI	RURAL	0.227	0.224
MISSISSIPPI	URBAN	0.165	0.167

TABLE 10—PROPOSED CY 2018 STATEWIDE AVERAGE CCRs—Continued

State	Urban/rural	Proposed CY 2018 default CCR	Previous default CCR (CY 2017 OPPS Final rule)
MONTANA	RURAL	0.475	0.450
MONTANA	URBAN	0.376	0.368
NORTH CAROLINA	RURAL	0.207	0.216
NORTH CAROLINA	URBAN	0.215	0.223
NORTH DAKOTA	RURAL	0.366	0.411
NORTH DAKOTA	URBAN	0.372	0.334
NEBRASKA	RURAL	0.298	0.294
NEBRASKA	URBAN	0.231	0.238
NEW HAMPSHIRE	RURAL	0.311	0.320
NEW HAMPSHIRE	URBAN	0.262	0.279
NEW JERSEY	URBAN	0.201	0.195
NEW MEXICO	RURAL	0.220	0.225
NEW MEXICO	URBAN	0.284	0.280
NEVADA	RURAL	0.194	0.196
NEVADA	URBAN	0.114	0.123
NEW YORK	RURAL	0.309	0.309
NEW YORK	URBAN	0.286	0.292
OHIO	RURAL	0.289	0.292
OHIO	URBAN	0.208	0.207
OKLAHOMA	RURAL	0.220	0.231
OKLAHOMA	URBAN	0.173	0.180
OREGON	RURAL	0.280	0.280
OREGON	URBAN	0.336	0.344
PENNSYLVANIA	RURAL	0.263	0.274
PENNSYLVANIA	URBAN	0.176	0.179
PUERTO RICO	URBAN	0.549	0.527
RHODE ISLAND	URBAN	0.292	0.291
SOUTH CAROLINA	RURAL	0.187	0.185
SOUTH CAROLINA	URBAN	0.186	0.190
SOUTH DAKOTA	RURAL	0.391	0.383
SOUTH DAKOTA	URBAN	0.238	0.229
TENNESSEE	RURAL	0.170	0.181
TENNESSEE	URBAN	0.177	0.180
TEXAS	RURAL	0.209	0.214
TEXAS	URBAN	0.171	0.177
UTAH	RURAL	0.351	0.349
UTAH	URBAN	0.303	0.315
VIRGINIA	RURAL	0.193	0.191
VIRGINIA	URBAN	0.222	0.226
VERMONT	RURAL	0.424	0.426
VERMONT	URBAN	0.340	0.340
WASHINGTON	RURAL	0.269	0.271
WASHINGTON	URBAN	0.295	0.294
WISCONSIN	RURAL	0.349	0.354
WISCONSIN	URBAN	0.311	0.290
WEST VIRGINIA	RURAL	0.259	0.266
WEST VIRGINIA	URBAN	0.292	0.285
WYOMING	RURAL	0.406	0.429
WYOMING	URBAN	0.326	0.311

E. Proposed 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) (Public Law 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 this CY 2018 OPPS/ASC proposed rule, for the CY 2018 OPPS, we are proposing 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. Proposed 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 recent 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 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 this CY 2018 OPPS/ASC proposed rule, for CY 2018, we are proposing 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 are available at the time of the development of this proposed rule, reduced by 1.0 percentage point to comply with section 16002(b) of the 21st Century Cures Act. We are not proposing 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 use the same extract of cost report data from HCRIS, as discussed in section II.A. of this 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 are proposing 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 below indicates the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2018 due to the proposed cancer hospital payment adjustment policy. 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 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 11—PROPOSED ESTIMATED CY 2018 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider No.	Hospital name	Proposed estimated percentage increase in OPPS payments for CY 2018 due to payment adjustment (%)
050146	City of Hope Comprehensive Cancer Center	32.9
050660	USC Norris Cancer Hospital	11.5
100079	Sylvester Comprehensive Cancer Center	24.3
100271	H. Lee Moffitt Cancer Center & Research Institute	23.1
220162	Dana-Farber Cancer Institute	45.8
330154	Memorial Sloan-Kettering Cancer Center	47.1
330354	Roswell Park Cancer Institute	21.4
360242	James Cancer Hospital & Solove Research Institute	28.9
390196	Fox Chase Cancer Center	8.8
450076	M.D. Anderson Cancer Center	76.9
500138	Seattle Cancer Care Alliance	53.9

G. Proposed 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 OPSS/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 OPSS. Our estimate of total outlier payments as a percent of total CY 2016 OPSS payment, using CY 2016 claims available for this proposed rule, is approximately 1.0 percent of the total aggregated OPSS payments. Therefore, for CY 2016, we estimate that we paid the outlier target of 1.0 percent of total aggregated OPSS payments.

For this proposed rule, using CY 2016 claims data and CY 2017 payment rates, we estimate that the aggregate outlier payments for CY 2017 would be approximately 1.0 percent of the total CY 2017 OPSS payments. We are providing 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. Proposed Outlier Calculation for CY 2018

In this CY 2018 OPSS/ASC proposed rule, for CY 2018, we are proposing to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPSS. We are proposing 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 OPSS 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 OPSS outlier payments. As discussed in section VIII.C. of this proposed rule, we are proposing 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 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 this proposed rule.

To ensure that the estimated CY 2018 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPSS, we are proposing 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 this 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 this 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 OPSS Pricer to pay claims. The claims that we use to model each OPSS update lag by 2 years.

In order to estimate the CY 2018 hospital outlier payments for this 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 OPSS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPSS 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 OPSS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPSS hospital outlier threshold if we did not

apply a CCR inflation adjustment factor. Therefore, we are proposing 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 OPSS 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 OPSS 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 OPSS 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 are proposing 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 refer readers to section XIII. of this proposed rule.

H. Proposed 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 OPSS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2018 OPSS/ASC proposed rule, the proposed payment rate for most services and procedures for which payment is made under the OPSS is the product of the proposed conversion factor calculated in accordance with section II.B. of this proposed rule and the proposed relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site) and for most HCPCS codes to which separate payment under the OPSS has been assigned in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) was calculated by multiplying the proposed CY 2018 scaled weight for the APC by the proposed CY 2018 conversion factor.

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 proposed rule.

We demonstrate below the steps on how to determine the APC payments that will be made in a calendar year under the OPSS 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 proposed rule, 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 would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (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 proposed 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 proposed 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 proposed 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 proposed full CY 2018 OPSS 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 OPSS, 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 OPSS 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 OPSS 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.*

$$X = .60 * (\text{national unadjusted payment rate}).$$

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 proposed CY 2018 OPSS 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 proposed rule. The proposed wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are proposed to be assigned for FY 2018 under the IPPS, reclassifications through the 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 proposed changes to the FY 2018 IPPS wage indexes, as applied to the CY 2018 OPSS, we refer readers to section II.C. of this proposed rule. We are proposing to continue 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 proposed rule (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 proposed rule available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>. 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).

$X_a = .60 * (\text{national unadjusted payment rate}) * \text{applicable wage index}.$

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.

$Y = .40 * (\text{national unadjusted payment rate}).$

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 proposed CY 2018 full national unadjusted payment rate for APC 5071 is approximately \$552.34. The proposed reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is approximately \$541.29. This proposed reduced rate is calculated by multiplying the proposed reporting ratio of 0.980 by the proposed full unadjusted payment rate for APC 5071.

The proposed FY 2018 wage index for a provider located in CBSA 35614 in New York is 1.2892. The labor-related portion of the proposed full national unadjusted payment is approximately \$427.25 (.60 * \$552.34 * 1.2892). The labor-related portion of the proposed reduced national unadjusted payment is approximately \$418.70 (.60 * \$541.29 * 1.2892). The nonlabor-related portion of the proposed full national unadjusted payment is approximately \$220.94 (.40 * \$552.34). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately \$216.52 (.40 * \$541.29). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately \$648.19 (\$427.25 + \$220.94). The sum of the portions of the proposed reduced national adjusted payment is approximately \$635.22 (\$418.70 + \$216.52).

I. Proposed 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 OPSS/ASC final rule with comment period (75 FR 72013).

2. Proposed OPSS Copayment Policy

For CY 2018, we are proposing 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 OPSS final rule with comment period (68 FR 63458).) In addition, we are proposing 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 OPSS/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 OPSS that would be effective January 1, 2018 are included in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

As discussed in section XIII.E. of this proposed, for CY 2018, the proposed 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 OPSS 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 OPSS cost modeling process. However, as described in the CY 2004 OPSS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPSS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPSS 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 OPSS 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 OPSS 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 OPSS payment rate for all OPSS 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. Proposed Calculation of an Adjusted Copayment Amount for an APC Group

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, \$110.47 is approximately 20 percent of the proposed full national unadjusted payment rate of \$552.34. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed 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.
 $B = \text{National unadjusted copayment for APC} / \text{National unadjusted payment rate for APC}.$

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 proposed rule. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this proposed rule.

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 proposed rule, 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 proposed unadjusted copayments for services payable under the OPSS that would be effective January 1, 2018, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed CY 2018 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

In addition, as noted above, 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. Proposed OPSS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPSS 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 OPSS. Specifically, CMS recognizes the following codes on OPSS 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 proposed rule discusses the various status indicators used under the OPPS.

In Table 12 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 12—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. Proposed Treatment of New HCPCS Codes That Were Effective April 1, 2017 for Which We Are Soliciting Public Comments in This 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 six new Level II HCPCS codes for separate payment under the OPPS. In this CY 2018 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for

these Level II HCPCS codes, which are listed in Table 13 of this proposed rule. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 13—NEW LEVEL II HCPCS CODES EFFECTIVE APRIL 1, 2017

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2018 SI	Proposed CY 2018 APC
C9484	Injection, eteplirsen, 10 mg	G	9484
C9485	Injection, olaratumab, 10 mg	G	9485
C9486	Injection, granisetron extended release, 0.1 mg	G	9486
C9487*	Ustekinumab, for intravenous injection, 1 mg	G	9487
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.

2. Proposed Treatment of New HCPCS Codes That Were Effective July 1, 2017 for Which We Are Soliciting Public Comments in This CY 2018 OPPTS/ASC Proposed Rule

Through the July 2017 OPPTS 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 OPPTS status indicators and APCs.

Three HCPCS codes are no longer payable under the OPPTS because they have been replaced with more specific or different codes effective July 1, 2017. In particular, the coverage indicator for

HCPCS codes J1725 (Injection, hydroxyprogesterone caproate, 1 mg) and P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit) was revised to “Not Payable by Medicare” because these codes were replaced with more specific HCPCS codes. HCPCS code J1725 was replaced with HCPCS codes Q9986, and HCPCS code P9072 was replaced with HCPCS code Q9988 (Platelets, pheresis, pathogen reduced, each unit). Further, HCPCS code C9487 (Ustekinumab, for intravenous injection, 1 mg) was deleted June 30, 2017 and replaced with HCPCS code Q9989 effective July 1, 2017. Because HCPCS code Q9989 describes the same drug as HCPCS code C9487, we are proposing to continue the drug’s

pass-through payment status and to assign HCPCS code Q9989 to the same APC and status indicators as its predecessor HCPCS code C9487, as shown in Table 14.

In this CY 2018 OPPTS/ASC proposed rule, we are soliciting 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 are listed in Table 14 below. The proposed payment rates and status indicators for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 14—NEW CATEGORY III CPT AND LEVEL II HCPCS CODES EFFECTIVE JULY 1, 2017

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2018 SI	Proposed CY 2018 APC
C9489	Injection, nusinersen, 0.1 mg	G	9489
C9490	Injection, bezlotoxumab, 10 mg	G	9490
C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube	J1	5165
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed.	J1	5377
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance.	J1	5376
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	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system.	Y	N/A
Q9984	Levonorgestrel-releasing intrauterine contraceptive system (Kyleena), 19.5 mg ..	E1	N/A
Q9985	Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg	N	N/A
Q9986*	Injection, hydroxyprogesterone caproate (Makena), 10 mg	K	9074
Q9987	Pathogen(s) test for platelets	S	1493
Q9988	Platelets, pheresis, pathogen reduced, each unit	R	9536
Q9989#	Ustekinumab, for intravenous injection, 1 mg	G	9487
0469T	Retinal polarization scan, ocular screening with on-site automated results, bilateral.	E1	N/A
0470T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; first lesion.	M	N/A
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	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	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	Insertion of anterior segment aqueous drainage device, with creation of intra-ocular reservoir, internal approach, into the supraciliary space.	J1	5492
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
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	Recording of fetal magnetic cardiac signal using at least 3 channels; signal extraction, technical analysis, and result.	Q1	5734
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

*HCPCS code J1725 (Injection, hydroxyprogesterone caproate, 1 mg) was replaced with HCPCS code Q9986 effective July 1, 2017.

#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.

3. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2017 and January 1, 2018 for Which We Will Be Soliciting Public Comments in the CY 2018 OPPTS/ASC Final Rule With Comment Period

As has been our practice in the past, we will solicit comments on those new Level II HCPCS codes that are effective October 1, 2017 and January 1, 2018 in the CY 2018 OPPTS/ASC final rule with comment period, thereby allowing us to finalize the status indicators, APCs, and payment rates for the codes in the CY 2019 OPPTS/ASC final rule with comment period. These codes will be released to the public through the October and January OPPTS quarterly update CRs and via the CMS HCPCS Web site (for Level II HCPCS codes).

For CY 2018, we are proposing to continue our established policy of assigning comment indicator “NI” in Addendum B to the OPPTS/ASC final rule with comment period to those new Level II HCPCS codes that are effective October 1, 2017 and January 1, 2018 to indicate that we are assigning them an interim payment status, which is subject to public comment. We will be inviting public comments in the CY 2018 OPPTS/ASC final rule with comment period on the status indicator, APC assignments, and payment rates for these codes, if applicable, which would then be finalized in the CY 2019 OPPTS/ASC final rule with comment period.

4. Proposed Treatment of New and Revised CY 2018 Category I and III CPT Codes That Will Be Effective January 1, 2018 for Which We Are Soliciting Public Comments in This CY 2018 OPPTS/ASC Proposed Rule

In the CY 2015 OPPTS/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 OPPTS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPTS/ASC final rules beginning with the CY 2016 OPPTS update. For those new/revised CPT codes that were received too late for inclusion in the

OPPTS/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 OPPTS 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 OPPTS update, we received the CY 2018 CPT codes from AMA in time for inclusion in this CY 2018 OPPTS/ASC proposed rule. The new, revised, and deleted CY 2018 Category I and III CPT codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). We note 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 current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we remind readers that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and their long descriptors for the new and revised CY 2018 CPT codes in Addendum O to this proposed rule (which is available via the Internet on

the CMS Web site) so that the public can adequately comment on our proposed APCs and status indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled “CY 2018 OPPTS/ASC Proposed Rule 5-Digit AMA Placeholder Code,” to this proposed rule. The final CPT code numbers will be included in the CY 2018 OPPTS/ASC final rule with comment period. We note that not every code listed in Addendum O is subject to comment. For the new and revised Category I and III CPT codes, we are requesting comments on only those codes that are assigned to comment indicator “NP”.

In summary, we are soliciting public comments on the proposed CY 2018 status indicators and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2018. The CPT codes are listed in Addendum B to this proposed rule with short descriptors only. We list them again in Addendum O to this proposed rule with long descriptors. We also are proposing to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2018 OPPTS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

5. Proposed Care Management Coding Changes Effective January 1, 2018 (APCs 5821 and 5822)

As noted in the CY 2018 MPFS proposed rule, 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. We are proposing to adopt CPT replacement codes for CY 2018 for several of the care management services finalized last year and are seeking public comment on ways we might further reduce burden on reporting providers, including through stronger alignment between CMS requirements and CPT guidance for existing and potential new codes. Table 15 below details the proposed care management coding changes. We refer 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.

TABLE 15—PROPOSED CARE MANAGEMENT CODING CHANGES EFFECTIVE JANUARY 1, 2018

CY 2017 HCPCS code	CY2017 HCPCS short descriptor	CY 2017 OPPTS SI	CY 2017 OPPTS ASC	Proposed CY 2018 replacement CPT code*	Proposed CY 2018 replacement HCPCS short descriptor	Proposed CY 2018 OPPTS SI	Proposed CY 2018 OPPTS APC
G0502	Init psych care Manag, 70min.	S	5822	994X1	1st psyc collab care mgmt.	S	5822
G0503	Subseq psych care man, 60mi.	S	5822	994X2	Sbsg psyc collab care mgmt.	S	5822
G0504	Init/sub psych Care add 30 m.	N	N/A	994X3	1st/sbsq psyc collab care.	N	N/A
G0505	Cog/func assess-ment outpt.	S	5822	99XX3	Assmt & care pln pt cog imp.	S	5822
G0507	Care manage serv minimum 20.	S	5821	99XX5	Care mgmt. svc bhvl hlth cond.	S	5821

*These are the 5-digit placeholder CPT codes. The final CPT code numbers will be included in the CY 2018 OPPTS/ASC final rule with comment period. The long descriptors for the codes can be found in Addendum O (New Category I and Category III CPT Codes Effective January 1, 2018) to this proposed rule, which is available via the Internet on the CMS Web site.

B. Proposed OPPTS 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 regulations at 42 CFR 419.31. 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 proposed rule.

Under the OPPTS, 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. For CY 2018, we are proposing 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

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, with respect to comparability of 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 (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). 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 both have more 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 or fewer 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 that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In this section of this proposed rule, for CY 2018, we are proposing to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low volume items and services.

For the CY 2018 OPPTS, we have identified the APCs with violations of the 2 times rule. Therefore, we are proposing changes to the procedure codes assigned to these APCs in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this CY 2018 OPPTS/ASC proposed rule. Rather, it is published and made available via the Internet on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. To eliminate a violation of the 2 times rule

and improve clinical and resource homogeneity, we are proposing 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 this 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. Addendum B to this CY 2018 OPPS/ASC proposed rule identifies with a comment indicator “CH” those procedure codes for which we are proposing 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>).

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we are proposing 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.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18457 and 18458).

Based on the CY 2016 claims data available for this 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 are proposing to make exceptions under the 2 times rule for CY 2018, and found that all of the 12 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2016 claims data available for this 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 a similar geometric mean costs and do not create a 2 time 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 this proposed rule lists the 12 APCs that we are proposing to except from 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, and processed on or before December 31, 2016. For the final rule with comment period, we intend 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. The geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>.

TABLE 16—PROPOSED APC EXCEPTIONS TO THE TWO TIMES RULE FOR CY 2018

Proposed CY 2018 APC	Proposed CY 2018 APC title
5112	Level 2 Musculoskeletal Procedures.
5161	Level 1 ENT Procedures.
5311	Level 1 Lower GI Procedures.
5461	Level 1 Neurostimulator and Related Procedures.
5521	Level 1 Imaging without Contrast.
5573	Level 3 Imaging with Contrast.
5611	Level 1 Therapeutic Radiation Treatment Preparation.
5691	Level 1 Drug Administration.
5731	Level 1 Minor Procedures.
5735	Level 5 Minor Procedures.
5771	Cardiac Rehabilitation.
5823	Level 3 Health and Behavior Services.

C. Proposed 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. 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 OPSS, 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, and 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 OPSS, 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 OPSS/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 OPSS 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 OPSS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314).

2. Proposed Revised and Additional New Technology APC Groups

As stated above, 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, for CY 2018 we are proposing to narrow the increments for New Technology APCs 1901–1906 from \$19,999 cost bands to \$14,999 cost bands. We also are proposing 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 in later in this section. Table 17 below includes the complete list of the proposed modified and additional New Technology APC groups for CY 2018.

TABLE 17—PROPOSED CY 2018 ADDITIONAL NEW TECHNOLOGY APC GROUPS

Proposed CY 2018 APC	Proposed CY 2018 APC Title	Proposed 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 proposed payment rates for New Technology APCs 1901 through 1908 can be found in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site).

3. Proposed Procedures Assigned to New Technology APC Groups for CY 2018

a. Overall Proposal

As we explained in the CY 2002 OPSS 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 this CY 2018 OPSS/ASC

proposed rule, we are proposing 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).

b. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114, and 5414)

Currently, there are four CPT/HCPCS codes that describe magnetic resonance image guided high intensity focused ultrasound (MRgFUS) procedures, three of which we are proposing to continue to assign to standard APCs and one of which we are proposing to continue to assign to a New Technology APC. 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 below, and as listed in Addendum B of this CY 2018

OPPS/ASC proposed rule, we are proposing 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 are proposing 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 are proposing to continue to assign HCPCS code C9734 to APC 5114 (Level 4

Musculoskeletal Procedures), with a proposed payment rate of approximately \$5,385 for CY 2018. We also are proposing to continue to assign HCPCS code C9734 to status indicator as “J1”.

Further, we are proposing to continue to assign CPT code 0398T to APC 1537 (New Technology—Level 37 (\$9501–\$10000)), with a proposed payment rate of approximately \$9,751 for CY 2018. We have only received one claim for CPT code 0398T, and, based on this limited information, are not proposing to assign this MRgFUS procedure to a standard APC. We refer readers to Addendum B of this 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.

TABLE 18—PROPOSED CY 2018 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES 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	Proposed CY 2018 OPPS SI	Proposed CY 2018 OPPS APC	Proposed 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	\$2,188.97
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	2,188.97
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	1537	9,750.50
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	J1	5114	5,219.36	J1	5114	5,385.23

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 which has 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 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 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 includes the cost of both the surgical procedure (CPT code 0100T) and the retinal prosthesis device (HCPCS code C1841).

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. For the CY 2018 OPPS/ASC final rule with comment period, the final payment rate will be based on claims submitted between January 1, 2016 and December 31, 2016, and processed through June 30, 2017.

Based on the CY 2016 OPPS claims data available, which show a geometric mean cost of approximately \$116,239, we are proposing to assign the Argus® II procedure to a New Technology APC with a payment band that covers the geometric mean of the procedure. Therefore, we are proposing to assign CPT code 0100T to APC 1904 (New Technology—Level 50 \$115,001–\$130,000), with a proposed payment of \$122,000.50 for CY 2018. We are inviting public comments on this proposal.

d. Pathogen Test for Platelets

The CMS HCPCS Workgroup has 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 July 1, 2017.

We are seeking 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 are proposing 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 assignment to a clinical APC. We are inviting public comments on this proposal.

D. Proposed 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 this code 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 comprehensive APC (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. L. 100–04), Chapter 4, Section 231.11 and Chapter 3, Section 90.3.1.)

There other donor acquisition costs, namely those costs for the procedure

described by HCPCS code 38230 (Bone marrow harvesting for transplantation; allogeneic), which are assigned to status indicator “S”. For consistency and to ensure that the donor acquisition costs are captured accurately, for CY 2018, we are proposing 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.

Our latest claims data used for this proposed rule, which include claims submitted between January 1, 2016, and December 31, 2016, and processed on or before December 31, 2016, show 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 are proposing to assign HCPCS code 38205 to APC 5242. We are inviting public comments on these proposals.

2. 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.

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.

For this CY 2018 proposed rule, 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 this 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 believe a Level 5 Imaging without Contrast APC is needed to more appropriately group certain imaging services with higher resource costs. Specifically, we believe the data support splitting the current 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 are proposing to add a fifth level within the Imaging without Contrast APCs. Below in Table 19, we list the CY 2017 imaging APCs, and in Table 20, we list 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 are listed in Addendum B to the proposed rule, which is available via the Internet on the CMS Web site. 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 are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We note that some of the imaging procedures are assigned to APCs that are not listed in the tables below (for example, the vascular procedures APCs). Also, the nuclear medicine services APCs are not

included in this proposal. These imaging services are not included in this proposal because we are not proposing changes to their APC structure.

We are inviting public comments on our proposal to add a Level 5 Imaging without Contrast APC in CY 2018.

TABLE 19—CY 2017 IMAGING APCS

CY 2017 APC	CY 2017 APC Group Title
5521	Level 1 Imaging without Contrast.
5522	Level 2 Imaging without Contrast.
5523	Level 3 Imaging without Contrast.
5524	Level 4 Imaging without Contrast.
5571	Level 1 Imaging with Contrast.
5572	Level 2 Imaging with Contrast.
5573	Level 3 Imaging with Contrast.

TABLE 20—PROPOSED CY 2018 IMAGING APCS

Proposed CY 2017 APC	Proposed CY 2017 APC Group Title
5521	Level 1 Imaging without Contrast.
5522	Level 2 Imaging without Contrast.
5523	Level 3 Imaging without Contrast.
5524	Level 4 Imaging without Contrast.
5525	Level 5 Imaging without Contrast.
5571	Level 1 Imaging with Contrast.
5572	Level 2 Imaging with Contrast.
5573	Level 3 Imaging with Contrast.

b. Non-Ophthalmic Fluorescent Vascular Angiography (APC 5524)

For the CY 2018 OPPS update, we are proposing 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 this proposed rule. We are proposing 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 latest claims data used for this proposed rule, which include claims submitted between January 1, 2016, and December 31, 2016, and processed on or before December 31, 2016, show 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 are proposing to reassign HCPCS code

C9733 from APC 5523 to APC 5524. 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), 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, HCPCS code C9733 is conditionally packaged under § 419.2(b)(14), which contains the policies governing packaging of intraoperative items and services. Consequently, we are proposing 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.

In summary, for the CY 2018 OPPS update, we are proposing to reassign HCPCS code C9733 to APC 5524 based on the latest claims data used for this proposed rule. In addition, we are proposing to maintain its status indicator assignment of “Q2” to indicate that the service is conditionally packaged. The proposed CY 2018 OPPS payment rate for HCPCS C9733 can be found in OPPS Addendum B to this proposed rule, which is available via the Internet on the CMS Web site.

3. Comment Solicitation on Intraocular Procedure APCs

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 this CY 2018 OPPS/ASC proposed rule, we are proposing 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 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 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. We are seeking 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.

IV. Proposed OPPS Payment for Devices

A. Proposed 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 has 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, we are proposing, 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.

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 OPPTS, 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 OPPTS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPTS 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 OPPTS 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 this CY 2018 OPPTS/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 OPPTS/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.

(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 2cm x 2cm up to 10cm x 15cm and is approximately 0.75mm 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 are inviting public comments on this issue.

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. proposes a new device category descriptor of “Stabilized Skin Substitute for Autologous Tissue Regeneration” for Architect® Px. We are inviting public comments on this issue.

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 identifies two references, neither of which we believe provide evidence of substantial clinical improvement. One reference is a 2012 summary report¹ 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 reference² is a small observational study of 34 subjects with no comparison group. We are inviting public comments on whether Architect® Px meets the substantial clinical improvement criterion.

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 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 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 ($\$5,495/\$1,411.21 \times 100$ 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, 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 \$4.52 exceeds 10 percent at 389 percent ($(\$5,495 - \$4.52)/\$1,411.21 \times 100$ 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 are inviting public comments on whether Architect® Px meets the device pass-through payment criteria discussed in this section.

(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

¹ Snyder, D.L. *et al.* Skin Substitutes for Treating Chronic Wounds. Technology Assessment Report. Project ID: HCPR0610. AHRQ. December 18, 2012.

² 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.

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 FDA regulatory path under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Under this regulatory path, FDA requires the manufacturer to register and list its HCT/Ps with the Center for Biologics Evaluation and Research (CBER) within 5 days after beginning operations and to 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.

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 are inviting public comments on this issue.

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,³ presented in 2015, 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 six cm² pieces of Dermavest per application on wounds up to 44 cm². 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,⁴ 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 cm². 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

³Connell et al., Human placental connective tissue matrix in the treatment of chronic wounds: A prospective multi-center case series. 2015 at Society of Advanced Wound Healing (SAWC) Spring meeting.

⁴McGuire 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.

provides an effective alternative to other skin replacement products.

We are 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. Based on the evidence submitted with the application, we are not yet convinced that the Dermavest and Plurivest HPCTM provide a substantial clinical improvement over other treatments for wound care. We are inviting public comments on whether the Dermavest and Plurivest HPCTM meet this criterion.

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 ($\$550/\$1,411 \times 100 = 39$ percent). Therefore, 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 ($\$550/\$4.52 \times 100 = 12,168$ percent). Therefore, 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 ($(\$550 - \$4.52)/\$1,411 \times 100 = 38.6$ percent). Therefore, we believe that Dermavest and Plurivest meet the third cost significance test.

We are inviting public comments on whether Dermavest and Plurivest meet the device pass-through payment criteria discussed in this section.

(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 FDA regulatory path under section 361 of the PHS Act and 21 CFR part 1271 for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Under this regulatory path, FDA requires the manufacturer to 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.

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 proposed a payment device category for FlōGraft®/Flōgraft Neogenesis® with a category descriptor of “Injectable Amniotic Fluid Allograft”. We are inviting public comments on this issue.

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 study⁵ 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 success rate when surgery was coupled with a FlōGraft® injection.

The next study⁶ 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,^{7,8} 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 study⁹ 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 believe there is insufficient data to determine whether FlōGraft®/Flōgraft Neogenesis® offers a substantial clinical improvement over other treatments for wound care. We are inviting public comments on whether the FlōGraft®/Flōgraft Neogenesis® meets the substantial clinical improvement criterion.

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 ($\$19,925/\$1,455 \times 100 = 1,369$ percent). Therefore, 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 ($\$19,925/\$15.86 \times 100 = 125,360$ percent). Therefore, 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 ($(\$19,925 - \$15.86)/\$1,455 \times 100 = 1,368$ percent). Therefore, we believe FlōGraft®/Flōgraft Neogenesis® meets the third cost significance test.

We are inviting public comments on whether FlōGraft®/Flōgraft Neogenesis® meets the device pass-through payment criteria discussed in this section.

⁷ Jacoby, Richard. Case Study 221: Non-surgical Resolution of Distal Fibula Fracture with Flograft Implant; 82 YO Male.

⁸ Jacoby, Richard. Tarsal Tunnel Compression Neuropathy Case Study Using Flograft.

⁹ Maling, Scott. A Case Series: A retrospective analysis of 34 patients receiving modified Bronstrom-Evans procedure with Flograft reduce time to full mobility by 52%

⁵ Bregman, Peter. (2014). Addressing Morton’s Nerve Entrapment Surgically and Non-surgically with FloGraft.

⁶ Gottlieb, et al. FloGraft Rapidly Moves Stalled Wounds Into the Proliferative Phase.

(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 are inviting public comments on this issue.

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 study¹⁰ 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 significant ($P = .041$). 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 an unrealistic 1-month endpoint of care instead of a 6-month endpoint of care.

The second study¹¹ 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 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 study¹² 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

¹¹ Yang, C.K. 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.

¹⁰ Tumi Balduresson, 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.

¹² Trinh, T.T., et al. Marine Omega3 wound matrix for: the treatment of complicated wounds; *Phlebologie* 2016; 45: 93–98.

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 is 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 are inviting public comments on whether Kerecis Omega3 Wound meets the substantial clinical improvement criterion.

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 ($\$2,030 / \$1,411.21 \times 100$ percent = 144 percent). Therefore, 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™ 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 = 449 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 ($(\$2,030 - \$4.52) / \$1,411.21 \times 100$ percent = 144 percent). Therefore, 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 are inviting public comments on whether Kerecis™ Omega3 Wound meets the device pass-through payment criteria discussed in this section.

(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 FDA regulatory path under section 361 of the PHS Act and 21 CFR part 1271 for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Under this regulatory path, FDA requires the manufacturer to register and list their HCT/Ps with the Center for Biologics Evaluation and Research (CBER) within 5 days after beginning operations and to 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 for 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.

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 are inviting public comments on this issue.

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 study¹³ 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 is insufficient data to determine whether X-WRAP® offers a substantial clinical improvement over other treatments for wound care. We are inviting public comments on whether the X-WRAP® meets the substantial clinical improvement criterion.

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 ($\$5,280/\$1,455 \times 100 = 363$ percent). Therefore, 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 ($\$5,280/\$15.86 \times 100 = 33,291$ percent). Therefore, 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 ($(\$5,280 - \$15.86)/\$1,455 \times 100 = 361$ percent). Therefore, it appears that X-WRAP® meets the third cost significance test.

We are inviting public comments on whether X-WRAP® meets the device pass-through payment criteria discussed in this section.

B. Proposed 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) applied to device-intensive APCs and is discussed in detail in section IV.B.4. of this proposed rule. 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

¹³ 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.

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 proposed rule, 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 is included in Addendum P to this proposed rule (which is available via the Internet on the CMS Web site).

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.

3. Changes to the Device Edit Policy for CY 2017 and Subsequent Years

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 are not proposing any changes to this policy for CY 2018.

4. Proposed 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 CY 2017 and Subsequent Years

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 will apply: (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 are not proposing any changes to this policy for CY 2018.

5. Proposed 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, we are proposing 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 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 is 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) is approximately \$16,963.69.

V. Proposed OPSS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPSS 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 proposed rule, 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 proposed rule 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 OPSS 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 OPSS 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. Proposed CY 2018 pass-through drugs and biologicals and their designated APCs are assigned status indicator “G” in Addenda A and B to this proposed rule (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 OPSS, 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 proposed rule, 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 OPSS 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 OPSS/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 believe that the timing of a pass-through payment application should not determine the duration of pass-through payment status, and this approach allows for the maximum pass-through payment period for each pass-through drug without exceeding the statutory limit of 3 years.

3. Proposed Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2017

We are proposing that the pass-through payment status of 19 drugs and biologicals would expire on December 31, 2017, as listed in Table 21 below. All of these drugs and biologicals will have received OPSS 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

proposed to be \$120 for CY 2018), as discussed further in section V.B.2. of this proposed rule. We are proposing 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 are proposing to provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for CY 2018, as discussed further in section V.B.3. of this proposed rule).

TABLE 21—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2017

CY 2017 HCPCS Code	CY 2017 Long descriptor	CY 2017 Status indicator	CY 2017 APC	Pass-through payment effective date
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664	01/01/2015
C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663	01/01/2015
J0596	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445	04/01/2015
J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	9452	04/01/2015
J0875	Injection, dalbavancin, 5 mg	G	1823	01/01/2015
J1833	Injection, isavuconazonium sulfate, 1 mg	G	9456	10/01/2015
J2407	Injection, oritavancin, 10 mg	G	1660	01/01/2015
J2502	Injection, pasireotide long acting, 1 mg	G	9454	07/01/2015
J2547	Injection, peramivir, 1 mg	G	9451	04/01/2015
J2860	Injection, siltuximab, 10 mg	G	9455	07/01/2015
J3090	Injection, tedizolid phosphate, 1 mg	G	1662	01/01/2015
J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450	04/01/2015
J8655	Netupitant (300 mg) and palonosetron (0.5 mg)	G	9448	04/01/2015
J9032	Injection, belinostat, 10 mg	G	1658	01/01/2015
J9039	Injection, blinatumomab, 1 mcg	G	9449	04/01/2015
J9271	Injection, pembrolizumab, 1 mg	G	1490	01/01/2015
J9299	Injection, nivolumab, 1 mg	G	9453	07/01/2015
Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter.	G	1657	01/01/2015
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9457	10/01/2015

The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

4. Proposed Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Payment Status in CY 2018

We are proposing 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 status between January 1, 2016, and July 1, 2017, are listed in Table 22 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status through July 1, 2017 are assigned status indicator “G” in Addenda A and B to this 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 are proposing 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 are proposing 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 is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is 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 are proposing that their pass-through payment amount would be equal to ASP+6 percent for CY 2018 because, if not for their pass-through status, payment for these products would be packaged into the associated procedure.

In addition, we are proposing 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 are proposing 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 OPPTS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2018, we are proposing to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act,

which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we are proposing to provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information also is not available, we are proposing to provide payment for the pass-through

radiopharmaceutical at 95 percent of its most recent AWP.

The 38 drugs and biologicals that we are proposing to continue to have pass-through payment status for CY 2018 or have been granted pass-through payment status as of July 2017 are shown in Table 22 below.

TABLE 22—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2018

CY 2017 HCPCS code	CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2018 status indicator	Proposed 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	C9140	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	C9483	Injection, atezolizumab, 10 mg	G	9483	10/01/2016
C9484	C9484	Injection, eteplirsen, 10 mg	G	9484	04/01/2017
C9485	C9485	Injection, olaratumab, 10 mg	G	9485	04/01/2017
C9486	C9486	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017
Q9989	Q9989	Ustekinumab, for Intravenous Injection, 1 mg	G	9487	04/01/2017
C9488	C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017
C9489	C9489	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017
C9490	C9490	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017
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:rho.	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, gel-syn, 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
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

5. Proposed 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). For CY 2018, as we did in CY 2017, we are proposing 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 are identified in Table 23 below.

TABLE 23—PROPOSED APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2018

Proposed CY 2018 APC	Proposed 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 are proposing to continue to post annually on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.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 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. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status

1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Proposed 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 proposed rule, 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 (\$117.98) 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 (BLS) series code WPUSI07003) from CMS' Office of the Actuary. Based on these calculations, we are proposing a packaging threshold for CY 2018 of \$120.

b. Proposed Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals Under the Cost Threshold ("Threshold-Packaged Drugs")

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 this proposed rule, or for the following policy-packaged items that we are proposing 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 are proposing for separately payable drugs and biologicals for CY

2018, as discussed in more detail in section V.B.2.b. of this 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 are proposing 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 this proposed rule (which are available via the Internet on the CMS Web site) because these are the most recent data available for use at the time of development of this 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 are proposing 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 display in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for proposed payment in CY 2018.

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 proposed rule, we are proposing to use ASP data from the fourth quarter of CY 2016, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2017,

along with updated hospital claims data from CY 2016. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for this CY 2018 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for the final rule with comment period will be based on ASP data from the second quarter of CY 2017. These data will be 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 would then 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 are proposing to recalculate their mean unit cost from all of the CY 2016 claims data and updated cost report information available for the CY 2018 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this 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. Under such circumstances, we are proposing 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 are proposing 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 the 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 the 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 the CY 2018 final rule, would receive separate payment in CY 2018.

c. Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned briefly earlier, in the OPPTS, 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 OPPTS 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 OPPTS/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).

d. Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes

In the CY 2014 OPPTS/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 codes 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 codes C5271, C5273, C5275, and 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 OPPTS/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 are proposing 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 OPPTS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPTS/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 OPPTS/ASC final rule with comment period (80 FR 70434 through 70435). For CY 2018, as in CY 2016 and CY 2017, we are proposing 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 are proposing 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 are proposing 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 are proposing that any skin substitute product that was assigned to the high cost group in CY 2017 will 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 OPPTS/ASC proposed rule, and consistent with previous methodology as established in the CY 2014 through CY 2017 final rules with comment period, we analyzed 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 proposed CY 2018 MUC threshold is \$47 per cm² (rounded to the nearest \$1) and the proposed CY 2018 PDC threshold is \$755 (rounded to the nearest \$1).

For CY 2018, we are proposing 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 are proposing 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 would use WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. 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 also 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 are proposing 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 will instead be assigned to the high cost group under this proposed policy. The skin substitute products affected by this proposed policy are identified with an "*" in Table 24. For CY 2019 and subsequent years, we are seeking public comment 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.

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 are seeking 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 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 is 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing to continue to assign new skin substitute products without pricing information to the low cost group.

Table 24 below displays the proposed CY 2018 high cost or low cost category assignment for each skin substitute product.

TABLE 24—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2018

CY 2018 HCPCS code	CY 2018 short descriptor	Current CY 2017 high/low assignment	Proposed 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 BMWWD	High	High.

TABLE 24—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2018—Continued

CY 2018 HCPCS code	CY 2018 short descriptor	Current CY 2017 high/low assignment	Proposed CY 2018 high/low assignment
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	High	High.
Q4133	Grafix Prime	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 1k, 1cm	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 1 square cm	High	High.
Q4157	Revitalon 1 square cm	High	High.
Q4158	MariGen 1 square cm	High	High.*
Q4159	Affinity 1 square cm	High	High.
Q4160	NuShield 1 square cm	High	High.
Q4161	Bio-Connekt per square cm	High	High.*
Q4162	Amnio bio and woundex flow	Low	High.
Q4163	Amnion bio and woundex sq cm	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.

* These products do not exceed either the MUC or PDC threshold for CY 2018, but are proposed to be assigned to the high cost group since they were assigned to the high cost group in CY 2017.

e. Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2010 OPPI/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, we are proposing 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 this 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 is displayed in Table 25 below.

TABLE 25—PROPOSED HCPCS CODES TO WHICH THE CY 2018 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2018 HCPCS code	CY 2018 long descriptor	Proposed 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. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Proposed 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 OPSS 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.¹⁴

It has been our longstanding policy 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 this CY 2018 OPSS/ASC proposed rule, we are proposing 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 OPSS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPSS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPSS/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. Proposed CY 2018 Payment Policy

For CY 2018, we are proposing 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 are proposing 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 are proposing 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 are proposing 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 this proposed rule.

Also, we note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule (available via the Internet on the CMS Web site), which illustrate the proposed CY 2018 payment of 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 April 1, 2017, or WAC, AWP, or mean unit cost from CY 2016 claims data and updated cost report information available for this proposed rule. 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 proposed rule for which there was no ASP information available for April 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 proposed rule (reflecting April 2017 ASP data) that do not have ASP information available for the quarter beginning in January 2018. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2016 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2018 payment purposes and are only illustrative of the proposed CY 2018 OPSS payment methodology using the most recently available information at the time of issuance of this proposed rule.

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 (80 FR 70445 through 70446). For CY 2018, we are proposing to continue this same payment policy for biosimilar biological products.

Public comments on the Medicare Part B biosimilar biological product payment policy should be submitted in response to the biosimilar payment policy comment solicitation in the CY 2018 MPFS proposed rule.

3. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2018, we are proposing 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

¹⁴ 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.

from hospital claims. We believe that the rationale outlined in the CY 2010 OPSS/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 are proposing 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 OPSS/ASC final rule with comment period (74 FR 60520 through 60521). We also are proposing 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 OPSS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPSS final rule with comment period (69 FR 65811), the CY 2006 OPSS final rule with comment period (70 FR 68655), and the CY 2010 OPSS/ASC final rule with comment period (74 FR 60524). The proposed CY 2018 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

4. Proposed 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 OPSS/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, for CY 2018, we are proposing to continue to provide an additional \$10 payment for radioisotopes produced by non-HEU sources.

5. Proposed 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 OPSS and continued paying an updated furnishing fee (81 FR 79676). That is, for CY 2017, we provided payment for blood clotting factors under the OPSS 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.

For CY 2018, we are proposing 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 OPSS 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 OPSS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPSS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is 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 OPSS/ASC proposed rules are published, we are 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 OPSS/ASC final rule with comment period (72 FR 66765), we are proposing 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>.

6. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPSS Hospital Claims Data

For CY 2018, we are proposing to continue to use the same payment policy as in CY 2017 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPSS 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 OPSS/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 OPSS hospital claims data is listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site.

7. Alternative Payment Methodology for Drugs Purchased Under the 340B Drug Discount Program

a. Background

The 340B Drug Discount 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.¹⁵

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 Pub. L. 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 with a DSH adjustment percentage of 8.0 percent or higher, rural referral centers 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) of the Public Health Service Act, DSH hospitals and CAH participants must meet other criteria, such as being owned by a State or local government, or be a nonprofit hospital under contract with a State or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid.

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 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 noninnovator multiple source (generic) drug. The ceiling price represents the maximum price a 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, in some circumstances, can negotiate even deeper discounts (known as “subceiling prices”) on many covered outpatient drugs. By the end of FY 2014, the PVP had nearly 7,000 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.¹⁶

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.^{17 18 19} Links to the full reports referenced in this section can be found in the 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 OPSS except for vaccines and orphan drugs provided by freestanding cancer hospitals, rural referral centers, and sole community hospitals. To estimate costs that 340B hospitals incur to acquire drugs covered under the OPSS, it generally used the formula for calculating the 340B ceiling price: (average manufacturer price (AMP) – unit rebate amount (URA)) × drug package size. Because MedPAC did not have access to AMP data, it used

¹⁶ Department of Health and Human Services. 2016. Fiscal Year 2017. Health Resources and Services Administration justification of estimates for appropriations committees. Washington, DC: HHS. <https://www.hrsa.gov/about/budget/budgetjustification2017.pdf>.

¹⁷ 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>.

¹⁸ 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>

¹⁹ 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>.

each drug’s ASP as a proxy for AMP. MedPAC notes that ASP is typically slightly lower than AMP. 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 its 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 [OPSS].”

In its March 2016 MedPAC Report to Congress, MedPAC noted that the 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 (MedPAC March 2016, page 79). 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. In addition, participation in the PVP often results in a covered entity paying a subceiling price (estimated to be approximately 10 percent below the ceiling price). (U.S. Department of Health and Human Services, HRSA FY 2015 Budget Justification.) Participation in the PVP is voluntary and free.

With respect to chemotherapy drugs and drug administration services, MedPAC examined 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, page 14). This is just one example of drug spending increases that is correlated with participation in the 340B program and calls into question whether Medicare’s current payment policy for separately payable drugs at ASP+ 6 percent is appropriate in light of the discounted rates at which 340B hospitals acquire such drugs, especially because beneficiary cost-sharing for these drugs is based on the Medicare payment rate.

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

¹⁵ 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. Rep No. 102–384(II), at 12 (1992)).

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 15-442, page 20)

Under the OPSS, 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 plus 6 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 OPSS 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 amount and the 340B ceiling price was so large that, in a 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, OEI-12-14-00030, page 9).

In the CY 2009 OPSS/ASC final rule with comment period, we requested comment 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 (73 FR 68655). 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. In addition, 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.²⁰ In

its November 2015 report entitled "Part B Payments for 340B-Purchased Drugs," the Office of the Inspector General (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). In the same report, the OIG described three options under which both the Medicare program and Medicare beneficiaries would be able to share in the savings realized by hospitals and other covered entities that participate in the 340B program (OEI-12-14-00030, pages 11-12). These options ranged from paying ASP with no additional add-on percentage, to 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 and the inability to identify which drugs were purchased through the 340B program within Medicare claims data was another limitation.

It is estimated that covered entities saved \$3.8 billion on outpatient drugs purchased through the 340B program in 2013.²¹ 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). 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 believe it is timely to reexamine the appropriateness of continuing to pay the current OPSS methodology of ASP+6 percent to hospitals that have acquired those drugs under the 340B program at significantly discounted rates. This is especially important because of the inextricable link of the Medicare payment rate to the beneficiary cost-sharing amount. In addition, we are concerned about the rising prices of certain drugs and that Medicare beneficiaries, including low-income seniors, are responsible for paying 20 percent of the Medicare payment rate for these drugs. We are concerned that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs.

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>.

²¹ U.S. Department of Health and Human Services, HRS-A FY 2015 Budget Justification, p. 342.

b. Proposed OPSS Payment Rate for 340B Purchased Drugs

In this proposed rule, we are proposing 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 Medicare beneficiaries (and the Medicare program) to pay less 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 while continuing to provide access to care. Medicare expenditures on Part B drugs are rising due to underlying factors such as growth of the 340B program, higher price drugs, or price increases for drugs.²² We believe that any payment changes we adopt should be limited to separately payable drugs under the OPSS, with other additional exclusions. These exclusions include (1) drugs on pass-through status, which are required to be paid based on the ASP methodology and (2) vaccines, which are excluded from the 340B program. Also, as stated later in this section, we are soliciting comment on whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment.

Current data limitations inhibit identification of which drugs were acquired under the 340B program in the Medicare OPSS 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, we intend 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 OPSS participate in the 340B program, we believe it is appropriate to presume that a separately payable drug reported on an OPSS claim was purchased under the

²² 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. <https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf>.

²⁰ Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare

340B program, unless the hospital identifies that the drug was not purchased under the 340B program. We intend to provide further details about this modifier in the CY 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.

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. Accordingly, we believe using an average discounted price is appropriate for our proposal. Therefore, for CY 2018, we are proposing to apply an average discount of 22.5 percent of the average sales price 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 separately payable drug, we have not attempted to do so for this proposed rule. Instead, we believe that using the analysis from the MedPAC report is appropriate and note 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. As GAO mentioned, discounts under 340B range from 20 to 50 percent (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, are proposing 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 this CY 2018 OPPS/ASC proposed rule, we are proposing to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. However, we are proposing to exercise the Secretary's authority to adjust the applicable payment rate as necessary and, for separately payable drugs and biologicals (other than drugs on pass-through and vaccines) acquired under the 340B program, are proposing 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 above, 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. Additionally, we believe that using an average discount to set payment rates for separately payable drugs would achieve the dual goals of (1) adjusting payments to better reflect resources expended to acquire such drugs while (2) also 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 is much lower than the ASP for the drug.

We note that MedPAC excluded vaccines from its analysis since vaccines are not covered under 340B, but it did not exclude drugs on pass-through status. Further, because data used to calculate ceiling prices is not publicly available, MedPAC instead estimated "the lower bound of the average discount received by 340B hospitals for drugs paid under the [OPPS]" (MedPAC 2015, 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. We encourage the public to analyze the analysis presented in Appendix A of MedPAC's May 2015 Report to Congress.

As noted above, we believe that the discount amount of 22.5 percent below the ASP reflects the average minimum

discount that 340B hospitals receive for drugs acquired under the 340B program, and it is likely that the average discount may be higher due to participation in the PVP, substitution of ASP (which includes additional rebates) for AMP, and that drugs with pass-through 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 hospital. Accordingly, as noted above, we are proposing to reduce payment for separately payable drugs, excluding drugs on pass-through 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 proposed above.

Finally, as detailed in the impact analysis section (section XIX.) of this proposed rule, we also are proposing 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 are soliciting 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 are seeking 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 are seeking comments on whether the redistribution of savings associated with this proposal would result in unnecessary increases in the volume of covered services paid under the OPPS which should be adjusted in accordance with section 1833(t)(2)(F) of the Act. More information on the impact estimate associated with this proposal is included in section XIX. of this proposed rule.

c. Comment Solicitation on Additional 340B Considerations

As discussed above, we recognize there are data limitations in estimating the average discount of 340B drugs. We welcome 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 OPPTS drugs purchased under the 340B drug discount program in CY 2018. We also are requesting comment on whether we should adopt a different payment rate to account for the average minimum discount of OPPTS drugs purchased under the 340B drug discount program. Also, we are seeking comment on whether the proposal to pay ASP minus 22.5 percent for 340B purchased 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 identify the actual acquisition costs that each hospital incurs rather than using an average minimum discounted rate that would apply uniformly across all 340B hospitals. We are seeking 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 OPPTS 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 are seeking comment on this point.

Lastly, for consideration for future policy refinements, we are seeking 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 OPPTS (for example, rural sole-community hospitals or PPS-exempt cancer hospitals) if a policy were adopted to adjust OPPTS 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.

VI. Proposed Estimate of OPPTS 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 OPPTS 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 a proposed 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 OPPTS/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 proposed CY 2018 pass-through spending estimates for these two groups of device categories equals the proposed 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 OPPTS/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 this proposed rule, we are proposing 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 are proposing 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 are proposing to pay for most nonpass-through separately payable drugs and biologicals under the CY 2018 OPPTS at ASP+6 percent, and because we are proposing to pay for CY 2018 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of this proposed rule, our estimate of drug and biological pass-through payment for CY 2018 for this group of items is \$0, as discussed below. We note that our estimate does not reflect the proposed payment policy for drugs purchased through the 340B program, as we discuss in section V.B.7. of this 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 this proposed rule. We are proposing 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 is not \$0, as discussed below. In section V.A.5. of this proposed rule, we discuss 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 are proposing 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 are proposing to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through 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 quarters 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

We are proposing 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 device active categories for CY 2018, we are proposing an estimate for the 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. We are proposing 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 this proposed rule, the proposed estimate of CY 2018 pass-through spending for this second group of device categories is \$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 are proposing 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 are proposing 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 this 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.

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 this 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 are proposing 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 are proposing 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.

In summary, in accordance with the methodology described earlier in this section, for this proposed rule, 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 \$26.2 million (approximately \$10 million for device categories and approximately \$16.2 million for drugs and biologicals), which represents 0.24 percent of total projected OPPS payments for CY 2018. 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. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

As we did in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79678), for CY 2018, we are proposing to continue with and not make any changes to 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 are proposing 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 this proposed rule, we are seeking public comments on any changes to these codes that we should consider for future rulemaking cycles. We encourage those parties who comment to provide the data and analysis necessary to justify any suggested changes.

VIII. Proposed 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 to establish relative payment weights for covered 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, 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-tiered 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-tiered 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 (CCR>5) 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 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. Proposed PHP APC Update for CY 2018

1. Proposed PHP APC Geometric Mean Per Diem Costs

For CY 2018, we are proposing 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 are proposing 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 would 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 Proposed PHP APC Geometric Mean Per Diem Costs

For CY 2018 and subsequent years, we are proposing 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' proposed geometric mean per diem costs and to calculate the proposed 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, the proposed 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, the proposed 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 proposed rule.

We are proposing to apply our established methodologies in developing the proposed 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 our 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 this 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. Before any trims or exclusions, there were 47 CMHCs in the data. 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 is 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 proposed rule, 4 CMHCs with geometric mean per diem costs per day below the trim's lower limit of \$49.33 and 2 CMHCs above the trim's upper limit of \$361.02 were excluded from the proposed ratesetting for CY 2018. This standard deviation trim removed 6 providers from ratesetting whose data would have skewed the calculated proposed geometric mean per diem cost.

In accordance with our PHP ratesetting methodology, in this 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 proposed rule ratesetting,

two CMHCs were excluded because they were missing wage index data for all of their service days.

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 our CY 2018 proposed 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 8 CMHCs, resulting in the inclusion of a total of 39 CMHCs in our CY 2018 proposed rule ratesetting modeling. The trims removed 1,733 CMHC claims from the 14,400 total CMHC claims, resulting in 12,667 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 proposed CY 2018 geometric mean per diem cost for all CMHCs for providing 3 or more services per day (APC 5853) is \$128.81.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this CY 2018 proposed rule, 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, in this proposed rule there were 420 hospital-based PHP providers in the claims data. 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 are associated with a CCR>5. Applying this trim removed service days from 4 hospital-based PHP providers with CCRs ranging from 6.6494 to 17.4803 from our proposed rule ratesetting. However, all of the service days for these 4 hospital-based PHP providers had at least one service associated with a CCR>5, so the trim removed these providers entirely from our proposed rule ratesetting. In addition, 1 hospital-based PHP was removed for missing wage index data, and 3 hospital-based

PHPs were removed by the OPPTS ±3 standard deviation trim on costs per day. Finally, in our proposed rule ratesetting, we excluded 19 hospital-based PHP providers that reported zero daily costs on their claims, in accordance with established PHP ratesetting policy (80 FR 70465). Therefore, we excluded a total of 27 hospital-based PHP providers, resulting in 393 hospital-based PHP providers in the data used for proposed rule ratesetting. After completing these data preparation steps, we calculated the proposed geometric mean per diem cost

for hospital-based PHP APC 5863 for hospital-based PHP services. The proposed 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 \$213.60. The proposed CY 2018 PHP APC geometric mean per diem costs for the CMHC and hospital-based PHP APCs are shown in Table 26 of this proposed rule. The proposed PHP APC payment rates are included in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 26—CY 2018 PROPOSED PHP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2018 APC	Group title	Proposed PHP APC geometric mean per diem costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	\$128.81
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	213.60

3. PHP Service Utilization Updates

In the CY 2016 OPPTS/ASC final rule with comment, we expressed concern over the low frequency of individual therapy provided to beneficiaries (81 FR 79684 through 79685). The CY 2016 claims data used for this CY 2018 proposed rule revealed some increases in the provision of individual therapy. In CY 2016, hospital-based PHPs provided individual therapy on 4.7 percent of days with only 3 services and 5.6 percent of days with 4 or more services (compared to 4.0 percent and

6.2 percent, respectively, in CY 2015). Similarly, in CY 2016, CMHCs provided individual therapy on 9.0 percent of days with only 3 services provided and 4.9 percent of days with 4 or more services provided (compared to 7.9 percent and 4.4 percent, respectively, in CY 2015 claims). 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 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 proposed rule, we used CY 2016 claims. The CY 2016 claims data showed that PHPs maintained an appropriately low utilization of 3 service days compared to CY 2015:

TABLE 27—PERCENTAGE OF PHP DAYS BY SERVICE UNIT FREQUENCY

	CY 2015 %	CY 2016 %	Change %
CMHCs:			
Percent of Days with 3 services	4.7	4.1	-0.6
Percent of Days with 4 services	62.9	72.6	9.7
Percent of Days with 5 or more services	32.4	23.3	-9.1
Hospital-based PHPs:			
Percent of Days with 3 services	12.4	10.2	-2.2
Percent of Days with 4 services	69.8	67.5	-2.3
Percent of Days with 5 or more services	17.8	22.3	4.5

As we noted in the CY 2017 OPPTS/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 combined 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 OPPTS/ASC final rule 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 OPPTS/ASC final rule with comment period, 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 (73 FR 68694). 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).

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 required a minimum of 20 hours per week of therapeutic services, with the understanding that patients may not always meet this minimum, such as during the week of admission and the week of discharge, 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 OPPTS/ASC final rules with comment periods 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 one 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.

We found that a majority of PHP patients did not receive at least 20 hours of PHP services per week. Just over half of PHP beneficiaries 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 beneficiaries in CMHCs and 34.8 percent of beneficiaries in hospital-based PHPs received at least 20 hours of PHP services in 100 percent of nontransitional weeks.

TABLE 28—NUMBER AND PERCENTAGE OF BENEFICIARIES RECEIVING AT LEAST 20 HOURS OF PHP SERVICES PER WEEK [CY 2015 Through CY 2016]

	Beneficiaries receiving 20 or more hours of PHP services per nontransitional week *	CY 2015 (%)	CY 2016 (%)
Number/Percentage of CMHC Beneficiaries	In 50% or more of weeks	1,205/53.1	1,016/57.3
	In 100% of weeks	319/14.1	291/16.4
Number/Percentage of Hospital-based PHP Beneficiaries.	In 50% or more of weeks	8,610/51.0	8,333/56.7
	In 100% 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 PHPs may not provide the intensive services that eligible beneficiaries actually need. We are concerned about these findings, and encourage PHPs to review their admission practices and ensure they are providing the services beneficiaries need.

Given these concerns, in the CY 2017 OPPTS/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 nine comments in response to our solicitation. Overall, commenters

requested that we monitor data for a year before implementing any payment edits. A number of commenters suggested that if CMS chose to edit PHP claims for the 20-hour minimum requirement, CMS should: (1) Provide exceptions to the editing; (2) not require weekly billing; and (3) implement the edits in a fashion that is not administratively burdensome.

A number of commenters were not supportive of editing that would lead to payment denial. A few commenters indicated that attending a PHP for 20 hours per week is not a condition of payment. Several commenters suggested that editing would be premature until CMS could analyze monitoring data, consider the effect of the newly implemented single APC payment tier, and seek engagement from the PHP provider community. Some commenters also noted that the current PHP HCPCS codes may require some refinement to fully enable providers to record service times.

Several commenters expressed concerns that edits to deny payment for weeks with fewer than 20 hours of PHP services could reduce access to the PHP benefit. Several commenters suggested that noncompliance with a 20-hour requirement could be addressed through medical review, and suggested that PHPs' documenting the reasons for absences in the medical record should be sufficient. Another commenter questioned the necessity of an edit for occasional beneficiary absences beyond the PHP's control. We will consider these comments as we evaluate our options for possible future editing.

In addition, in this CY 2018 OPPS/ASC proposed rule, we are soliciting 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 are soliciting public comments addressing the need for exceptions to such a policy. Specifically, we want 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.

Our goal is for PHP providers to continue to have flexibility in providing PHP services. However, we must ensure that 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 patients, we also will continue to monitor the intensity of services provided on a weekly basis, and look forward to reviewing stakeholder comments when considering options to address situations where an appropriately intensive level of service is not provided.

C. Proposed 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 this CY 2018 OPPS/ASC proposed rule, we are proposing 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. CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2018, excluding outlier payments. Therefore, we are proposing 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.

Based on our simulations of CMHC payments for CY 2018, in this proposed rule, we are proposing 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 are proposing to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2018, we are proposing 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 this proposed rule, for the hospital outpatient outlier payment policy, we are proposing 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 are not proposing to set a dollar threshold for CMHC outlier payments.

In summary, we are proposing to continue to calculate our CMHC outlier threshold and CMHC outlier payments according to our established policies.

IX. Proposed Procedures That Would 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 proposed list of codes that would be paid by Medicare in CY 2018 as inpatient only procedures (the proposed IPO list) is included as Addendum E to this proposed rule (which is available via the Internet on the CMS Web site).

B. Proposed Changes to the Inpatient Only (IPO) List

In this proposed rule, for CY 2018, we are proposing 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 OPPI/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 OPPI 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, we are proposing to remove the procedures described by the following codes from the IPO list for CY 2018: CPT code 27447 (Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)) and CPT code 55866 (Laparoscopy, surgical prostatectomy, retroperitoneal radical, including nerve sparing, includes robotic assistance, when performed).

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 OPPI/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 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.

The public comments we received were varied and nuanced. A number of commenters believed that continued refinements in 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 OPPI/ASC final rule with comment period (81 FR 79699) that we would consider all public comments received in future policymaking.

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 have considered input from the comment solicitation in the CY 2017 OPPI/ASC final rule with comment period and the professional opinions of orthopedic surgeons and CMS clinical advisors. In addition, we have taken into account the recommendation from the summer 2016 Advisory Panel on Hospital Outpatient Payment (HOP Panel) meeting to remove the TKA procedure from the IPO list. Based on this information, we have determined that the TKA procedure would be an appropriate candidate for removal from the IPO list. 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.

We believe that the TKA procedure meets a number of criteria for removal from the IPO list, including criteria 1, 2, and 4. We are seeking 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.

We are proposing that CPT code 27447 would be assigned to C-APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator "J1".

We also note, as stated in the CY 2017 OPPI/ASC final rule with comment period (81 FR 79697), that removal from the IPO list does *not* require the covered surgical procedures to be performed only on an outpatient basis. Removal of a procedure from the IPO list allows for Medicare coverage and payment for the procedure when it is furnished either in an inpatient or outpatient hospital setting. 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 may still be

covered and paid for by Medicare when they are performed on individuals who are inpatients. 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. Therefore, if we finalize our proposal to remove the TKA procedure from the IPO list, we would also prohibit Recovery Audit Contractor (RAC) review for patient status for TKA procedures performed in the inpatient setting for a period of 2 years to allow time and experience for these procedures under this setting. We

would not want hospitals to err on the side of inappropriately performing the procedure on an outpatient basis due to concerns about the possibility of an inpatient TKA claim being denied for patient status. That is, given that this surgical procedure would be newly eligible for payment under either the IPPS or the OPSS, RAC denial of a hospital claim for patient status would be prohibited. We note that contractor reviews for issues other than patient status as an inpatient or outpatient would continue to be permitted, including those for underlying medical necessity.

We also are proposing to remove the procedure described by CPT code 55866 from the IPO list for CY 2018. We are

proposing that CPT code 55866 would be assigned to C-APC 5362 (Level 2 Laparoscopy & Related Services) with status indicator "J1". After consulting with stakeholders and our clinical advisors regarding this procedure, we believe that this procedure meets criteria 1 and 2. We are seeking comment on whether the public believes that these criteria are met and whether CPT code 55866 meets any other of the five criteria stated in the beginning of this section.

The procedures that we are proposing to remove from the IPO list for CY 2018 and subsequent years, including the HCPCS code, long descriptors, and the proposed CY 2018 payment indicators, are displayed in Table 29 below.

TABLE 29—PROPOSED PROCEDURES TO BE REMOVED FROM THE INPATIENT ONLY LIST FOR CY 2018

CY 2018 CPT code	CY 2018 long descriptor	Proposed CY 2018 OPSS APC assignment	Proposed CY 2018 OPSS status indicator
27447	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty).	5115	J1
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed.	5362	J1

We are inviting public comments on our proposals to remove the procedures described by CPT code 27447 and CPT code 55866 from the IPO list beginning in CY 2018. In addition, in section XII.C.1.b. of this proposed rule, we are soliciting public comments on whether the TKA procedure meets the criteria to be added to the list of ASC covered surgical procedures.

The complete proposed list of codes (the IPO list) that would be paid by Medicare in CY 2018 as inpatient only procedures is included as Addendum E to this proposed rule (which is available via the Internet on the CMS Web site).

C. 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

OPSS 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 OPSS/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.

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 OPPTS/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.

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 OPPTS/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 note 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

We are seeking 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 are also specifically seeking 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 are soliciting 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.c. of this proposed rule 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 Comprehensive Care for Joint Replacement (CJR) Model and the Bundled Payment for Care

Improvements (BPCI) Model. We refer readers to the CY 2017 OPPTS/ASC proposed rule for a discussion of questions we raised for public comments and again are seeking 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.

X. Proposed 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 OPPTS 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 OPPTS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (79720 through 79729).

2. Summary of Public Comments and Our Responses Regarding Expansion of Services by Excepted Off-Campus Hospital Outpatient Departments

In the CY 2017 OPPTS/ASC final rule with comment period, we expressed interest in receiving feedback on the limitation on expansion of services of hospital outpatient departments as it related to excepted off-campus provider-based departments (PBDs) (81 FR 79707). Below we discuss certain proposals and present a summary of the public comments received and our responses to those comments.

As discussed in the CY 2017 OPPTS/ASC proposed rule and final rule with comment period (81 FR 45685 through 45686 and 81 FR 79706 through 79707), we stated that we believe section

1833(t)(21)(B)(ii) of the Act, as added by section 603 of Public Law 114–74, excepts off-campus provider based departments (PBDs) and the items and services that are furnished by such excepted off-campus PBDs for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act as they were being furnished on the date of enactment of section 603 of Public Law 114–74, as guided by our regulatory definition of a department of a provider at § 413.65(a)(2). Therefore, we proposed that the excepted off-campus PBD items and services that would continue to be paid under the OPSS would be limited to the provision of items and services it was furnishing prior to the date of enactment of section 603 of Public Law 114–74. Moreover, we proposed that items and services that are not part of a clinical family of services furnished and billed by the excepted off-campus PBD prior to November 2, 2015 would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act; that is, not payable under the OPSS (81 FR 45685 through 45686).

As noted in both the CY 2017 OPSS/ASC proposed rule and final rule with comment period, we believe that the amendments to section 1833(t) of the Act by section 603 of Public Law 114–74 were intended to address items and services furnished at physicians' offices that are converted to hospital off-campus PBDs on or after November 2, 2015 from being paid at OPSS rates (81 FR 45685 through 45686 and 81 FR 79706 through 79707). One issue we contemplated is how expanded services of an excepted off-campus PBD could affect payments to a hospital in regard to newly acquired physicians' offices or new off-campus PBDs established after the date of enactment of section 603 of Public Law 114–74. Particularly, in the CY 2017 OPSS/ASC proposed rule, we indicated that we were concerned that if excepted off-campus PBDs could expand the types of services provided at the excepted off-campus PBDs and also be paid OPSS rates for these new types of services, hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off campus PBDs (81 FR 45685). This could result in newly purchased physician practices furnishing services that are paid at OPSS rates, which we believe these amendments to section 1833(t) of the Act were intended to address.

After reviewing the statutory authority and the concerns raised by stakeholders, we proposed for CY 2017, for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act, that

excepted status of items and services furnished in excepted off-campus PBDs would be limited to the items and services (defined as clinical families of services in Table 21 of the proposed rule (81 FR 45685 through 45686)) such a department was billing for under the OPSS and were furnished prior to November 2, 2015. We proposed that if an excepted off-campus PBD furnishes services from a clinical family of services that it did not furnish prior to November 2, 2015, and therefore did not also bill for, these new or expanded clinical families of services would not be covered OPD services, and instead would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act. We did not propose to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish.

In addition, we considered, but did not propose, specifying a timeframe in which service lines had to be billed under the OPSS for covered OPD services furnished prior to November 2, 2015. We sought public comment through the CY 2017 OPSS/ASC proposed rule on whether we should adopt a specific timeframe for which the billing had to occur, such as CY 2013 through November 1, 2015.

Under our CY 2017 proposal, while excepted off-campus PBDs would not be eligible to receive OPSS payments for expanded clinical families of services, such excepted off-campus PBDs would continue to be eligible to receive OPSS payment for clinical families of services that were furnished and billed prior to that date.

After consideration of the public comments we received in response to the CY 2017 OPSS/ASC proposed rule, we did not finalize our proposed policy to limit service line expansion. Therefore, for CY 2017, an excepted off-campus PBD receives payments under the OPSS for all billed items and services, regardless of whether it furnished such types of items and services prior to the date of enactment of Public Law 114–74, as long as the excepted off-campus PBD remains excepted; that is, it meets the relocation and change of ownership requirements adopted in the CY 2017 OPSS/ASC final rule with comment period (81 FR 79707). Furthermore, in the CY 2017 OPSS/ASC final rule with comment period, we stated our intent to monitor service line expansion and continue to consider how a potential limitation on expansion would work. To that end, in the CY 2017 OPSS/ASC final rule with comment period, we sought public comments on how either a limitation on volume of services, as MedPAC

described in its comments, or a limitation on lines of service, as we laid out in the proposed rule, could be implemented (81 FR 79707). Specifically, we stated we were interested in what data are currently available or could be collected that would allow us to implement a limitation on service expansion. We also stated our interest in receiving suggestions for changes to the clinical families of services that we set forth in Table 21 of the proposed rule (81 FR 45685 through 45686) as we move forward.

Several of the public comments received in response to the November 2016 comment solicitation were repeated from the same stakeholders in response to the CY 2017 OPSS/ASC proposed rule. These commenters again expressed concern regarding CMS' authority to address changes in service-mix; how a limitation on service expansion or volume would stifle innovative care delivery and use of new technologies; and how the clinical families of service are not workable. Because these commenters did not provide new information, we refer readers to the CY 2017 OPSS/ASC final rule with comment period for our response to comments on statutory authority and hindrance to access to innovative technologies (81 FR 79707). A summary of and our responses to the other comments received in response to the November 2016 comment solicitation follow:

Comment: One commenter raised concern that CMS will implement policies that prohibit expansion of services at excepted off-campus PBDs. The commenter believed that excepted and nonexcepted off-campus PBDs should be allowed to expand their service offerings.

Response: We believe the commenter may have misunderstood the policy proposal to limit service line expansion as a proposal to disallow excepted off-campus PBDs from ever altering their service offerings or from treating new patients. To clarify, we proposed that the items and services furnished by an excepted off-campus PBD that would continue to be paid under the OPSS would be limited to the provision of items and services within the clinical families of services the excepted off-campus PBD was furnishing prior to November 2, 2015. In addition, we proposed that items and services that were not part of a clinical family of services furnished and billed by the excepted off-campus PBD prior to November 2, 2015 would be paid under the MPFS. We did not propose to prohibit expansion of clinical services

furnished by either excepted or nonexcepted off-campus PBDs. In the CY 2017 OPPS/ASC final rule with comment period, in response to public comments, we did not finalize our proposal to limit payment under the OPPS for expansion of services at excepted off-campus PBDs, but expressed interest in additional feedback to help us consider whether excepted off-campus PBDs that expand the types of services offered after November 2, 2015 should be paid for furnishing those items and services under the applicable payment system (that is, the MPFS) instead of the OPPS. Specifically, we requested comments on how either a limitation on volume or a limitation on lines of service would work in practice (81 FR 79707). For example, if we were to adopt a limitation on payment for expanded service lines at an excepted off-campus PBD and such PBD primarily provided infusion services prior to November 2, 2015, but added cardiology services after November 2, 2015, should payment for the cardiology services be made under the MPFS while payment for the infusion services would be made under the OPPS?

We recognize that services provided in off-campus PBDs may evolve to reflect changes in clinical practice and community health care needs. However, as stated in prior rulemaking, we believe that section 1833(t)(21)(B)(ii) of the Act excepted off-campus PBDs as they existed at the time that Public Law 114–74 was enacted, and provides the authority to define excepted off-campus PBDs, including those items and services furnished and billed by such a PBD that may be paid under the OPPS, as opposed to the authority under section 1833(t)(21)(C) of the Act.

Comment: A few commenters supported CMS' intent to monitor service line expansion and changes in billing patterns by excepted off-campus PBDs. These commenters urged CMS to work to operationalize a method that would preclude an excepted off-campus PBD from expanding its payment advantage under the OPPS into wholly new clinical areas.

Response: We appreciate the commenters' support. We are collecting data on the claims billed by off-campus PBDs with modifier "PO" (for excepted services) and modifier "PN" (for nonexcepted services). We believe that data collected using these modifiers will be a useful tool in furthering our efforts to monitor service line expansion, and address any issues as they may arise.

Comment: A few commenters urged CMS to pursue a limitation on service line expansion to ensure designation as

an excepted off-campus PBD is not "abused." One commenter suggested that CMS already has the necessary data to limit excepted off-campus PBDs to billing under the OPPS for only those items and services that were furnished prior to November 2, 2015. The commenter suggested that CMS evaluate outpatient claims with the "PO" modifier to develop a list of "grandfathered" items and services for which the excepted off-campus PBD may continue to be paid under the OPPS.

Response: We appreciate the commenters' suggestions. While the "PO" modifier claims data are helpful to assess the billing patterns of off-campus PBDs, reporting of this modifier was voluntary for CY 2015 and did not become mandatory until CY 2016. Because of the voluntary nature of "PO" modifier reporting in CY 2015, the data may not accurately reflect all items and services furnished at excepted off-campus PBDs. We also are concerned with the practicality of developing a list of excepted items and services for each excepted off-campus PBD, given the magnitude of such a list. Any future proposal on service expansion would need to be practicable and take into consideration the administrative burden on providers and the Federal Government.

Comment: A few commenters expressed concern that either a limitation on services or volume of services at an excepted off-campus PBD would result in varying beneficiary copayments at a single site, which could create confusion and inequity. Therefore, the commenters requested that CMS minimize beneficiary confusion by treating all items and services furnished at an excepted off-campus PBD as excepted under § 419.48.

Response: We appreciate these comments. We note that the cost-sharing liability under both the OPPS and the MPFS is prescribed by statute and that there is not flexibility with respect to the copayment amount that would be due for a given service.

Comment: A few commenters believed that MedPAC's proposal to cap service volume from a baseline period would still be administratively complex and unduly burdensome. In addition, the commenters disagreed with MedPAC's proposal to establish the baseline period using the 12-month period that preceded November 2, 2015 (that is, November 2, 2014 through November 1, 2015) as a baseline for volume caps. These commenters believed that such an approach would negatively affect excepted off-campus

PBDs that began operations any time during the year before the enactment of section 603 of Public Law 114–74, by possibly preventing all of the items and services furnished by that excepted off-campus PBD from being excepted from the provisions of section 603. Therefore, the commenters requested that any baseline period run no earlier than the 12-month period immediately prior to the effective date of the policy, or, for excepted off-campus PBDs that began operations within the 5-year period prior to the effective date of the policy, the 12-month period following the excepted off-campus PBD's fifth year of operations. The commenters also believed that establishment of a cap based on the modifier "PO" data is inappropriate, given that use of the modifier was not mandatory until January 1, 2016, or nearly 2 months after enactment of section 603 of Public Law 114–74. One commenter suggested that a volume cap would need to be adjusted annually to account for changes in coding and bundling of services; changes in population of community served; hospital market basket increases to OPPS payment rates; and efficiency improvements.

Response: We appreciate these comments and concerns relating to proposing a cap on service volume and the limitations of the "PO" modifier data. We will take this feedback into consideration in the development of potential future proposals to either limit service expansion or cap volume of services payable under the OPPS.

Comment: A few commenters suggested that CMS delay establishing any limitation on service expansion or volume until claims data with the "PN" modifier are available. However, the commenters believed that, even with "PO" modifier data from excepted off-campus PBDs and "PN" modifier data from nonexcepted off-campus PBDs, it would be a challenging task for CMS and providers to retroactively assess and compare which services were provided at each PBD for a 1-year period prior to November 2, 2015. As an alternative, one commenter suggested that additional questions on the CMS 855A enrollment form would be a more sensible approach to gathering information on types of services furnished at excepted off-campus PBDs, but did not provide any specific questions.

Response: We agree that evaluating data reported with the "PN" modifier by nonexcepted off-campus PBDs will be instructive as we consider options for any potential future proposal on limitation of service line expansion or volume. While we did not finalize any

policy on clinical service expansion that would establish the baseline period as a 1-year period prior to November 2, 2015, we appreciate the feedback. Regarding changes to the CMS 855A enrollment form, we are unclear on what types of questions could be added to glean a better understanding of services provided at nonexcepted off-campus PBDs; therefore, we cannot respond to this comment at this time.

We appreciate the commenters' suggestions and concerns on the issue of a limitation on clinical service line expansion or a limitation on service line volume. After consideration of the public comments we received, for CY 2018, we are not making any proposals to limit clinical service line expansion or volume increases at excepted off-campus PBDs, but will continue to monitor claims data for changes in billing patterns and utilization, and continue to invite public comments on this issue.

We refer readers to the CY 2018 MPFS proposed rule for proposed payment rates under the MPFS for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments of hospitals.

3. Implementation of Section 16002 of the 21st Century Cures Act (Treatment of Cancer Hospitals in Off Campus Outpatient Department of a Provider Policy)

In the CY 2017 OP/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 OP/ASC statute to require that certain items and services furnished by certain off-campus outpatient departments of a provider (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 OP/ASC, 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 OP/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. Through operational guidance, we have provided direction to all MACs regarding this provision. We have also 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 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 proposed rule for a discussion on the calculation of the proposed 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 OP/ASC payment system and the estimated beneficiary liability applicable to the item or service. We are announcing our plan to establish the searchable Web site required by section 1834(t) of the Act. Details regarding the Web site will be issued through our subregulatory process. We anticipate that the Web site will be made available in early CY 2018.

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 three key 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 with comment period (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 MPFS proposed rule, we are proposing 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 communicate information about the AUC consultation to the furnishing professional, and for the furnishing professional to include that 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 OPFS; and the ASC payment system. Information on the latest proposals for requirements for the AUC program can be found in the CY 2018 MPFS proposed rule. Public comments on these proposals should be submitted in response to the CY 2018 MPFS proposed rule.

D. Enforcement Instruction for the Supervision of Outpatient Therapeutic Services in Critical Access Hospitals (CAHs) and Certain Small Rural Hospitals

In the CY 2009 OPFS/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 provider-based departments (PBDs) of hospitals, as set forth in the CY 2000 OPFS final rule with comment period (65 FR 18525). In the CY 2010 OPFS/ASC final rule with comment period (74 FR 60575 through 60591), we finalized a technical correction to the title and text of the applicable regulations 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 Medicare administrative contractors 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 OPFS/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 OPFS notice-and-comment rulemaking, and implemented an independent review process in 2012 to obtain advice from the Hospital Outpatient Payment Panel (the Panel) on this matter (76 FR 74360 through 74371). Under this process used since CY 2012, the 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 of 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>.

Stakeholders have consistently requested that we continue the nonenforcement of the direct supervision of 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 contributing factors cited were difficulty recruiting physician 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 general physician supervision as compared to direct physician supervision for outpatient hospital therapeutic services.

Therefore, we are proposing to reinstate the nonenforcement of direct supervision enforcement instruction for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for CY 2018 and 2019 to give

CAHs and small rural hospitals having 100 or fewer beds more time to comply with the supervision requirements for outpatients therapeutic services and to give all parties time to submit specific services to be evaluated by the Advisory Panel on Hospital Outpatient Payment for a recommended change in the supervision level. These hospitals will continue to be subject to conditions of participation for hospitals and other Medicare rules regarding supervision. We welcome public comments on this proposal.

E. Payment Changes for Film X-Ray Services and Proposed Payment Changes for X-Rays Taken Using Computed Radiography Technology

Section 502 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 OPFS 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 OPFS (without application of subparagraph (F)(i) and before application of any other adjustment under section 1833(t)) 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.

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 will be 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 proposed rule (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), shall 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.

To implement this provision, we are establishing a new modifier “XX”, 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 are proposing 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. The applicable HCPCS codes describing imaging services can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). We note that modifier “XX” is a placeholder modifier whose 2-digit modifier and long descriptor will be described in the CY 2018 OPPS/ASC final rule with comment period. 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 are inviting public comments on these proposals.

Although we adopted the payment reduction 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 this CY 2018 OPPS/ASC proposed rule, we are proposing 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 are proposing 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. 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 are proposing that the phased-in payment reduction for computed radiography technology imaging services would be codified at paragraph (c) of proposed new § 419.71. 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 are inviting public comments on this proposed regulation text.

F. Potential Revisions to the Laboratory Date of Service Policy

1. Background on the Medicare Part B Laboratory Date of Service Policy

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 OPFS

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 OPFS for certain diagnostic tests that are not commonly performed by hospitals. In CY 2014, we finalized a policy to package certain CDLTs under the OPFS (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 OPFS/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 OPFS/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.²³ 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.

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

²³ Under section 1834A(d)(5)(A) of the Act, an ADLT is a "CDLT 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 . . . 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.

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. Additionally, an ADLT cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. And, 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 (FDA).

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. Potential Revisions to the Laboratory DOS Policy

In the December 1, 2006 MPFS final rule (71 FR 69706), we explained that we were very concerned that only tests that can legitimately be distinguished from the care a beneficiary receives in the hospital be subject to the 14-day rule, which changes the DOS from the date the specimen was collected to the date the test was performed and results in a separate payment for the test. We also stated that we believed it is more difficult to determine that a test ordered less than 14 days before discharge is appropriately separable from the hospital stay that preceded the test. We indicated that we wanted more information about tests that may be ordered by the patient’s physician less than 14 days following the date of the discharge that would not guide the care

during a hospital stay before taking any additional action in this area.

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 OPPTS, 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, 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 Medicare Administrative Contractor (MAC) used by the laboratory, a different MAC may be billed.

- 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 forgoing 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.

We recognize that the current laboratory DOS rule may impose administrative difficulties for hospitals and laboratories that furnish laboratory tests that are excluded from OPPTS 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 are considering potential modifications to the DOS policy that would allow laboratories to bill Medicare directly for certain laboratory tests excluded from the OPPTS packaging policy. 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 OPPTS/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. We are seeking 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.

For example, we are considering modifying § 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 are requesting 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.

(a) Limiting the DOS Rule Exception to ADLTs

We also are 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 are 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, 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 believe the circumstances may be different for molecular pathology tests, which are not required to be furnished by a single laboratory. In particular, we understand there may be "kits" for certain molecular pathology tests that a hospital can purchase, allowing the hospital to perform the test. Therefore, 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.

We are requesting 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 are requesting 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.

(b) Other Alternative Approaches

Finally, we are inviting public comments on alternative approaches to addressing stakeholders' concerns regarding the DOS policy, such as potentially modifying the "under arrangements" provisions in § 410.42 and § 411.15(m). Specifically, we are requesting 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.

We believe that feedback on the topics discussed in this section will help inform us regarding potential refinements to our DOS policy. We welcome comments on these topics from the public, including hospitals, laboratories, and other interested stakeholders. We are especially interested in comments regarding how the current DOS policy and "under arrangements" provisions may affect access to care for Medicare beneficiaries. We would consider finalizing the modifications described in this section.

XI. Proposed CY 2018 OPPS Payment Status and Comment Indicators

A. Proposed 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.

For CY 2018, we are not proposing to make any changes to the definitions of status indicators that were listed in Addendum D1 of 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-Regulations-and-Notices-Items/CMS-1656-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>. We believe that the existing definitions of the OPPS status indicators would continue to be appropriate for CY 2018.

The complete list of the payment status indicators and their definitions

that we are proposing to apply for CY 2018 is displayed in Addendum D1 to this proposed rule, which is available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

The proposed CY 2018 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

B. Proposed CY 2018 Comment Indicator Definitions

In this CY 2018 OPPS/ASC proposed rule, we are proposing 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 are proposing 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 are requesting 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.

The definitions of the proposed OPPS comment indicators for CY 2018 are listed in Addendum D2 to this proposed rule, which is available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

We are requesting public comment on our proposed status indicators and comment indicators for CY 2018.

XII. Proposed 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 payment 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, logically related to the categorization of services by physician experts who both establish the codes and perform the procedures, and 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 this CY 2018 OPPTS/ASC proposed rule, we are soliciting 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 payable when furnished in the ASC

setting. In particular, we are interested in commenters’ views regarding additional criteria we might use to consider when a procedure that is surgery-like could be included on the ASC CPL. We are requesting 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 are interested in commenters’ views on whether and how, if we were to include such services as ASC covered surgical procedures, we would need to revise our definition ASC covered surgical procedures.

B. Proposed 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 OPPTS/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 OPPTS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we are proposing to solicit public comments in this proposed rule (and respond to those comments in the CY 2018 OPPTS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2018 OPPTS/ASC final rule with comment period (and responding to those comments in the CY 2019 OPPTS/ASC final rule with comment period).

We note that we sought public comments in the CY 2017 OPPTS/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 OPPTS/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 OPPTS/ASC final rule with comment period. We will respond to public comments and finalize the treatment of these codes under the ASC payment system in the CY 2018 OPPTS/ASC final rule with comment period.

In Table 30 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 OPPTS.

TABLE 30—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 OPPTS/ASC proposed rule.	CY 2018 OPPTS/ASC final rule with comment period.

TABLE 30—COMMENT AND FINALIZATION TIMEFRAMES FOR NEW OR REVISED HCPCS CODES—Continued

ASC quarterly update CR	Type of code	Effective date	Comments sought	When finalized
July 1, 2017	Level II HCPCS Codes	July 1, 2017	CY 2018 OPPTS/ASC proposed rule.	CY 2018 OPPTS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2017	CY 2018 OPPTS/ASC proposed rule.	CY 2018 OPPTS/ASC final rule with comment period.
October 1, 2017	Level II HCPCS Codes	October 1, 2017	CY 2018 OPPTS/ASC final rule with comment period.	CY 2019 OPPTS/ASC final rule with comment period.
January 1, 2018	Level II HCPCS Codes	January 1, 2018	CY 2018 OPPTS/ASC final rule with comment period.	CY 2019 OPPTS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2018	CY 2018 OPPTS/ASC proposed rule.	CY 2018 OPPTS/ASC final rule with comment period.

Note: In the CY 2015 OPPTS/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 OPPTS/ASC proposed rule for further discussion of this issue.

2. Proposed Treatment of New and Revised Level II HCPCS Codes Implemented in April 2017 for Which We Are Soliciting Public Comments in This Proposed Rule

In the April 2017 ASC quarterly update (Transmittal 3726, CR 9998,

dated March 3, 2017), we added six new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 31 below lists the new Level II HCPCS codes that were implemented April 1, 2017, along with their proposed payment indicators for

CY 2018. The proposed payment rates, where applicable, for these April codes can be found in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 31—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2017

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2018 payment indicator
C9484	Injection, eteplirsen, 10 mg	K2
C9485	Injection, olaratumab, 10 mg	K2
C9486	Injection, granisetron extended release, 0.1 mg	K2
C9487*	Ustekinumab, for intravenous injection, 1 mg	K2
C9488	Injection, conivaptan hydrochloride, 1 mg	K2
J7328	Hyaluronan or derivative, gel-syn, 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.

We are inviting 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 above. We are proposing to finalize their payment indicators and their

payment rates in the CY 2018 OPPTS/ASC final rule with comment period.

3. Proposed Treatment of New and Revised Level II HCPCS Codes Implemented in July 2017 for Which We Are Soliciting Public Comments in This 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 below lists the new Level II HCPCS codes that are effective July 1, 2017. The proposed payment rates, where applicable, for these July codes can be found in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 32—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2017

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2018 payment indicator
C9489	Injection, nusinersen, 0.1 mg	K2
C9490	Injection, bezlotoxumab, 10 mg	K2
C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube	J8
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed.	J8

TABLE 32—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2017—Continued

CY 2017 HCPCS code	CY 2017 long descriptor	Proposed CY 2018 payment indicator
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance.	G2
Q9986	Injection, hydroxyprogesterone caproate (Makena), 10 mg	K2
Q9989*	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.

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 is listed in Table 33 below, along with its proposed payment indicator. The proposed payment rate for this new

Category III CPT code can be found in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

TABLE 33—NEW CATEGORY III CPT CODE FOR COVERED SURGICAL PROCEDURE EFFECTIVE ON JULY 1, 2017

CY 2017 CPT code	CY 2017 long descriptor	Proposed CY 2018 payment indicator
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space.	J8

We are inviting 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 above. We are proposing to finalize their payment indicators and their payment rates in the CY 2018 OPPTS/ASC final rule with comment period.

4. Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2017 and January 1, 2018 for Which We Will Be Soliciting Public Comments in the CY 2018 OPPTS/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 OPPTS 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 OPPTS quarterly update CRs. In the past, we also released new and revised Level II HCPCS codes that are effective October 1 through the October OPPTS quarterly update CRs and incorporated these new codes in the final rule with comment period.

For CY 2018, consistent with our established policy, we are proposing

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 OPPTS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPTS payment status for CY 2018. We will invite public comments in the CY 2018 OPPTS/ASC final rule with comment period on the interim status indicator and APC assignments, and payment rates for these codes that will be finalized in the CY 2019 OPPTS/ASC final rule with comment period.

5. Proposed Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2018 for Which We Will Be Soliciting Public Comments in the CY 2018 OPPTS/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 this proposed rule, we are proposing APC and status indicator assignments. We will accept comments and finalize the APC and status indicator assignments in the OPPTS/ASC final rule with comment period. For those new/revised CPT codes that are received too late for inclusion in this OPPTS/ASC proposed rule, 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.

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 can be found in ASC Addendum AA and Addendum BB to this 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 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 current calendar year and that comments will be accepted on the proposed payment indicator. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and their long descriptors for the new and revised CY 2018 CPT codes in Addendum O to this 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. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled “CY 2018 OPPTS/ASC Proposed Rule 5-Digit Placeholder Code,” to this

proposed rule. The final CPT code numbers would be included in the CY 2018 OPPS/ASC final rule with comment period. We note that not every code listed in Addendum O is subject to comment. For the new/revised Category I and III CPT codes, we are requesting comments on only those codes that are assigned to comment indicator “NP”.

In summary, we are soliciting 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 are listed in Addendum AA and Addendum BB to this proposed rule with short descriptors only. We list them again in Addendum O to this proposed rule with long descriptors. We also are proposing 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 indicator for these codes can be found in Addendum AA and Addendum BB to this proposed rule (which are available via the Internet on the CMS Web site).

C. Proposed 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) Proposed Changes for CY 2018 to Covered Surgical Procedures Designated as Office-Based

In developing this proposed rule, 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).

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 are proposing to permanently designate as office-based for CY 2018 is listed in Table 34 below.

TABLE 34—ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2018

CY 2018 CPT code	CY 2018 long descriptor	CY 2017 ASC payment indicator	Proposed 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, varicoceles).	G2	P2/P3
67227	Destruction of extensive or progressive retinopathy (eg, diabetic retinopathy), cryotherapy, diathermy.	G2	P2/P3

* Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed 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 proposed rule.

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 (e.g., abscess, hematoma, seroma, lymphocele, cyst), soft tissue (e.g., 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 are proposing to maintain the temporary office-based designations for these eight codes for CY 2018. We list all of these codes for which we are proposing to maintain the temporary office-based designations for CY 2018 in Table 35 below. The procedures for which the proposed office-based designations for CY 2018 are temporary also are indicated by asterisks in Addendum AA to this 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 are proposing 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 are inviting public comment on our proposals.

TABLE 35—PROPOSED CY 2018 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED IN THE CY 2017 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2018 CPT code	CY 2018 long descriptor	CY 2017 ASC payment indicator *	CY 2018 proposed 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/P3 **
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated.	P2 *	P2/P3 **
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/P3 **
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	P3 *	P2/P3 **
64463	Continuous infusion by catheter (includes imaging guidance, when performed).	P3 *	P2/P3 **
65785	Implantation of intrastromal corneal ring segments	R2 *	P2/P3 **
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 *	P2/P3 **
G0429	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	P3 *	P2/P3 **

* If designation is temporary.

** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed 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 proposed rule.

For CY 2018, we are proposing to designate one new CY 2018 CPT code for ASC covered surgical procedures as temporary office-based, as displayed in Table 36 below. 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 are proposing to make the office-based designation temporary rather than permanent, and we will reevaluate the procedure when data become available. The procedure

for which the proposed office-based designation for CY 2018 is temporary is indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comments on these proposals.

TABLE 36—PROPOSED CY 2018 PAYMENT INDICATORS FOR NEW CY 2018 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED

Proposed CY 2018 OPSS/ASC proposed rule 5-Digit CMS placeholder code	CY 2018 long descriptor	Proposed CY 2018 ASC payment indicator**
382X3	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	P2/P3*

* If designation is temporary.

** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed 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 proposed rule.

b. Proposed ASC Covered Surgical Procedures To Be Designated as Device-Intensive

(1) Background

As discussed in the CY 2017 OPSS/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 OPSS APC ratesetting methodology.

According to this ASC payment methodology, we apply the device offset percentage based on the standard OPSS APC ratesetting methodology to the OPSS national unadjusted payment to determine the device cost included in the OPSS 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 OPSS 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 OPSS/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) Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2018

For CY 2018, we are proposing 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 OPSS claims and cost report data available for the proposed rule.

The ASC covered surgical procedures that we are proposing to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2018, are assigned payment indicator “J8” and are included in Addendum AA to this 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 are included in Addendum AA to this proposed rule.

We are inviting public comments on the proposed list of ASC device-intensive procedures.

c. Proposed 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 OPPTS policy that was in effect until CY 2014. Specifically, the OPPTS policy that was in effect through CY 2013 provided a reduction in OPPTS 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 OPPTS to which this policy applies. We refer readers to the CY 2009 OPPTS/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 OPPTS/ASC final rule with comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing OPPTS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPPTS, our policy was to reduce OPPTS 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 OPPTS 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 OPPTS, 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 OPPTS, 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.

We are proposing to update the list of ASC covered device-intensive procedures, which 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 are proposing 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 OPPTS/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 are inviting public comments on our proposals to adjust ASC payments for no cost/full credit and partial credit devices.

d. Proposed Additions to the List of ASC Covered Surgical Procedures

We conducted a review of HCPCS codes that currently are paid under the OPPTS, 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 are proposing to update the list of ASC covered surgical procedures by adding three procedures to the list for CY 2018. We determined that these three procedures are separately paid under the OPPTS, 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 are proposing to include these three procedures on the list of ASC covered surgical procedures for CY 2018.

The procedures that we are proposing to add to the ASC list of covered surgical procedures, including the HCPCS code long descriptors and the proposed CY 2018 payment indicators, are displayed in Table 37 below.

TABLE 37—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2018

CY 2018 CPT code	CY 2018 long descriptor	Proposed CY 2018 ASC payment indicator
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy 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 osteophyctomy 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

We are inviting public comments on our proposals.

e. 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 inpatient only list for possible inclusion on the ASC list of covered surgical procedures. We are proposing to remove the following two procedures described by CPT codes from the OPPS inpatient only list for CY 2018: CPT codes 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)) and 58666 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed). We evaluated each of the two procedures we are proposing 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. Because our understanding is that these procedures typically require more than 24 hours of active medical care following the procedure, we believe they should continue to be excluded from the list of ASC 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 inpatient only 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 proposed rule, we only

solicited public comments on removing the TKA procedure from the OPPS inpatient only list for CY 2017. However, in this CY 2018 proposed rule, we are proposing to remove the TKA procedure from the OPPS inpatient only list for CY 2018, as discussed in section IX. of this proposed rule. In light of the public comments we received on the CY 2017 proposed rule (81 FR 79697 through 79699) and our proposal to remove the TKA procedure from the OPPS IPO list for CY 2018, in this proposed rule, we are soliciting public comments on whether the TKA procedure should also be added to the ASC list of covered surgical procedures. We also are inviting public comments on our proposed continued exclusion of CPT code 58666 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 are requesting that commenters take into consideration the regulations at 42 CFR 416.2 and 416.166. For example, commenters should assess 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).

In addition, in this CY 2018 proposed rule, we are soliciting comment on whether CPT codes 27125 (Hemiarthroplasty, hip, partial (e.g., 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 this proposed rule. As noted in that section, we also are soliciting comment on whether these two procedures meet the criteria to be added to the ASC covered surgical procedure list.

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, we are proposing to update the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2018 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary services because of changes that are being proposed under the OPPS for CY 2018. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2017, but is proposed for packaged status under the CY 2018 OPPS, to maintain consistency with the OPPS, we would also propose to package the ancillary service under the ASC payment system for CY 2018. We are proposing to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator “CH”, which is discussed in section XII.F. of this proposed rule, is used in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we are proposing a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2018.

All ASC covered ancillary services and their proposed payment indicators for CY 2018 are included in Addendum BB to this proposed rule. We are inviting public comments on this proposal.

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Proposed 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 OPPTS/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 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 OPPTS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2017 OPPTS/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 OPPTS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2017 OPPTS 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 rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2017 OPPTS/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 OPPTS data. We compared the estimated CY 2017 rate for each of the office-based procedures, calculated according to the ASC standard ratesetting 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 OPPTS/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 OPPTS. Under the OPPTS, 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 OPPTS are always packaged (payment indicator “N1”) under the ASC payment system. Under the OPPTS, 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 OPPTS (status indicator “Q2”), we assigned the current ASC payment indicators associated with these procedures and continued to provide separate payment since CY 2014.

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2018

We are proposing 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 this proposed rule. Because the proposed OPPTS 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 are proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators “A2” and “G2”.

We are proposing 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 this proposed rule. Therefore, we are proposing to update the payment amount for the service portion of the device-intensive procedures using the ASC standard ratesetting methodology and the payment amount for the device portion based on the proposed CY 2018 OPPTS device offset percentages that have been calculated using the standard OPPTS 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 are proposing to continue our policy for device removal procedures such that device removal procedures that are conditionally packaged in the OPPTS (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 are inviting public comments on these proposals.

2. Proposed 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 OPPTS. 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 OPPTS 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 OPPTS. In the CY 2013 OPPTS/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 OPPTS (status indicators “Q1” and “Q2”). Under the OPPTS, 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 OPPTS are always packaged (payment indicator “N1”) under the ASC payment system (except for device removal codes as discussed in section IV. of this proposed rule). Thus, our policy generally aligns ASC payment bundles with those under the OPPTS (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 OPPTS at the OPPTS 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 OPPTS/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 OPPTS 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 OPPTS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPTS or, if OPPTS 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 OPPTS.

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 OPPTS. 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 OPPTS 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 (nondevice) portion of the procedure’s OPPTS 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 OPPTS pass-through payment status.

In the CY 2015 OPPTS/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 OPPTS 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

OPPTS/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 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 reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2018

For CY 2018 and subsequent years, we are proposing to update the ASC payment rates and to make changes to ASC payment indicators as necessary to maintain consistency between the OPPTS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2018 OPPTS and ASC payment rates and subsequent year payment rates. We also are proposing 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 OPPTS payment rates for CY 2018 and subsequent year payment rates.

Covered ancillary services and their proposed payment indicators for CY 2018 are listed in Addendum BB to this 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 ratesetting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed MPFS rates effective January 1, 2018. For a discussion of the MPFS rates, we refer 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>.

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 OPSS 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 OPSS 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 OPSS/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 are not proposing to revise the payment adjustment amount for CY 2018.

F. Proposed 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 OPSS/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, OPSS 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 OPSS/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 OPSS/ASC final rule with comment period (74 FR 60622). In the CY 2017 OPSS/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

OPSS/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 OPSS/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. Proposed ASC Payment and Comment Indicators

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 are included in ASC Addenda AA and BB to this proposed rule are labeled with proposed new comment indicator “NP” to indicate that these CPT and Level II HCPCS codes are open for comment as part of this proposed rule. Proposed new comment indicator “NP” means 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; comments will be accepted on the proposed ASC payment indicator for the new code.

We will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2018 OPSS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 to this 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.

G. Calculation of the Proposed ASC Conversion Factor and the Proposed 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 OPSS 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 OPSS, 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 OPSS/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

OPSS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPSS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPSS 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 proposed rule), 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 OPSS/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 cost 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 OPSS/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.

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.)

2. Proposed 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, we are proposing

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 are proposing 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 are proposing 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 is 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 this proposed rule, we have 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>.

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 this 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 and 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 OPSS/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 OPSS/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 OPSS/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 this proposed rule, based on IHS Global Insight'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 OPSS/ASC final rule with comment period (80 FR 70500 through 70501).

For CY 2018, we are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 results 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 are proposing 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 results in a proposed CY 2018 ASC conversion factor of \$44.976.

We are inviting public comments on these proposals.

4. 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.²⁴ ASCs were recognized by Medicare as a less costly

²⁴ Omnibus Reconciliation Act of 1980 (ORA), Pub. L. 96-499, 934(b), 94 Stat. 2599, 2637 (codified, as amended, at 42 U.S.C. 1395(i)).

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 (P.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 OPSS, 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).²⁵ As directed by section 626(d) of Pub. L. 108-173, the report included recommendations on the following issues:

1. Appropriateness of using groups of covered services and relative weights established for the OPSS as the basis of payment for ASCs.

2. If the OPSS 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 OPSS, 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 OPSS/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 OPSS, 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 OPSS 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.²⁶

b. Solicitation of Comments

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 OPSS payments rates over the past 10 years, from 65 percent of average OPSS rates in CY 2008 to 56 percent (as proposed) of average OPSS 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 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.

²⁶ MedPAC. March 2017 Report to Congress. Chapter 5 "Ambulatory Surgical Center Services". http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch5.pdf?sfvrsn=0.

²⁵ <http://www.gao.gov/assets/260/253992.pdf>.

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 this proposed rule, we are soliciting comment on the ASC payment system update factor and 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, 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. We are seeking public comment 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. Information on the cost structure of ASCs will help to identify an appropriate alternative update factor.

In addition, we are seeking public comment 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 are seeking comment 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 are 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 note that the ability to calculate ASC-specific costs may obviate the need for tying the ASC payment system to that of the OPSS. 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 OPSS 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 OPSS 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 OPSS 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. We are 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 are 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.

5. Display of CY 2018 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS Web site) display the proposed 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 proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed MPFS rates that would be effective January 1, 2018. For a discussion of the MPFS rates, we refer readers to the CY 2018 MPFS proposed rule.

The proposed 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 proposed 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 would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPSS/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 "Proposed CY 2018 Payment Weight" are the proposed relative payment weights for each of the listed services for CY 2018. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPSS 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 proposed CY 2018 payment rate displayed in the “Proposed CY 2018 Payment Rate” column, each ASC payment weight in the “Proposed CY 2018 Payment Weight” column was multiplied by the proposed CY 2018 conversion factor of \$45.876. The proposed 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 proposed rule).

In Addendum BB, there are no relative payment weights displayed in the “Proposed CY 2018 Payment Weight” column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The “Proposed CY 2018 Payment” column displays the proposed CY 2018 national unadjusted ASC payment rates for all items and services. The proposed 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 April 2017.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2018. We are inviting public comments on these proposals.

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. In this proposed rule, we are not proposing 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 this proposed rule, we are proposing editorial changes to 42 CFR 419.46, 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. In this proposed rule, we are not proposing 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)²⁷ 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.²⁸ 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.²⁹

²⁷ 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>.

²⁸ 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>.

²⁹ National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

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 entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures, and we will closely review its findings.

As we continue to consider the analyses and recommendations from these reports and await 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, we are seeking 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 are seeking 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 are seeking 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.

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 OPPI/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. In this proposed rule, we are not proposing 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 OPPI/ASC final rule with comment period (74 FR 60634 through 60635). We refer readers to the CY 2013 OPPI/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. In this proposed rule, we are not proposing any changes to our policy to immediately remove measures as a result of patient safety concerns.

In the CY 2013 OPPI/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. In this proposed rule, we are not proposing 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). In this proposed rule, we are not proposing any changes to our “topped-out” criteria policy.

c. Measures Proposed for Removal From the Hospital OQR Program

In this proposed rule, we are proposing to remove a total of six measures. Specifically, beginning with the CY 2020 payment determination, we are proposing 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 are proposing 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. These proposals are discussed in detail below.

(1) Proposed 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 are proposing 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 non-medical 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.³⁰

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 non-opioid 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

³⁰ CMS Opioid Misuse Strategy 2016. Retrieved from: <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Prescription-Drug-Information-for-Partners-Items/CMS-Opioid-Misuse-Strategy-2016.html>.

not aware of any scientific studies that support an association between this measure and opioid prescribing practices, out of an abundance of caution, we are proposing 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 proposed rule (82 FR 20035 through 20039), we proposed new pain management questions to replace the current ones in the HCAHPS Survey measure for the Hospital IQR Program.

We are inviting 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.

(2) Proposed 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.³¹ This information, number of surgical procedures, does not offer insight into the facilities’ overall performance or quality improvement in regards 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

³¹ OP–26 Measure Information Form. Retrieved from: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPPage%2FSpecsManualTemplate&cid=1228775748170>.

measure, which is submitted via a web-based tool, outweighs the value, and therefore, we are proposing 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 proposed rule, where the ASCQR Program is proposing to remove a similar measure.

We are inviting public comment on our proposal to remove 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.

(3) Proposed Removal of OP–1: Median Time to Fibrinolysis Beginning With the CY 2021 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.³² As a result, because OP–1 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 continuing to collect OP–1 would be redundant with OP–2. As a result, we are proposing 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 is finalized as proposed.

We are inviting 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.

(4) Proposed Removal of OP–4: Aspirin at Arrival Beginning With the CY 2021 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 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 measure, and the truncated coefficient of variation has been below 0.10 since 2014. Therefore, this OP–4 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 are proposing to

remove OP–4: Aspirin at Arrival from the program for the CY 2021 payment determination and subsequent years.

We are inviting 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.

(5) Proposed Removal of OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional Beginning With the CY 2021 Payment Determination

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72087–72088) 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

³² 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). J Am Coll Cardiol. 2008; 51:210–47.

arrival to provider contact for Emergency Department patients.

During regular measure maintenance, specific concerns about OP–20 were raised by a Technical Expert Panel (TEP), which was made up 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 are proposing to remove OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional for the CY 2021 payment determination and subsequent years.

We are inviting 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.

(6) Proposed Removal of OP–25: Safe Surgery Checklist Use Beginning With the CY 2021 Payment Determination

We refer readers to the CY 2012 OP/ASC final rule with comment period (76 FR 74464–74466), 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 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 the 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 are proposing 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 proposed rule, where the ASCQR Program is also proposing to remove a similar measure.

We are inviting 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.

5. 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

We refer readers to the CY 2017 OP/ASC final rule with comment period where we adopted OP–37a–e (81 FR 79771–79784), 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 this proposed rule, we are proposing 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 lack important 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 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 OP/ASC final rule with comment period (81 FR 79777). We believe that the national implementation of the survey, which began in January 2016 and will conclude in December 2017, 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 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

are proposing 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 proposed rule where we are making a similar proposal in the ASCQR Program.

We are inviting 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.

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.†
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).

**** Proposed to delay measure reporting beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of this proposed rule.

7. Summary of the Hospital OQR Program Measure Set Proposed for the CY 2020 and CY 2021 Payment Determinations and Subsequent Years

In this proposed rule, we are not proposing any new measures for the Hospital OQR Program. However, we are proposing to remove a number of

measures for both the CY 2020 and 2021 payment determinations in section XIII.B.4.c. of this proposed rule, above, and we are proposing to delay OP-37a-e beginning with the CY 2020 payment determination (2018 data collection) in section XIII.B.5. of this proposed rule. The tables below outline the Hospital OQR Program measure set we are

proposing in this proposed rule for the CY 2020 and CY 2021 payment determination and subsequent years, respectively. Both of these charts reflect the measure set as if our proposals to remove measures and to delay reporting of OP-37a-e beginning with CY 2018 reporting and for subsequent years are finalized as proposed.

HOSPITAL OQR PROGRAM MEASURE SET PROPOSED FOR THE CY 2020 PAYMENT DETERMINATION

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.†
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.
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.
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 OPPI/ASC final rule with comment period (79 FR 66946 through 66947).

*** Proposed to delay measure reporting beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of this proposed rule.

In addition, the table below outlines for the CY 2021 payment determination the Hospital OQR Program measure set and subsequent years we are proposing in this proposed rule

HOSPITAL OQR PROGRAM MEASURE SET PROPOSED FOR THE CY 2021 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.†
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.*

HOSPITAL OQR PROGRAM MEASURE SET PROPOSED FOR THE CY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF No.	Measure name
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 OPPTS/ASC final rule with comment period (79 FR 66946 through 66947).

*** Proposed to delay measure reporting beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of this proposed rule.

8. Hospital OQR Program Measures and Topics for Future Consideration

In this proposed rule, we are seeking 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 are inviting public comments on possible measure topics for future consideration in the Hospital OQR Program. We specifically request 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.

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 OPPTS/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 OPPTS/ASC final rule with comment period (72 FR 66865), where it was designated as ED-AMI-3. In the CY 2009 OPPTS/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 Arrival³³ 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 in particular because we believe it is the most feasible out of all the existing Hospital OQR Program measures.

We are inviting 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.

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 OPPTS/ASC final rule with comment period (74 FR 60631), the CY 2011 OPPTS/ASC final rule with comment period (75 FR 72069), and the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68469 through 68470). In this proposed rule, we are not proposing any changes to our technical specifications policies.

³³ eCQI Resource Center: [https://ecqi.healthit.gov/eh/ecqms-2016-reporting-period/fibrinolytic-](https://ecqi.healthit.gov/eh/ecqms-2016-reporting-period/fibrinolytic-therapy-received-within-30-minutes-hospital-arrival)

[therapy-received-within-30-minutes-hospital-arrival](https://ecqi.healthit.gov/eh/ecqms-2016-reporting-period/fibrinolytic-therapy-received-within-30-minutes-hospital-arrival).

10. Public Display of Quality Measures

a. Background

We refer readers to the CY 2014 and CY 2017 OPPTS/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 this proposed rule, we are proposing to update public reporting for the OP-18 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 was finalized for reporting for the CY 2013 payment determination and subsequent years in the CY 2011 OPPTS/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),^{34 35} 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 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.³⁶

The ICD-10 diagnostic codes for OP-18c include numerous substance abuse codes for inclusion in this subset, along with numerous non-substance 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 this proposed rule, we are proposing 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,³⁷ 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 that our proposal to publicly report OP-18c does not create additional burden. We note that hospitals would be able to preview this 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 are inviting 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.

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 OPPTS/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 OPPTS/ASC final rule with comment period (78 FR 75108 through 75109) and the CY 2016 OPPTS/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 this proposed rule, we are proposing changes to the NOP submission deadline, as described below.

b. Proposed Changes to the NOP Submission Deadline

We finalized in the CY 2014 OPPTS/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 OPPTS/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:

³⁴ A Measure Information Form provides detail on the rationale for a measure as well as the relevant numerator statements, denominator statements and measure calculations.

³⁵ Hospital OQR Program ED Throughput Measures Information Form: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228775748170>.

³⁶ Hospital OQR Program ED Throughput Measures Information Form: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228775748170>.

³⁷ Hospital OQR Program ED Throughput Measures Information Form: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228775748170>.

- 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 this proposed rule, beginning with the CY 2020 payment determination, we are proposing to: (1) Revise the NOP submission deadline described above, and (2) make corresponding revisions at 42 CFR 419.46(a). Specifically, we are proposing 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 proposed rule, below and finalized in the CY 2016 OPPTS/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 are proposing to make conforming revisions at 42 CFR 419.46(a).

We are inviting public comment on our proposals as discussed above.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Payment Determinations

In the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75110 through 75111) and the CY 2016 OPPTS/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 OPPTS/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

In this proposed rule, for the CY 2020 payment determination and subsequent years, we are proposing to revise the data submission requirements for hospitals that did not participate in the previous year’s Hospital OQR Program. Specifically, we are proposing to revise the first quarter for which newly participating hospitals are required to submit data (see details below). We are not proposing changes to the previously finalized data submission deadlines for each quarter.

In the CY 2013 OPPTS/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 this proposed rule, we are proposing 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 are proposing 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 are inviting 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).

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPTS/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.

In this proposed rule, we are not proposing 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 proposed rule, we are proposing to remove OP–21: Median Time to Pain Management for Long Bone Fracture for the CY 2020 payment determination and subsequent years and 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 2021 payment determination and subsequent years. Therefore, if these proposals are finalized as proposed, the following previously finalized Hospital OQR

Program chart-abstracted measures will require patient-level data to be submitted for the CY 2021 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 OPPTS/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. In this proposed rule, we are not proposing 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 OPPTS/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 proposed rule, where we are proposing 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 OPPTS/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.

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 OPPTS/ASC final rule with comment period (78 FR 75112 through 75115) and the CY 2016 OPPTS/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 OPPTS/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. In this proposed rule, we are not proposing 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 proposed rule, we are proposing to remove OP-25: Safe Surgery Checklist Use (beginning with CY 2021), and OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (beginning with CY 2020). Therefore, if these proposals are finalized as proposed, 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 2021 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 OPPTS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our population and sampling requirements.

In this proposed rule, we are not proposing 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 this proposed rule, we are: (1) Clarifying the hospital selection process previously finalized for validation; (2) proposing to codify the procedures for targeting hospitals at 42 CFR 419.46(e); and (3) proposing 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, in this proposed rule, we are clarifying 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.

b. Proposed Codification

We note that the previously finalized procedures for targeting hospitals for validation, described in section XIII.D.7.a., above, 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. In this proposed rule, we are proposing 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 are inviting public comment on our proposal to codify our validation targeting criteria as discussed above.

c. Proposed 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.³⁸ 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 believe 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 are proposing 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, in this proposed rule, we are proposing 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 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) Proposed 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.³⁹ 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 basis⁴⁰ 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.⁴¹ 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

³⁹ Data Validation—Educational Reviews: Hospitals-Outpatient. <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic/Page/QnetTier3&cid=1228764927987>.

⁴⁰ QualityNet: Data Validation Overview. Retrieved from: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228758729356>.

⁴¹ The educational review request form can be found at: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228764927987>.

³⁸ Data Validation—Educational Reviews: Hospitals-Outpatient. <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic/Page/QnetTier3&cid=1228764927987>.

educational review results and responses via a secure file transfer to the hospital.⁴²

In this proposed rule, we are proposing 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 are inviting 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.

(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.⁴³ If the upper bound of this confidence interval is 75 percent or higher, the hospital will pass the Hospital OQR Program validation requirement.⁴⁴ In this proposed rule, we are proposing 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.

In order to determine whether a quarterly validation score was correct, we are proposing to use a similar process as one previously finalized for reconsideration requests. Specifically, we are proposing 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 are further proposing 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 and proposed 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.⁴⁵ 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 proposed rule 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.

⁴⁵ 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>.

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 are inviting 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 described and proposed in section XIII.D.7.c.(2)(a) of this proposed rule above, to compute the final confidence interval for the first 3 quarters of validation.

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

⁴² Hospital OQR Validation Educational Review Process: Retrieved from: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228764927987>.

⁴³ QualityNet Data Validation Overview. Retrieved from: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228758729356>.

⁴⁴ QualityNet Data Validation Overview. Retrieved from: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228758729356>.

(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.

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 proposed 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 19967, 19990, 20075, 20085 and 20128) and proposed to address differences in these areas for those programs. In section XIV.D.6. of this proposed rule, we are also proposing revisions to our 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, in this proposed rule, we are proposing 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 are therefore proposing 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 name of this policy does not change the availability for a hospital to request an extension under the Hospital OQR Program.

We are inviting public comment on these proposals as discussed above.

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 OPSS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPSS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPSS/ASC final rule with comment period (80 FR

70524), and the CY 2017 OPSS/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 are not proposing any changes to our reconsideration and appeals procedures.

E. Proposed 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 OPSS 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 OPSS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPSS equal the product of the OPSS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPSS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPSS payment rate for services with the following status indicators (listed in Addendum B to this proposed 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 proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2018

We are proposing 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 is 0.980, calculated by dividing the proposed reduced conversion factor of 74.953 by the proposed full conversion factor of 76.483. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2018 OPPS, we are proposing 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”). As noted above, 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. We are proposing to continue to exclude services paid under New Technology APCs. We are proposing 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 are proposing 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 are proposing 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 are inviting public comments on these proposals.

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 proposed rule 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 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 OPPTS/ASC final rule with comment period (78 FR 75122), section XIV. of the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66966 through 66987), section XIV. of the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70526 through 70538) and section XIV. of the CY 2017 OPPTS/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 OPPTS/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 are not proposing 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)⁴⁶ 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.⁴⁷ 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.⁴⁸

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 entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures, and we will closely review its findings.

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF trial on risk adjustment for quality

⁴⁶ 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-medicare-value-based-purchasing-programs>.

⁴⁷ 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-medicare-value-based-purchasing-programs>.

⁴⁸ National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

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, we are seeking 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 are seeking 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 are seeking 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.

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 are not proposing any changes to this policy.

b. Proposed 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 are not proposing any changes to this process.

In this proposed rule, we are proposing 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) Proposed 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.

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 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 measure, and the truncated coefficient of variation has been below 0.10 since 2014. Therefore, this ASC-5 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 ASC-5, 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 2013.⁴⁹ 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, we are

proposing 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 are inviting 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.

(2) Proposed 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 ASC-6: Safe Surgery Checklist Use 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 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.

⁴⁹ 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.

ASC-6 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 ⁵⁰	(*)	(*)	(*)	(*)	(*)
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 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, we are proposing to remove ASC-6 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 proposed rule, where the Hospital OQR Program is also proposing to remove a similar measure.

We are inviting 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.

(3) Proposed 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 OPPI/ASC final rule with comment period (76 FR 74507 through 74509), where we adopted ASC-7: ASC Facility Volume Data on Selected Procedures 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 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 are proposing and intend to continue to adopt, more measures assessing ASCs' performance on specific procedure types. For example, in the CY 2017 OPPI/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 are proposing to adopt a second ophthalmology-specific measure, ASC-16: Toxic Anterior Segment Syndrome, in section XIV.B.6.a. of this proposed rule. We believe these procedure-type-specific measures will provide patients with more valuable ASC performance data than the ASC-7 measure in selecting an ASC for their care. For this reason, we believe the ASC-7 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, we are proposing 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 proposed rule where we are proposing to remove a similar measure from the Hospital OQR Program.

We are inviting 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.

4. Proposal to Delay 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 OPPI/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 this proposed rule, we are proposing 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 lack important 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 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 OPPI/ASC final rule with comment period (81 FR 79810). We believe that the national implementation of the survey, which began in January 2016 and will conclude in December 2017, 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

⁵⁰ 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. https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890196351&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DASC_wbmr_prsntn_121813_1ppg.pdf&blobcol=urldata&blobtable=MungoBlobs.

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 are proposing 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 proposed rule where we are making a similar proposal in the Hospital OQR Program.

We are inviting public comment on our proposal to delay the OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination as discussed above.

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 includes the ASC-5, ASC-6, and ASC-7 measures, which are being proposed for removal as discussed above, as well as the ASC-15a-e. measures, which are being proposed 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 proposed for removal beginning with the CY 2019 payment determination, as discussed in section XIV.B.3.b. of this proposed rule.

** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPSS/ASC final rule with comment period (79 FR 66984 through 66985).

*** Measure proposed 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 proposed rule.

6. Proposed New ASCQR Program Quality Measures for the CY 2021 and CY 2022 Payment Determinations and Subsequent Years

We refer readers to the CY 2014 OPSS/ASC final rule with comment period (78 FR 75124) for a detailed discussion of our approach to measure selection for the ASCQR Program. In this proposed rule, we are proposing 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. Proposed Adoption of 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.⁵¹ 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.⁵² Prevention requires careful attention to solutions, medications, and ophthalmic devices and to cleaning and sterilization of surgical equipment because of the numerous potential etiologies.⁵³ Despite

⁵² Breebaart AC, Nuyts RM, Pels E, Edelhauser HF, Verbraak FD. Toxic Endothelial Cell Destruction of the Cornea after Routine Extracapsular Cataract Surgery. Arch Ophthalmol 1990; 108:1121-1125.

⁵³ 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

⁵¹ Centers for Disease Control and Prevention. Toxic Anterior Segment Syndrome after Cataract Surgery—Maine, 2006. MMWR Morb Mortal Wkly Rep. 2007 Jun 29;56(25):629-630.

a recent focus on prevention, cases of TASS continue to occur, sometimes in clusters.⁵⁴ 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.⁵⁵

(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, we are proposing 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 proposed ASC-16 measure was included on the 2015 MUC list⁵⁶ and reviewed by the MAP.

Instruments. J Cataract Refract Surg. 2007 Jun;33(6):1095-1100.

⁵⁴ Moyle W, Yee RD, Burns JK, Biggins T. Two Consecutive Clusters of Toxic Anterior Segment Syndrome. *Optom Vis Sci.* 2013 Jan;90(1):e11-23.

⁵⁵ 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>.

⁵⁶ National Quality Forum. *2015 Measures Under Consideration List*. National Quality Forum, Dec. 2016. Available at: <http://www.qualityforum.org/>

The MAP reviewed the measure (MUC15-1047) and conditionally supported it for the ASCQR Program pending NQF review and endorsement.⁵⁷ 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.⁵⁸ 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 proposed measure meets these statutory requirements.

The proposed ASC-16 measure is not NQF-endorsed. However, this measure is maintained by the ASC Quality

2015 Measures Under Consideration.aspx, under "2015 Measures Under Consideration List (PDF)."

⁵⁷ 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>.

⁵⁸ 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>.

Collaboration,⁵⁹ an entity recognized within the community as an expert in measure development for the ASC 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 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 measure⁶⁰ 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.⁶¹ Furthermore, we believe that this measure is scientifically acceptable, because the measure steward has completed reliability testing and validity assessment of the measure.⁶² Specifically, a 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.

⁵⁹ ASC Quality Collaboration. "ASC Quality Collaboration." Available at: <http://www.ascquality.org/>.

⁶⁰ 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>.

⁶¹ 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>.

⁶² AHRQ Measure Summary. Retrieved from: <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>.

(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 are proposing 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 are proposing 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 proposed rule 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 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 measure is not risk-adjusted; risk adjustment for patient characteristics is not appropriate for this measure.

We are inviting 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. If the proposals in section XIV.B.3.b., XIB.b.4. and XIV.B.6.a. of this proposed rule are finalized, the measure set for the ASCQR Program CY 2021 payment determination and subsequent years would be as listed below. We note that the measures being proposed for removal in this proposed rule are not included in this chart.

ASCQR PROGRAM MEASURE SET PREVIOUSLY FINALIZED AND PROPOSED 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.
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-16	None	Toxic Anterior Segment Syndrome.***

† 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 proposed for delay in reporting 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 proposed rule.

*** New measure proposed for the CY 2021 payment determination and subsequent years.

b. Proposed 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.⁶³ In 2015, more than 3.4 million fee-for-service Medicare beneficiaries were treated at 5,475 Medicare-certified ASCs, and

⁶³ Cullen KA, Hall MJ, Golosinskiy A, Statistics NfCh. Ambulatory Surgery in the United States, 2006. *Nat Health Stat Rept*; 2009.

spending on ASC services by Medicare and its beneficiaries amounted to 4.1 billion dollars.⁶⁴ The patient population served at ASCs has increased not only in volume, but also in age and complexity, which can be partially

⁶⁴ 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.

attributed to improvements in anesthetic care and innovations in minimally invasive surgical techniques.^{65 66} 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.⁶⁷ 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 2007.⁶⁸

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.⁶⁹ 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, we are proposing 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. 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 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 measure we are proposing was included on a publicly available document entitled "List of Measures under Consideration for December 1, 2016."⁷⁰ 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.⁷¹ MAP also recommended that this measure be submitted to NQF for review and

endorsement.⁷² 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.⁷³ 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.⁷⁴ 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

⁶⁵ 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.

⁶⁶ Fuchs K. Minimally invasive surgery. *Endoscopy*. 2002;34(2):154-159.

⁶⁷ Cullen KA, Hall MJ, Golosinskiy A, Statistics Nfch. Ambulatory Surgery in the United States, 2006. *Nat Health Stat Rept*; 2009.

⁶⁸ 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.

⁶⁹ Martín-Ferrero MA, Faour-Martín O. Ambulatory surgery in orthopedics: experience of over 10,000 patients. *Journal of Orthopaedic Surgery*. 2014;19:332-338.

⁷⁰ National Quality Forum. *List of Measures under Consideration for December 1, 2016*. National Quality Forum, Dec. 2016. Available at: <http://www.qualityforum.org/map/>.

⁷¹ 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>.

⁷² 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>.

⁷³ Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. 1977;33(1):159-174.

⁷⁴ 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.

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 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.⁷⁵ 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 measure addresses the MAP-identified priority measure area of surgical complications for the ASCQR

Program.⁷⁶ 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 are proposing that the data collection period for the proposed ASC-17 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 proposed rule for a more detailed discussion of 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.⁷⁷ 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 procedure codes.⁷⁸ 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-

⁷⁵ 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>.

⁷⁶ 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>.

⁷⁷ 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.

⁷⁸ 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.

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-notice-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.⁷⁹ 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.⁸⁰ Additional risk adjustment details are available in the technical report at: <https://www.cms.gov/medicare/Quality->

⁷⁹ Healthcare Cost and Utilization Project. *Clinical Classifications Software for Services and Procedures*. Available at: https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcsproc.jsp.

⁸⁰ S. Coberly. *The Basics; Relative Value Units (RVUs)*. National Health Policy Forum. January 12, 2015. Available at: http://www.nhpj.org/library/the-basics/Basics_RVUs_01-12-15.pdf.

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.⁸¹ Reliability testing showed fair measure score reliability.⁸² 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. If this measure is adopted, we are proposing to publicly report results only for facilities with sufficient case numbers to meet moderate reliability standards.⁸³ CMS will determine the case size cutoff for meeting moderate reliability standards using the interclass 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. 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>.

⁸¹ 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.

⁸² Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. 1977;33(1):159–174.

⁸³ Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. 1977;33(1):159–174.

(8) Provision of Facility-Specific Information Prior to Public Reporting

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.

We are inviting 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.

c. Proposed 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.⁸⁴ Similarly, a recent study found outpatient urology surgery has an overall 3.7 percent readmission rate.⁸⁵ 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.⁸⁶

Because urology surgery performed at an ASC is a significant predictive factor for unanticipated admissions compared to other procedures,⁸⁷ 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.⁸⁸ However, increased patient and staff education present opportunities to improve the success rate of urology

surgeries in ASCs.⁸⁹ 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, we are proposing 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 measure we are proposing was included on a publicly available document entitled "List of Measures under Consideration for December 1, 2016."⁹⁰ 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.⁹¹

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 reliability⁹² 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 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

⁸⁴ Fortier J. Unanticipated Admission after Ambulatory Surgery—A Prospective Study. *Can J Anaesth.* 1998;45(7):612-619.

⁸⁵ 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.

⁸⁶ Hollingsworth JM. Surgical Quality Among Medicare Beneficiaries Undergoing Outpatient Urological Surgery. *The Journal of Urology.* 2012;188(4):1274-1278.

⁸⁷ Fortier J. Unanticipated Admission after Ambulatory Surgery—A Prospective Study. *Can J Anaesth.* 1998;45(7):612-619.

⁸⁸ Paez, A. Adverse Events and Readmissions after Day-Care Urological Surgery. *International Braz J Urol.* 2007;33(3):330-338.

⁸⁹ Paez, A. Adverse Events and Readmissions after Day-Care Urological Surgery. *International Braz J Urol.* 2007;33(3):330-338.

⁹⁰ National Quality Forum. *List of Measures under Consideration for December 1, 2016.* National Quality Forum, Dec. 2016. Available at: <http://www.qualityforum.org/map/>.

⁹¹ National Quality Forum. 2016-2017 Spreadsheet of Final Recommendations to HHS and CMS, available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=81593>.

⁹² Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159-174.

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 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.⁹³ 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 measure addresses the MAP-identified priority measure area of surgical complications for the ASCQR Program.⁹⁴ Therefore, we believe it is appropriate to incorporate this measure

⁹³ 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>.

⁹⁴ 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.>

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 are proposing that the data collection period for the proposed ASC-18 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 proposed rule 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 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.⁹⁵ Medicare developed this 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.⁹⁶ Medicare annually reviews and updates this list, and includes a transparent public comment submission and review process for addition and/or removal of procedure codes.⁹⁷ 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

⁹⁵ 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.

⁹⁶ 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.

⁹⁷ 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.

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-notice-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."⁹⁸ 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.⁹⁹ 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>.

⁹⁸ Healthcare Cost and Utilization Project. *Clinical Classifications Software for Services and Procedures*. Available at: https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcsproc.jsp.

⁹⁹ S. Coberly. *The Basics: Relative Value Units (RVUs)*. National Health Policy Forum. January 12, 2015. Available at: http://www.nhpforum.org/library/the-basics/Basics_RVUs_01-12-15.pdf.

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.¹⁰⁰ Reliability testing showed fair measure score reliability.¹⁰¹ 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. If this measure is adopted, we are proposing to publicly report results only for facilities with sufficient case numbers to meet moderate reliability standards.¹⁰² CMS will determine the case size cutoff for meeting moderate reliability standards using the interclass 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

If this proposed measure is finalized, but before the official data collection

¹⁰⁰ 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.

¹⁰¹ Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. 1977;33(1):159-174.

¹⁰² Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. 1977;33(1):159-174.

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.

Confidential dry run results are not publicly reported and do not affect payment. We expect the dry run to take approximately 1 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, the measure would affect payment and would be publicly reported beginning with the CY 2022 payment determination and subsequent years as proposed.

We are inviting 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.

d. Summary of Previously Adopted Measures and Newly Proposed ASCQR Program Measures for the CY 2022 Payment Determination and Subsequent Years

If the proposals in sections XIV.B.3.b., XIV.B.4. and XIV.B.6.a. through c. of

this proposed rule are finalized, the measure set for the ASCQR Program CY 2022 payment determination and subsequent years would be as listed below.

ASCQR PROGRAM MEASURE SET WITH PREVIOUSLY FINALIZED AND NEWLY PROPOSED 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-16	None	Toxic Anterior Segment Syndrome.***
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 OPPI/ASC final rule with comment period (79 FR 66984 through 66985).

** Measure proposed for delay beginning with CY 2018 reporting until further action in future rulemaking as discussed in section XIV.B.4. of this proposed rule.

*** New measure proposed for the CY 2021 payment determination and subsequent years.

**** New measure proposed for the CY 2022 payment determination and subsequent years.

7. ASCQR Program Measures and Topics for Future Consideration

In the CY 2013 OPPI/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 OPPI/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.

In this proposed rule, we are inviting 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 Outcome measure (NQF #3025), and are seeking public comment on accounting for social risk factors in the ASCQR Program. 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 2011.¹⁰³ 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.¹⁰⁴

¹⁰³ Magill S.S., Edwards J.R., Bamberg W., Beldavs Z.G., Dumyati G., Kainer M.A. Multistate Point-Prevalence Survey of Health Care-Associated Infections. *N Engl J Med.* 2014;370:1198–1208.

¹⁰⁴ Magill S.S., Edwards J.R., Bamberg W., Beldavs Z.G., Dumyati G., Kainer M.A. Multistate

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.¹⁰⁵ While SSI rates following breast procedures vary from one percent to over 30 percent depending on procedure type,¹⁰⁶ the trend in surgery transitioning to outpatient and ambulatory surgery

Point-Prevalence Survey of Health Care-Associated Infections. *N Engl J Med.* 2014;370:1198–1208.

¹⁰⁵ 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.

¹⁰⁶ 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; Mannin J., Wille J.C., Snoeren R.L. 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. *Infect Control Hosp Epidemiol.* 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 5-year Experience. *American Journal of Infection Control.* 2009;37(8):674–679.

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.¹⁰⁷ Although standardized metrics have been developed to measure SSI rates for inpatient surgeries in the hospital setting,¹⁰⁸ 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.¹⁰⁹ 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.¹¹⁰ 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.¹¹¹

The Ambulatory Breast Procedure Surgical Site Infection Outcome measure was included on the 2016 MUC list¹¹² 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.¹¹³ The MAP further noted that this measure should be submitted for NQF review and endorsement.¹¹⁴ 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.¹¹⁵

The Ambulatory Breast Procedure Surgical Site Infection (SSI) 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).¹¹⁶ 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 are inviting public comment on the possible inclusion of this measure in the ASCQR Program measure set in the future.

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 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 are not proposing 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

¹⁰⁷ Anderson D.J., Podgorny K., Berríos-Torres S. et al. Strategies to Prevent Surgical Site Infections in Acute Care Hospitals: 2014 Update. *Infection Control & Hospital Epidemiology*. 2014;35:605–627; Mangram A.J, Horan T.C., Pearson M.L., Silver L.C., Jarvis W.R. Guideline for Prevention of Surgical Site Infection. *Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol*. 1999;720:250–278; Gaynes R., Richards C., Edwards J.R., et al Feeding Back Surveillance Data to Prevent Hospital-Acquired Infections. *Emerg Infect Dis*. 2001;7:295–298.

¹⁰⁸ Mu Y., et al. Improving Risk-Adjusted Measures of Surgical Site Infection for the National Healthcare Safety Network. *Infect Control Hosp Epidemiol*. 2011;32(10):970–986.

¹⁰⁹ Mu Y., et al. Improving Risk-Adjusted Measures of Surgical Site Infection for the National Healthcare Safety Network. *Infect Control Hosp Epidemiol*. 2011;32(10):970–986.

¹¹⁰ Cullen KA, Hall MJ, Golosinskiy A, Statistics NfCh. Ambulatory Surgery in the United States, 2006. *Nat Health Stat Rept*; 2009.

¹¹¹ 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>.”

¹¹² http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx, under “2016 Measures Under Consideration List (PDF).”

¹¹³ 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>.

¹¹⁴ 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>.

¹¹⁵ National Quality Forum. Endorsed measure specification available at: <http://www.qualityforum.org/QPS/3025>.

¹¹⁶ Centers for Disease Control and Prevention. “Surgical Site Infection (SSI) Event. Available at: <https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscasicurrent.pdf>.

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 are not proposing any changes to these policies. However, we note that in section XIV.B.6.b. and c. of this proposed rule we are proposing 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 proposed 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). In section XIV.D.3. of this proposed rule, we are proposing 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 are not proposing 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 are not proposing any changes to these requirements.

We note that, in section XIV.B.3.b.(1) of this proposed rule, we are proposing to remove one claims-based measure using QDCs, ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing, beginning with the CY 2019 payment determination. If this proposal is finalized as proposed, 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 are not proposing 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 proposing to remove two measures submitted via a CMS online data submission tool in section XIV.B.3.b.(2) and XIV.B.3.b.(3) of this proposed rule and to adopt one measure submitted via a CMS online data submission tool in section XIV.B.6.a. of this proposed rule.

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 are not proposing any changes to the reporting requirements for this measure.

b. Proposals Regarding 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 this proposed rule, we are making one proposal to the method of data submission via a CMS online data submission tool.

(1) Batch Submission

We are not proposing 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 are proposing 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 are proposing 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 are inviting 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.

(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 proposed rule, respectively, we are proposing 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. If these proposals are finalized as proposed, 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.¹¹⁷

Furthermore, in section XIV.B.6.a. of this proposed rule, we are proposing 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.

4. Requirements for Claims-Based Measure Data

We refer readers to the CY 2015 OPPS/ASC final rule with comment

¹¹⁷ 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 are not proposing 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 proposed rule, we are proposing 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 proposed rule, we are proposing 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.

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 OPSS/ASC final rule with comment period (78 FR 75140 through 75141), the CY 2017 OPSS/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.¹¹⁸

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.

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 proposed 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 19967, 19990, 20074 through 20075, 20085 through 20086 and 20128 through 20130, respectively) and proposed to address differences in these areas for those programs. In section XIII.D.8. of this proposed rule, we are also proposing 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 this proposed rule, we are proposing to rename the process as the extraordinary circumstances exceptions (ECE) policy and make conforming changes to 42 CFR 416.310(d).

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 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 are proposing 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 are inviting public comment on this proposal as discussed above.

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 OPSS/ASC final rule with comment period (78 FR 75141), the CY 2016 OPSS/ASC final rule with comment period (80 FR 70537), and 42 CFR 416.330 for the ASCQR Program's reconsideration policy. We are not proposing 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 OPSS/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

¹¹⁸In the CY 2015 OPSS/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.

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 OPPI/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 proposed rule.

In the CY 2013 OPPI/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 OPPI 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 OPPI/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 OPPI 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 OPPI/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 OPPI/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 OPPI/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.

We are not proposing any changes to these policies for CY 2018.

XV. Request for Information and Public Comments

A. Request for Information on CMS Flexibilities and Efficiencies

CMS is committed to transforming the health care delivery system—and the Medicare program—by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. We seek to reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. These are the reasons we are including this Request for Information in this proposed rule.

As we work to maintain flexibility and efficiency throughout the Medicare program, we would like to start a national conversation about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. We aim to increase quality of care, lower costs, improve program integrity, and make the health care

system more effective, simple, and accessible.

We would like to take this opportunity to invite the public to submit their ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those of Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences. Responses to this Request for Information could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers. Where practicable, data and specific examples would be helpful. If the proposals involve novel legal questions, analysis regarding CMS' authority is welcome for CMS' consideration. We are particularly interested in ideas for incentivizing organizations and the full range of relevant professionals and paraprofessionals to provide screening, assessment, and evidence-based treatment for individuals with opioid use disorder and other substance use disorders, including payment methodologies, care coordination, systems and services integration, use of paraprofessionals such as community paramedics, and other strategies. We are requesting commenters to provide clear and concise proposals that include data and specific examples that could be implemented within the law.

We note that this is a Request for Information only. Respondents are encouraged to provide complete but concise responses. This Request for Information is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This Request for Information does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this Request for Information and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this Request for Information; all costs associated with responding to this Request for

Information will be solely at the interested party's expense. We note that not responding to this Request for Information does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this Request for Information announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this Request for Information. CMS will not respond to comment submissions in response to this Request for Information in the CY 2018 OPPI/ASC final rule with comment period. Rather, CMS will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. CMS may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this Request for Information. Responses to this Request for Information are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this Request for Information may be used by the U.S. Government for program planning on a nonattribution basis. Respondents should not include any information that might be considered proprietary or confidential. This Request for Information should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may post on a Web site for public use the public comments received, or a summary of those public comments, in response to this Request for Information.

B. Eliminating Inappropriate Medicare Payment Differentials for Similar Services in the Inpatient and Outpatient Settings

In the past, CMS has requested public comment on potential payment policy options to address the issue of payment differentials between hospital services provided in the inpatient and outpatient settings. CMS has recognized that, even when particular hospital inpatient services and hospital outpatient services are similar, Medicare payment differentials may exist because different statutory provisions and different payment methodologies apply. CMS is committed to eliminating inappropriate Medicare payment differentials for similar services in the inpatient and

outpatient settings in order to execute our responsibility to taxpayers to prudently pay for high quality care. As MedPAC has previously noted, "The high profitability of one-day stays under the inpatient prospective payment system (IPPS) and the generally lower payment rates for similar care under the outpatient prospective payment system (OPPS) have heightened concern about the appropriateness of inpatient one-day stays" (Medicare and the Health Care Delivery System Report to Congress, June 2015). Furthermore, we are concerned that, to the extent Medicare payment differentials exist (and may be inappropriate), there is a corresponding effect on financial liability of patients.

Our most recent solicitation for public comments on these issues occurred in the CY 2016 OPPI/ASC final rule with comment period (80 FR 70549). Since that time, both hospitals and CMS have had the opportunity to gain experience under the various policy changes that have occurred with respect to short inpatient hospital stays. In this context, we believe it is an appropriate time to seek public comment again on transparent ways to identify and eliminate inappropriate payment differentials for similar services provided in the inpatient and outpatient settings.

C. Request for Information Regarding Physician-Owned Hospitals

We are seeking public comments on the appropriate role of physician-owned hospitals in the delivery system. We would like to explore whether physician-owned hospitals could play a more prominent role in the delivery system. In addition, we are seeking public comments on the impact of the current requirements of the physician self-referral law regarding physician-owned hospitals. In particular, we are interested in comments on the impact on Medicare beneficiaries.

XVI. Files Available to the Public via the Internet

The Addenda to the OPPI/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 proposed rule pertaining to proposed CY 2018 payments under the OPPI, 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-P" from the list of regulations. All OPPI Addenda to this proposed rule are contained in the zipped folder entitled "2018 OPPI

1678–P Addenda” at the bottom of the page. To view the Addenda to this proposed rule pertaining to the proposed 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–P” from the list of regulations. All ASC Addenda to this proposed rule are contained in the zipped folders entitled “Addendum AA, BB, DD1, DD2, and EE.”

XVII. 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 this proposed rule, we are soliciting 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 OP/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 proposed rule, we are proposing to remove six measures: (1) OP–21: Median Time to Pain Management for Long Bone Fracture beginning with the CY 2020 payment determination; (2) OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures beginning with the CY 2020 payment determination; (3) OP–1: Median Time to Fibrinolysis beginning with the CY 2021 payment determination; (4) OP–4: Aspirin at Arrival beginning with the CY 2021 payment determination; (5) OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional beginning with the CY 2021 payment determination; and (6) OP–25: Safe Surgery Checklist beginning with the CY 2021 payment determination. We expect these proposals would reduce the burden of reporting for the Hospital OQR Program, as discussed below. We note that we discuss only the changes in burden resulting from the provisions in this proposed rule.

In this proposed rule, we are proposing to publicly report OP–18c using data beginning with patient encounters during the third quarter of 2017. We are also proposing 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 proposed rule, beginning with the CY 2020 payment determination, we are proposing: (1) To codify at § 419.46(e) our previously finalized process for targeting hospitals for validation of chart-abstracted measures; (2) to formalize the educational review process and use it to correct incorrect validation results for chart-abstracted measures; (3) 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); (4) 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); and (5) to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy and make conforming changes to the CFR. We do not believe that these proposed changes would affect our

burden estimates, as further discussed below.

2. Proposed 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. In this proposed rule, we are proposing 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.¹¹⁹ 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.¹²⁰ Acting as an independent agency, the BLS provides objective information for not only the government, but also for the public.¹²¹ The BLS describes Medical Records and Health Information Technicians as those responsible for processing and maintaining health information data.¹²² 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 are proposing 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 \times 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 are inviting public comment on these proposals.

¹¹⁹ BLS Occupational Employment Statistics; May 2016. Retrieved from: <https://www.bls.gov/oes/current/oes292071.htm>.

¹²⁰ <http://www.bls.gov/bls/infhome.htm>.

¹²¹ <http://www.bls.gov/bls/infhome.htm>.

¹²² BLS Occupational Employment Statistics; May 2016. Retrieved from: <https://www.bls.gov/oes/current/oes292071.htm>.

3. Estimated Burden Due to 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 proposed rule, we are proposing 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). We recognize that delaying mandatory implementation of the survey-based measures will reduce the number of HOPDs administering the OAS CAHPS Survey in CY 2018 and future years. Implementation of the survey-based measures would have made survey administration mandatory for all eligible HOPDs participating in the program. Delaying implementation of the survey-based measures also delays the requirement that HOPDs must administer the survey to eligible patients and we therefore expect fewer HOPDs to administer the survey. Given the proposed delay in mandatory implementation of the OAS CAHPS Survey, there is a corresponding reduction in burden for HOPDs. 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. This PRA package assumes 4,006 HOPDs would administer the OAS CAHPS Survey. The estimated average burden per HOPD as captured in this PRA package is \$6,070 annually and includes patient/respondent burden, time for preparing patient records to send to a survey vendor, and contracting with a survey vendor. Consistent with the voluntary national implementation of the OAS CAHPS Survey that began in 2016, however, we anticipate that not all HOPDs will voluntarily administer the survey.¹²³ For this reason, we

¹²³ Currently, 1,124 HOPDs have selected a vendor to conduct the survey on their behalf as part of a national voluntary implementation of the OAS CAHPS Survey, for a total estimated burden of voluntary survey administration of \$6,822,680 (1,124 HOPDs × \$6,070 per HOPD). If the survey were to become part of the Hospital OQR Program as mandatory, we estimate approximately 3,228 HOPDs that meet eligibility requirements for the Hospital OQR Program would begin administering the survey and reporting data to CMS under OMB Control Number 0938–1240. We assume HOPDs voluntarily administering the survey will continue to do so even if implementation of the survey-based

anticipate that each HOPD participating in the Hospital OQR Program that chooses not to voluntarily administer the OAS CAHPS Survey under the voluntary national implementation in CY 2018 and future years would experience an anticipated burden reduction of approximately \$6,070 as a result of this proposal. However, as noted above, this burden reduction is included under OMB Control Number 0938–1240 and is not included in our burden estimates for the Hospital OQR Program.

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 proposed rule we are proposing 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 do not expect this proposal to affect burden.

5. Estimated Burden Due to Proposals for the CY 2020 Payment Determination and Subsequent Years

a. Burden Due to Proposed Measure Removals

In section XIII.B.4.c.(1) and (2) of this proposed rule, we are proposing, beginning with the CY 2020 payment determination, to remove one chart-abstracted measure (OP–21: Median Time to Pain Management for Long Bone Fracture) and one web-based measure (OP–26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures). In total, we expect these proposals would reduce burden by 152,680 hours and \$5.6 million for the

measures is delayed for the Hospital OQR Program; therefore, we anticipate that approximately 2,104 HOPDs (3,228 eligible HOPDs–1,124 HOPDs voluntarily reporting under the voluntary national implementation) that would have administered the survey as a mandatory requirement of the Hospital OQR Program will not do so for CY 2018 and future years if the survey-based measures are delayed. This results in an estimated aggregate burden reduction of \$12,771,280 (2,104 HOPDs × \$6,070 per HOPD) across all HOPDs meeting eligibility requirements for the Hospital OQR Program. As noted above, this burden reduction is included under OMB Control Number 0938–1240 and is not included in our burden estimates for the Hospital OQR Program.

CY 2020 payment determination. These estimates are described in detail below.

We calculated the burden reduction associated with the proposed removal of OP–21: Median Time to Pain Management for Long Bone Fracture by considering the time per case to report chart-abstracted measures, which are 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 proposed rule, we estimate that 3,300 Hospital Outpatient Departments (HOPDs) 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. Accordingly, we estimate a total burden reduction of 46.1 hours per HOPD due to the removal of one chart-abstracted measure (2.92 minutes per measure/60 minutes per hour × 1 measure × 947 cases per hospital). In total, across 3,300 HOPDs, we estimate a burden reduction of 152,130 hours (46.1 hours per hospital × 3,300 hospitals) and \$5,564,915 (152,130 total hours × \$36.58 per hour) for the CY 2020 payment determination due to the proposed removal of OP–21: Median Time to Pain Management for Long Bone Fracture.

We calculated the burden reduction associated with the proposed removal of 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 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 HOPDs report data under the Hospital OQR Program. Accordingly, for the CY 2020 payment determination, we estimate a total burden reduction of 550 hours across 3,300 HOPDs due to the removal of one web-based measure (10 minutes per measure/60 minutes per hour × 1 measure × 3,300 hospitals). We further estimate a cost reduction of \$20,119 due to this proposal (550 total hours × \$36.58 per hour).

In total, we expect these proposals would reduce burden by 152,680 hours (152,130 + 550) and \$5,585,034 (\$5,564,915 + \$20,119) 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 proposed rule, 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 influence 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 proposed rule, we are proposing 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 proposing 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 would be used to compute the hospital's final validation score at the end of the calendar year. Under this proposal, 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 would be used to correct a hospital's validation score. As stated in the CY 2014 OPPS/ASC final rule (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 would include, but would not be limited to, maintaining familiarity with the Hospital OQR Program requirements, which includes checking feedback reports to indicate a facility's current status or performance. The overall administrative burden, which we believe includes the educational review process, is estimated at 42 hours per hospital and has previously been calculated (78 FR 75171). This burden would not be changed by the proposal to use revised scores identified through an educational review to correct a hospital's validation score.

c. Burden Due to Proposed 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 proposed rule, we are proposing 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. While we expect this proposal to make it generally easier for hospitals to comply with the Hospital OQR Program requirements by extending the NOP deadline, we anticipate a negligible effect on the time and cost of completing the participation requirements. As a result, the proposal to revise the NOP submission deadline would not impact our burden estimates.

d. Burden Due to Proposal 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

In section XIII.D.1 of this proposed rule, we are proposing 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 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 influence burden.

e. Burden Due to Proposed 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 proposed rule, we discuss our intent to align the naming of this exception policy and 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 are not seeking any new or additional information in our ECE proposals, we believe the updates would have no effect on burden for hospitals.

6. Estimated Burden Due to Proposals for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.c.(3) through (6) of this proposed rule, we are proposing to remove four measures beginning with the CY 2021 payment determination: three chart-abstracted measures (OP-1: Median Time to Fibrinolysis, OP-4: Aspirin at Arrival, and OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional); and one web-based measure (OP-25: Safe Surgery Checklist Use). In total, we expect the removal of these measures would reduce burden by 304,810 hours and \$11.1 million for the CY 2021 payment determination, as described 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, as well as the number of cases per hospital and the number of participating hospitals. As previously stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582), we estimate that hospitals spend approximately 2.92 minutes per case per chart-abstracted measure and that 3,300 HOPDs report data under the Hospital OQR program. In addition, based on the most recently available data from CY 2015 reporting, we 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 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 as an underlying part of OP-2 even if the proposal to remove OP-1 is finalized as proposed. Accordingly, there is no change in burden associated with the proposed removal of this measure included in our calculations below.

We estimate a total burden reduction of 92.2 hours per HOPD due to the removal of OP-4: Aspirin at Arrival and OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional (2.92 minutes per measure/60 minutes per hour \times 2 measures \times 947 cases per hospital). In total, across 3,300 HOPDs we estimate a burden reduction of 304,260 hours (92.2 hours per hospital \times 3,300 hospitals) and \$11,129,831 (304,260 total hours \times \$36.58 per hour) for the CY 2021 payment determination due to the proposed removal of OP-4: Aspirin at Arrival and OP-20: Door to

Diagnostic Evaluation by a Qualified Medical Professional.

We calculated the burden reduction associated with the removal of OP–25: Safe Surgery Checklist Use by considering the time per measure to report web-based measures as well as the number of participating hospitals. As 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 HOPDs report data under the Hospital OQR program. Accordingly, for the CY 2021 payment determination, we estimate a total burden reduction of 550 hours across 3,300 HOPDs due to the removal of one web-based measure (10 minutes per measure/60 minutes per hour × 1 measure × 3,300 hospitals). We further estimate a cost reduction of \$20,119 due to this proposal (550 total hours × \$36.58 per hour).

In total, we expect these proposals would reduce burden by 304,810 hours (304,260 + 550) and \$11,149,950 (\$11,129,831 + \$20,119) for the CY 2021 payment determination for the Hospital OQR Program.

We are inviting public comment on the burden associated with these information collection requirements.

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 would result from the provisions in this proposed rule.

In section XIV.B.3.b. of this proposed rule, we are proposing, 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 proposed rule, we are proposing, 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 proposed rule, we are proposing, 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 proposals would reduce the overall burden of reporting data for the ASCQR Program, as discussed below.

In this proposed rule, we are also proposing: (1) To delay ASC–15a–e: OAS CAHPS survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection); (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; 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. As discussed below, we do not expect these proposals to influence our burden estimates.

2. Proposed 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 proposing to update our burden calculation methodology to standardize elements within our burden calculation. Specifically, we are proposing 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.¹²⁴ The BLS is the principal Federal agency responsible for measuring labor market activity, working conditions, and price changes

¹²⁴ <http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.

in the economy.¹²⁵ Acting as an independent agency, the BLS provides objective information for not only the government, but also for the public.¹²⁶ The BLS describes Medical Records and Health Information Technicians as those responsible for processing and maintaining health information data.¹²⁷ Therefore, we believe it is reasonable to assume that these individuals would 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.¹²⁸ 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 labor cost of \$36.58. Therefore, we are proposing 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 are inviting public comment on this proposal.

3. Estimated Burden of ASCQR Program Proposals Beginning With CY 2018

In section XIV.B.4. of this proposed rule we are proposing 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. We recognize that delaying mandatory implementation of the survey-based measures will reduce the number of ASCs administering the OAS CAHPS Survey in CY 2018 and future years. Implementation of the survey-based measures would have made survey administration mandatory for all eligible ASCs participating in the program. Delaying implementation of the survey-based measures also delays the requirement that ASCs must administer the survey to eligible patients and we therefore expect fewer ASCs to administer the survey. Given the proposed delay in mandatory implementation of the OAS CAHPS Survey, there is a corresponding reduction in burden for ASCs. As described in the CY 2017 OPPS/ASC final rule with comment period (81 FR

¹²⁵ <http://www.bls.gov/bls/infohome.htm>.

¹²⁶ <http://www.bls.gov/bls/infohome.htm>.

¹²⁷ BLS Occupational Employment Statistics; May 2016. Retrieved from: <https://www.bls.gov/oes/current/oes292071.htm>.

¹²⁸ <https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.

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. This PRA package assumes 5,357 ASCs, or roughly all ASCs paid under the ASC payment system, would administer the OAS CAHPS Survey. The estimated average burden per ASC as captured in this PRA package is \$6,070 annually and includes patient/respondent burden, time for preparing patient records to send to a survey vendor, and contracting with a survey vendor. Consistent with the voluntary national implementation of the OAS CAHPS Survey that began in 2016, however, we anticipate that not all ASCs will voluntarily administer the survey.¹²⁹ For this reason, we anticipate that each ASC participating in the ASCQR Program that chooses not to voluntarily administer the OAS CAHPS Survey under the voluntary national implementation in CY 2018 and future years would experience an anticipated burden reduction of approximately \$6,070 as a result of this proposal. However, as noted above, this burden reduction is included under OMB Control Number 0938–1240 and is not included in our burden estimates for the ASCQR Program.

In section XIV.D.3. of this proposed rule, we are proposing 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 proposal to increase the efficiency of data submission via the CMS online

¹²⁹ Currently, 719 ASCs have selected a vendor to conduct the survey on their behalf as part of a national voluntary implementation of the OAS CAHPS Survey, for a total estimated burden of voluntary survey administration of \$4,364,330 (719 ASCs × \$6,070 per ASC). If the survey were to become part of the ASCQR Program as mandatory, we estimate approximately 3,937 ASCs that meet eligibility requirements for the ASCQR Program would begin administering the survey and reporting data to CMS under OMB Control Number 0938–1240. We assume ASCs voluntarily administering the survey will continue to do so even if implementation of the survey-based measures is delayed for the ASCQR Program; therefore, we anticipate that approximately 3,218 ASCs (3,937 eligible ASCs—719 ASCs voluntarily reporting under the voluntary national implementation) that would have administered the survey as a mandatory requirement of the ASCQR Program will not do so for CY 2018 and future years if the survey-based measures are delayed. This results in an estimated aggregate burden reduction of \$19,533,260 (3,218 ASCs × \$6,070 per ASC) across all ASCs meeting eligibility requirements for the ASCQR Program. As noted above, this burden reduction is included under OMB Control Number 0938–1240 and is not included in our burden estimates for the ASCQR Program.

tool. However, the 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 proposed rule, we are proposing 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 are not seeking any new or additional information in our ECE proposals, we believe the updates would have no effect on burden for hospitals.

4. Estimated Burden of ASCQR Program Proposals for the CY 2019 Payment Determination

In section XIV.B.3.b. of this proposed rule, we are proposing, 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 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 would experience a reduction in burden associated with our proposals to remove ASC–6 and ASC–7 from the ASCQR Program measure set. In the CY 2014 OPPI/ASC final rule with comment period (78 FR 75173), we finalized our estimates that each participating ASC would 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 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 Proposals for the CY 2021 Payment Determination

In section XIV.B.6.a. of this proposed rule, we are proposing, beginning with the CY 2021 payment determination, to adopt one new measure collected via a CMS online data submission tool, ASC–16: Toxic Anterior Segment Syndrome.

We believe 3,937 ASCs would incur a burden associated with abstracting numerators, denominators, and exclusions for the proposed ASC–16 measure collected and reported via a CMS online data submission tool. In addition, we estimate that each ASC reporting data for this measure would report data on approximately one case per year, and would spend 15 minutes (0.25 hours) per case to collect and submit this data. Therefore, we estimate a total burden for all reporting ASCs with a single case per ASC of 984 hours (3,937 ASCs × 1 case per ASC × 0.25 hours per case) and \$36,004 (984 hours × \$36.58 per hour). The additional burden associated with these requirements is available for review and comment under OMB Control Number 0938–1270.

6. Estimated Burden of ASCQR Program Proposals for the CY 2022 Payment Determination

In section XIV.B.6.b. and c. of this this proposed rule, we are proposing, 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 would be any additional burden associated with these proposals.

We are inviting public comment on the burden associated with these information collection requirements.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention: CMS Desk Officer*, CMS-1678-P, *Fax: (202) 395-6974*; or, *Email: OIRA_submission@omb.eop.gov*.

XVIII. 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 proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XIX. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this proposed rule, 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 Contract with America Advancement Act of 1996 (Pub. L. 104-121) (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). This section of the proposed rule contains the impact and other economic analyses for the provisions that we are proposing 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 proposed rule has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104-121). Accordingly, this proposed rule 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 proposed rule. We are soliciting public comments on the regulatory impact analysis in this proposed rule, and we will address any public comments we receive in the final rule with comment period as appropriate.

2. Statement of Need

This proposed rule is necessary to make updates to the Medicare hospital OPSS rates. It is necessary to make proposed 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 OPSS 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 proposing to revise 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 December 31, 2016, and updated cost report information.

This proposed rule 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 OPSS 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 OPSS 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 Proposed OPSS and ASC Payment Provisions

We estimate that the total increase in Federal government expenditures under the OPSS for CY 2018, compared to CY 2017 due to the changes in this proposed rule, will be approximately \$897 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the OPSS expenditures for CY 2018 will be approximately \$5.7 billion

higher relative to expenditures in CY 2017. Because this proposed rule 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 38 displays the distributional impact of the proposed CY 2018 changes in OPSS payment to various groups of hospitals and for CMHCs.

We estimate that the proposed update to the conversion factor and other proposed adjustments (not including the effects of proposed outlier payments, the proposed pass-through estimates, and the proposed application of the frontier State wage adjustment for CY 2017) would increase total OPSS payments by 1.8 percent in CY 2018. The proposed changes to the APC relative payment weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase OPSS payments because these changes to the OPSS are budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system. We estimate that the proposed total change in payments between CY 2017 and CY 2018, considering all payments, proposed 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, would increase total estimated OPSS payments by 1.9 percent.

We estimate the proposed total increase (from proposed changes to the ASC provisions in this proposed rule 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 \$67 million. Because the provisions for the ASC payment system are part of a proposed rule that is economically significant as measured by the \$100 million threshold, we have prepared a regulatory impact analysis of the proposed changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of this proposed rule. Table 39 and 40 of this proposed rule display the redistributive impact of the proposed 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 proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's 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 proposed rule. We welcome any comments on the approach in estimating the number of entities that will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. We are seeking public comments on this assumption.

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 would take approximately 6.4 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is \$673 (6.4 hours x \$105.16). Therefore, we estimate that the total cost of reviewing this regulation is \$1,708,074 (\$673 x 2,538 reviewers).

5. Detailed Economic Analyses

a. Estimated Effects of OPSS Changes in This Proposed Rule

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed 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 proposed rule. 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-P" 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 proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 38 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 proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed 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.

We are soliciting public comment and information about the anticipated effects of the proposed changes included in this proposed rule on providers and our methodology for estimating them. Any public comments that we receive will be addressed in the applicable sections of the final rule with comment period that discuss the specific policies.

(2) Estimated Effects of Proposed OPSS Changes to Part B Drug Payment on 340B Eligible Hospitals Paid Under the OPSS

In section V.B.7. of this proposed rule, we discuss our proposal to reduce the payment for nonpass-through, separately payable drugs purchased by 340B-participating hospitals through the 340B drug pricing program. Specifically, we are proposing to pay for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through status and vaccines, at the average sales price (ASP) minus 22.5 percent instead of ASP+6 percent.

We recognize that it is difficult to determine precisely what the impact on Medicare spending would be because OPSS 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, we assumed that all applicable drugs purchased by hospitals eligible to participate in the 340B drug pricing program were purchased at a discounted price under the 340B program. We assumed that all governmental-owned, cancer, and children's hospitals, as well as those hospitals with a DSH percentage greater than 11.75 percent, sole community hospitals with a DSH percentage greater than 8 percent, and rural referral centers with a DSH percentage greater than 8 percent, all participated in the 340B program. We did not assume changes in the quantity of 340B purchased drugs provided (thereby affecting unit volume) or changes in the number of hospitals participating in the 340B program that may occur due to the proposed payment reduction.

While we acknowledge that there are some limitations in Medicare's ability to prospectively calculate a precise estimate for purposes of this proposed rule, we note that each hospital has the ability to calculate how this proposal would change its Medicare payments for separately payable drugs in CY 2018. Specifically, each hospital that is not participating in the 340B program would know that its Medicare payments for drugs would be unaffected by this proposal; 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, an affected hospital is able to estimate the difference in payment that it would receive if Medicare were to pay ASP minus 22.5 percent instead of ASP+6 percent for 340B drugs.

Using CY 2016 claims data for the applicable separately payable drugs and biologicals, excluding those on pass-through status and vaccines, billed by hospitals eligible to participate in the 340B program, we estimate that OPSS payments for separately payable drugs, including beneficiary copayment, could decrease by as much as \$900 million under this proposal. Because we are proposing to implement this payment reduction in a budget neutral manner within the OPSS, the reduced payments for separately payable drugs purchased through the 340B drug pricing program would increase payment rates (and by extension, beneficiary coinsurance

liabilities) for other items and services paid under the OPSS by an offsetting aggregate amount.

Because data on drugs that are purchased with a 340B discount are not publicly available, it is not 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, if we finalize this proposal in the CY 2018 OPSS/ASC final rule with comment period, 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 OPSS, similar to the adjustment we made for clinical diagnostic laboratory test packaging policy in the CY 2017 OPSS/ASC final rule with comment period (81 FR 79592).

We project that reducing payment for 340B drugs to ASP minus 22.5 percent would increase non-drug OPSS payment rates by approximately 1.4 percent in CY 2018. We note that the proposed payment rates and estimated impacts included in this proposed rule do not reflect the effects of this proposal. We remind 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 are seeking public comment on our estimate and are 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 OPSS were acquired under the 340B program.

In addition, we are soliciting 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 OPSS, or under Part B generally, in CY 2018, rather than simply increasing the conversion factor. In particular, we are seeking 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 are seeking public comment on whether the redistribution of savings associated with this proposal would result in

unnecessary increases in the volume of covered services paid under the OPSS that should be adjusted in accordance with section 1833(t)(2)(F) of the Act.

(3) Estimated Effects of Proposed OPSS Changes on Hospitals

Table 38 below shows the estimated impact of this proposed rule 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 38, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPSS and are a different provider type from hospitals. In CY 2018, we are proposing to pay CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs), and we are proposing to pay hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the proposed total payments made under the OPSS 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 proposed rule. 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 proposed IPPS market basket percentage increase for FY 2018 is 2.9 percent (82 FR 19931). Section 1833(t)(3)(F)(i) of the Act reduces that 2.9 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.4 percentage point for FY 2018 (which is also the proposed MFP adjustment for FY 2018 in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19931 through 19932)), 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 proposed OPD fee

schedule increase factor of 1.75 percent. We are using the proposed OPD fee schedule increase factor of 1.75 percent in the calculation of the CY 2018 OPSS 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 38.

To illustrate the impact of the proposed 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 38 shows the estimated redistribution of the proposed 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 proposed APC reconfiguration and recalibration changes between CY 2017 and CY 2018 (Column 2); the proposed wage indexes and the provider adjustments (Column 3); the combined impact of all of the proposed changes described in the preceding columns plus the proposed 1.75 percent OPD fee schedule increase factor update to the conversion factor; and the estimated impact taking into account all proposed payments for CY 2018 relative to all payments for CY 2017, including the impact of proposed changes in estimated outlier payments, the frontier State wage adjustment, and proposed changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are proposing to maintain the current adjustment percentage for CY 2018. Because the proposed updates to the conversion factor (including the proposed update of the OPD fee schedule increase factor), the estimated cost of the proposed rural adjustment, and the estimated cost of proposed 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 would change), and the impact of the proposed wage index changes on the hospital. However, proposed total payments made under this system and the extent to which this proposed rule would 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 are seeking 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 issue is discussed in section X.F. of this proposed rule. 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, if any aspect of this discussion would be finalized, it would not result in a net costs or savings to the program. Accordingly, section X.F. of this proposed rule is not included in the impact table in the regulatory impact analysis.

Overall, we estimate that the proposed rates for CY 2018 would increase Medicare OPPS payments by an estimated 1.9 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 a proposed estimated 2.0 percent increase in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 38 shows the total number of facilities (3,828), 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 proposed 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 proposed

CY 2018 payment and entities that are not paid under the OPSS. 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 proposed rule. At this time, we are unable to calculate a disproportionate share hospital (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 OPSS hospitals (3,714), 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 48 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Proposed Changes

Column 2 shows the estimated effect of proposed APC recalibration. Column 2 also reflects any proposed changes in multiple procedure discount patterns or conditional packaging that occur as a result of the proposed changes in the relative magnitude of payment weights. As a result of proposed APC recalibration, we estimate that urban hospitals would experience no change, with the impact ranging from an increase of 0.2 percent to a decrease of 0.1 percent, depending on the number of beds. Rural hospitals would experience no change, with the impact ranging from an increase of 0.1 percent to a decrease of 0.1 percent, depending on the number of beds. Major teaching hospitals would experience a decrease of 0.1 percent overall.

Column 3: Proposed Wage Indexes and the Effect of the Proposed Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the proposed APC recalibration; the proposed updates for the wage indexes with the proposed FY 2018 IPPS post-reclassification wage indexes; the proposed rural adjustment; and the proposed cancer hospital

payment adjustment. We modeled the independent effect of the proposed budget neutrality adjustments and the proposed 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 proposed updated wage indexes, including the application of proposed budget neutrality for the proposed rural floor policy on a nationwide basis. This column excludes the effects of the proposed frontier State wage index adjustment, which is not budget neutral and is included in Column 5. We did not model a budget neutrality adjustment for the proposed rural adjustment for SCHs because we are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2018, as described in section II.E. of this proposed rule.

We modeled the independent effect of proposing to update the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the proposed CY 2018 scaled weights and a CY 2017 conversion factor that included a budget neutrality adjustment for the effect of the proposed changes to the wage indexes between CY 2017 and CY 2018. The proposed FY 2018 wage policy results in modest redistributions.

There is a slight increase of less than 0.1 in Column 3 for the proposed 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 0.89, compared to the CY 2017 OPSS/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 proposed cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we are proposing to apply in section II.F. of this proposed rule.

Column 4: All Proposed Budget Neutrality Changes Combined With the Proposed Market Basket Update

Column 4 demonstrates the combined impact of all of the proposed changes previously described and the proposed update to the conversion factor of 1.75 percent. Overall, these proposed changes would increase payments to

urban hospitals by 1.8 percent and to rural hospitals by 1.8 percent. Most classes of hospitals would receive an increase in line with the proposed 1.8 percent overall increase after the proposed update is applied to the proposed budget neutrality adjustments.

Column 5: All Proposed Changes for CY 2018

Column 5 depicts the full impact of the proposed CY 2018 policies on each hospital group by including the effect of all of the proposed changes for CY 2018 and comparing them to all estimated payments in CY 2017. Column 5 shows the combined budget neutral effects of Columns 2 and 3; the proposed OPD fee schedule increase; the impact of the proposed frontier State wage index adjustment; the impact of estimated proposed OPPS outlier payments as discussed in section II.G. of this proposed rule; the proposed 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 proposed rule); 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 30 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 proposed changes for CY

2018 would increase payments to all facilities by 1.9 percent for CY 2018. We modeled the independent effect of all of the proposed changes in Column 5 using the final relative payment weights for CY 2017 and the proposed relative payment weights for CY 2018. We used the final conversion factor for CY 2017 of \$75.001 and the proposed CY 2018 conversion factor of \$76.483 discussed in section II.B. of this proposed rule.

Column 5 contains simulated outlier payments for each year. We used the proposed 1-year charge inflation factor used in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20173) of 5.1 percent (1.05074) to increase individual costs on the CY 2016 claims, and we used the most recent overall CCR in the April 2017 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2017. Using the CY 2016 claims and a proposed 5.1 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 would be approximately 1.04 percent of total payments. The estimated current outlier payments of 1.04 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 10.4 percent (1.104055) and the CCRs in the April 2017 OPSF, with an adjustment of 0.979187, to reflect relative changes in cost and charge inflation between CY 2016 and CY 2018, to model the proposed CY 2018 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of \$4,325. The charge inflation and CCR

inflation factors are discussed in detail in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20173).

Overall, we estimate that facilities would experience an increase of 1.9 percent under this proposed rule in CY 2018 relative to total spending in CY 2017. This projected increase (shown in Column 5) of Table 38 reflects the proposed 1.75 percent OPD fee schedule increase factor, plus 0.22 percent for the proposed change in the pass-through estimate between CY 2017 and CY 2018, minus a decrease of 0.04 percent for the difference in estimated outlier payments between CY 2017 (1.04 percent) and CY 2018 (proposed 1.0 percent). We estimate that the combined effect of all of the proposed changes for CY 2018 would increase payments to urban hospitals by 2.0 percent. Overall, we estimate that rural hospitals would experience a 2.0 percent increase as a result of the combined effects of all of the proposed changes for CY 2018.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects of all changes would include an increase of 1.7 percent for major teaching hospitals and an increase of 2.1 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 2.0 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 1.9 percent, proprietary hospitals would experience an increase of 2.3 percent, and governmental hospitals would experience an increase of 1.9 percent.

TABLE 38—ESTIMATED IMPACT OF THE PROPOSED CY 2018 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	APC recalibration (all proposed changes)	Proposed new wage index and provider adjustments	All proposed budget neutral changes (combined cols 2,3) with market basket update	All proposed changes
	(1)	(2)	(3)	(4)	(5)
ALL FACILITIES*	3,828	0.0	0.0	1.8	1.9
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,714	0.0	0.0	1.8	2.0
URBAN HOSPITALS	2,902	0.0	0.0	1.8	2.0
LARGE URBAN (GT 1 MILL.)	1,577	0.1	-0.1	1.8	1.9
OTHER URBAN (LE 1 MILL.)	1,325	0.0	0.1	1.9	2.0
RURAL HOSPITALS	812	0.0	0.0	1.8	2.0
SOLE COMMUNITY	371	0.0	0.2	1.9	2.1
OTHER RURAL	441	0.0	-0.2	1.6	1.8
BEDS (URBAN)					
0-99 BEDS	988	0.2	0.0	1.9	2.1
100-199 BEDS	841	0.2	0.0	1.9	2.1
200-299 BEDS	465	0.1	0.0	1.8	2.0
300-499 BEDS	395	0.0	0.0	1.8	2.0

TABLE 38—ESTIMATED IMPACT OF THE PROPOSED CY 2018 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	APC recalibration (all proposed changes)	Proposed new wage index and provider adjustments	All proposed budget neutral changes (combined cols 2,3) with market basket update	All proposed changes
	(1)	(2)	(3)	(4)	(5)
500 + BEDS	213	-0.1	0.1	1.7	1.8
BEDS (RURAL)					
0-49 BEDS	337	0.0	-0.2	1.5	1.7
50-100 BEDS	289	0.1	-0.2	1.6	1.9
101-149 BEDS	101	0.0	0.1	1.9	2.1
150-199 BEDS	46	0.0	0.1	1.9	2.1
200 + BEDS	39	-0.1	0.3	2.0	2.1
REGION (URBAN)					
NEW ENGLAND	144	0.2	0.1	2.1	2.2
MIDDLE ATLANTIC	343	0.1	-0.3	1.5	1.7
SOUTH ATLANTIC	461	0.1	0.2	2.0	2.2
EAST NORTH CENT.	464	0.0	0.1	1.8	1.9
EAST SOUTH CENT.	172	-0.2	-0.1	1.5	1.7
WEST NORTH CENT.	185	-0.2	0.5	2.0	2.2
WEST SOUTH CENT.	501	0.1	0.2	2.0	2.2
MOUNTAIN	202	0.2	-0.9	1.0	1.3
PACIFIC	382	0.1	0.0	1.8	2.0
PUERTO RICO	48	-0.3	0.3	1.7	1.9
REGION (RURAL)					
NEW ENGLAND	21	0.0	1.6	3.4	3.5
MIDDLE ATLANTIC	53	0.1	-0.1	1.8	2.0
SOUTH ATLANTIC	123	0.0	-0.7	1.0	1.2
EAST NORTH CENT.	121	0.0	-0.1	1.7	1.9
EAST SOUTH CENT.	155	-0.1	-0.1	1.5	1.7
WEST NORTH CENT.	96	0.0	0.2	2.0	2.3
WEST SOUTH CENT.	162	0.1	0.3	2.1	2.3
MOUNTAIN	57	0.0	-0.3	1.5	1.9
PACIFIC	24	0.1	0.1	1.9	2.1
TEACHING STATUS					
NON-TEACHING	2,624	0.1	0.1	2.0	2.1
MINOR	746	0.0	0.0	1.8	2.0
MAJOR	344	-0.1	-0.1	1.6	1.7
DSH PATIENT PERCENT					
0	11	0.0	-0.1	1.7	1.8
GT 0-0.10	277	0.2	0.0	2.0	2.1
0.10-0.16	269	0.2	-0.1	1.8	2.0
0.16-0.23	577	0.1	0.2	2.1	2.2
0.23-0.35	1,121	0.0	0.0	1.8	1.9
GE 0.35	920	0.0	-0.1	1.7	1.8
DSH NOT AVAILABLE **	539	-1.5	0.1	0.3	0.5
URBAN TEACHING/DSH					
TEACHING & DSH	982	0.0	-0.1	1.7	1.8
NO TEACHING/DSH	1,394	0.2	0.2	2.1	2.2
NO TEACHING/NO DSH	11	0.0	-0.1	1.7	1.8
DSH NOT AVAILABLE **	515	-1.5	0.1	0.4	0.5
TYPE OF OWNERSHIP					
VOLUNTARY	1,970	0.0	0.0	1.8	1.9
PROPRIETARY	1,253	0.2	0.1	2.1	2.3
GOVERNMENT	491	-0.1	0.1	1.8	1.9
CMHCs	48	-0.1	0.2	1.9	2.1

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed 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 proposed FY 2018 hospital inpatient wage index, including all hold harmless policies and transitional wages. The proposed rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 1.0003 because the target payment-to-cost ratio changes from 0.91 in CY 2017 to 0.90 in CY 2018 and is further reduced by one percentage point to 0.89 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 all budget neutrality adjustments and the addition of the proposed 1.75 percent OPD fee schedule update factor (2.9 percent reduced by 0.4 percentage points for the proposed productivity adjustment and further reduced by 0.75 percentage point as required by law).

Column (5) 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 3,828 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 Proposed OPPS Changes on CMHCs

The last line of Table 38 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 proposed rule. 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 would experience an overall 2.1 percent increase in payments from CY 2017 (shown in Column 5). We note that this includes the trimming methodology described in section VIII.B. of this proposed rule.

Column 3 shows that the estimated impact of adopting the proposed FY 2018 wage index values would result in a small increase of 0.2 percent to CMHCs. Column 4 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2018 and the proposed FY 2018 wage index updates, would result in an estimated increase of 1.9 percent. Column 5 shows that adding the proposed changes in outlier and pass-through payments would result in a total 2.1 percent increase in payment for CMHCs. This reflects all proposed changes to CMHCs for CY 2018.

(5) Estimated Effect of Proposed 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 proposed rule. 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 would 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 proposed rule.

(6) Estimated Effects of Proposed 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 proposed rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs would be affected by the proposed changes in this proposed rule.

(7) Estimated Effects of Proposed OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of \$897 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 XIX.A.4.a.(4) of this proposed rule.

(8) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing and the reasons for our selected alternatives are discussed throughout this proposed rule.

- 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 nonphysician practitioners.

Therefore, we are proposing to extend 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 proposed rule 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 proposed rule 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 would 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, 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 final rule with comment period.

b. Estimated Effects of Proposed 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 proposed rule, we are proposing to set the CY 2018 ASC relative payment weights by scaling the proposed CY 2018 OPPS relative payment weights by the ASC scalar of 0.9002. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 39 and 40 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 proposed CY 2018 ASC conversion factor by adjusting the CY 2017 ASC conversion factor by 1.0004 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2017 and CY 2018 and by applying the proposed CY 2018 MFP-adjusted CPI-U update factor of 1.9 percent (projected CPI-U update of 2.3 percent minus a proposed projected productivity adjustment of 0.4 percentage point). The proposed CY 2018 ASC conversion factor is \$45,876.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed 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 proposed 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 Proposed 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 proposed 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 proposed 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 39 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 40 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 39 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 39.

- 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 Proposed 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 proposed updates to ASC payment rates for CY 2018 compared to CY 2017.

As seen in Table 39, 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 2-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 3-percent increase in aggregate payment amounts for digestive system procedures, 2-percent increase in aggregate payment amounts for nervous system procedures, a 4-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 39 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 would decrease by 43 percent for CY 2018.

TABLE 39.—ESTIMATED IMPACT OF THE PROPOSED 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 (1)	Estimated CY 2017 ASC payments (in millions) (2)	Estimated Proposed CY 2018 percent change (3)
Total	\$4,460	2%
Eye and ocular adnexa	1,688	2
Digestive system	852	3
Nervous system	849	2
Musculoskeletal system	530	3
Genitourinary system	186	1
Integumentary system	141	5
Ancillary items and services	55	-43

Table 40 below shows the estimated impact of the proposed 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 proposed payment for CY 2018 based on the proposed update.

TABLE 40—ESTIMATED IMPACT OF THE PROPOSED CY 2018 UPDATE TO THE ADC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code (1)	Short descriptor (2)	Estimated CY 2017 ASC payment (in millions) (3)	Estimated CY 2018 percent change (4)
66984	Cataract surg w/iol 1 stage	\$1,172	%2
45380	Colonoscopy and biopsy	216	3
43239	Egd biopsy single/multiple	178	3
63685	Insrt/redo spine n generator	151	-4
45385	Colonoscopy w/lesion removal	146	3
63650	Implant neuroelectrodes	118	3
64483	Inj foramen epidural l/s	99	3
66982	Cataract surgery complex	94	2
0191T	Insert ant segment drain int	86	1
66821	After cataract laser surgery	69	1
64635	Destroy lumb/sac facet jnt	68	2
29827	Arthroscop rotator cuff repr	61	3
64493	Inj paravert f jnt l/s 1 lev	60	3
64590	Insrt/redo pn/gastr stimul	50	-1
G0105	Colorectal scrn; hi risk ind	45	3
62323	Njx interlaminar lmr/sc	45	4
45378	Diagnostic colonoscopy	44	3
G0121	Colon ca scrn not hi rsk ind	42	3
64721	Carpal tunnel surgery	34	2
15823	Revision of upper eyelid	32	6
29881	Knee arthroscopy/surgery	30	3
29880	Knee arthroscopy/surgery	26	3
67042	Vit for macular hole	25	2
28285	Repair of hammertoe	24	3
52000	Cystoscopy	23	-1
26055	Incise finger tendon sheath	23	2
43235	Egd diagnostic brush wash	23	2
64561	Implant neuroelectrodes	22	6
50590	Fragmenting of kidney stone	21	2
67904	Repair eyelid defect	20	1

(3) Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2018 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures that we are proposing to add to the ASC list of covered surgical procedures and for those that we are proposing to designate 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 OPSS, 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 OPSS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPSS 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 OPSS 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 proposing to designate 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 proposing and the reasons for our selected alternatives are discussed throughout this proposed rule.

c. Accounting Statements and Tables

As required by OMB Circular A-4 (available on the Office of Management and Budget Web site at: [https://](https://www.whitehouse.gov/omb/circulars_a004_a-4#a)

www.whitehouse.gov/omb/circulars_a004_a-4#a), we have prepared two accounting statements to illustrate the impacts of this proposed rule. The first accounting statement, Table 41 below, illustrates the classification of expenditures for the proposed CY 2018 estimated hospital OPSS incurred benefit impacts associated with the proposed CY 2018 OPD fee schedule increase, based on the 2017 Trustee's Report. The second accounting statement, Table 42 below, illustrates the classification of expenditures associated with the proposed 1.9 percent CY 2018 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the 2017 Trustee's Report. Lastly, the tables classify most estimated impacts as transfers.

TABLE 41—ACCOUNTING STATEMENT: PROPOSED CY 2018 ESTIMATED HOSPITAL OPSS TRANSFERS FROM CY 2017 TO CY 2018 ASSOCIATED WITH THE PROPOSED CY 2018 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers.	\$897 million.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPSS.
Total	\$897 million.

TABLE 42—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2017 TO CY 2018 AS A RESULT OF THE PROPOSED CY 2018 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers.	\$67 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Total	\$67 million.

d. Effects of Requirements for the Hospital OQR Program

(1) Background

We refer readers to the CY 2017 OPSS/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.(1) and (2) of this proposed rule, we are proposing 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 beginning with the CY 2020 payment determination and for subsequent years. In section XIII.B.4.c.(3) through (6) of this proposed rule, we are proposing 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 and for subsequent years. We expect these proposals to reduce the burden of reporting for the Hospital OQR Program, as discussed below.

In this proposed rule, we are proposing to publicly report OP-18c using data from patient encounters beginning with the third quarter of 2017. We are also proposing 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) and until further notice in future rulemaking. In addition, in this proposed rule, beginning with the CY 2020 payment determination, we are proposing: (1) To codify at § 419.46(e) our previously finalized process for targeting hospitals for validation of chart-abstracted measures; (2) to formalize the educational review process and use it to correct incorrect validation results for chart-abstracted measures; (3) 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); (4) 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); and (5) to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy and make conforming changes to the CFR. We do not believe that these proposed changes would affect our burden estimates, as further discussed below.

(2) Estimated Burden Due to 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 proposed rule, we are proposing 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). 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 proposal to delay reporting for these measures does not influence our current burden estimates.

(3) 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 proposed rule, we are proposing 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 do not expect this proposal to affect burden.

(4) Estimated Impact of Proposals for the CY 2020 Payment Determination and Subsequent Years

(a) Impact of Proposed Measure Removals

In section XIII.B.4.c.(1) and (2) of this proposed rule, we are proposing to remove one chart-abstracted measure (OP-21: Median Time to Pain Management for Long Bone Fracture) and one web-based measure (OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures) for the CY 2020 payment determination and subsequent years. As described in detail in section XVII.B. of this proposed rule, we expect these proposals to reduce burden by 152,680 hours and \$5.6 million for the CY 2020 payment determination for the Hospital OQR Program.

(b) Impact of Updates to Previously Finalized Validation Procedures and the Educational Review Process

In section XIII.D.7.a. of this proposed rule, 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 influence burden, as 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 proposed rule, we are proposing 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. Additionally, we are proposing to update the process to specify that if the results of an educational review indicate that we incorrectly scored a hospital, the corrected score would be used to compute the hospital's final validation score whether or not the hospital submits a reconsideration request. Under this proposal, 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 would be used to correct a hospital's validation score. As 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 would include, but would not be limited to, maintaining familiarity with

the Hospital OQR Program requirements, which includes checking feedback reports to indicate a facility's current status or performance. The overall administrative burden, which we believe includes the educational review process, is estimated at 42 hours per hospital (78 FR 75171) and would not be changed by the proposal to use revised scores identified through an educational review to correct a hospital's validation score.

(c) Impact of Proposed Updates to NOP Submission Deadlines

In section XIII.C.2. of this proposed rule, we are proposing 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. While we expect this proposal to make it generally easier for hospitals to comply with the Hospital OQR Program requirements by extending the NOP deadline, we anticipate a negligible effect on the time and cost of completing the participation requirements. As a result, the proposal to revise the NOP submission deadlines does not impact our burden estimates.

(d) Burden Due to Proposal 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

In section XIII.D.1. of this proposed rule, we are proposing 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 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 influence burden.

(e) Impact of Proposed Updates to the Previously Finalized ECE Policy

In section XIII.D.8. of this proposed rule, we discuss our intent to align the naming of this exception policy and update 42 CFR 419.46(d) to reflect our current ECE policies. We are also clarifying the timing of CMS' response to ECE requests. Because we are not seeking any new or additional information in our ECE proposals, we believe the updates will have no effect on burden for hospitals.

(5) Estimated Impact of Proposals for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.c. of this proposed rule, we are proposing to remove three chart-abstracted measures (OP-1: Median Time to Fibrinolysis, OP-4: Aspirin at Arrival, and OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional) and one web-based measure (OP-25: Safe Surgery Checklist Use) for the CY 2021 payment determination and subsequent years. As described in detail in section XVII.B. of this proposed rule, we expect the removal of one web-based measure and three chart-abstracted measures to reduce burden by \$11.1 million and 304,810 hours for the CY 2021 payment determination.

We refer readers to section XVII.B. of this proposed rule (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 proposed rule, 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 OPSS/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 this proposed rule, we are also proposing: (1) To delay ASC-15a-e: OAS CAHPS survey-based measures beginning with the CY 2020 payment determination (CY 2018 data collection); (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; 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. As discussed below, we do not expect these proposals to influence our burden estimates.

2. Estimated Burden of ASCQR Program Proposals Beginning With CY 2018

As described in section XIV.B.4. of this proposed rule, we are proposing to delay 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 (CY 2018 data collection). As described in the CY 2017 OPSS/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 OPSS/ASC final rule with comment period (81 FR 79864). Similarly, our proposal to delay reporting on these measures does not affect our current burden estimates.

For CY 2018, we are making two additional proposals. First, in section XIV.D.3.b. of this proposed rule, we are proposing 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 proposed rule, 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 neither of these proposals changes the reporting requirements of the ASCQR Program nor 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 ASCQR Program Proposals for the CY 2019 Payment Determination

In section XIV.B.3.b. of this proposed rule, we are proposing to remove one claims-based measure (ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing¹³⁰) and two measures collected via a CMS online data submission tool

¹³⁰ As discussed in section XVII.C.4. of this proposed rule, 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 proposal to remove the ASC-5 measure from the ASCQR Program measure set beginning with the CY 2019 payment determination.

(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 XVII.C.4. of this proposed rule, we estimate the proposals to remove ASC-6 and ASC-7 from the ASCQR Program measure set would 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 are not proposing 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 would cause any additional ASCs to fail to meet the ASCQR Program requirements. (We refer readers to section XIV.B.5. of this proposed rule for a list of these measures.) Therefore, we do not believe that these proposals would 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 Proposals for the CY 2021 Payment Determination

For the CY 2021 payment determination and subsequent years, we are making one new proposal. In section XIV.B.6.a. of this proposed rule, we are proposing to adopt one measure collected via a CMS online data submission tool, ASC-16: Toxic Anterior Segment Syndrome. As discussed in section XXI.C.5. of this proposed rule, we estimate a data collection and submission burden of approximately 0.25 hours per ASC for reporting data for the proposed ASC-16 measure. This results in a total estimated burden of 984 hours (3,937 ASCs × 1 case per ASC × 0.25 hours per case) and \$36,004 (984 hours × \$36.58 per hour) for the proposed ASC-16 measure across all ASCs.

5. Estimated Burden of ASCQR Program Proposals for the CY 2022 Payment Determination

In sections XIV.B.6.b. and c. of this proposed rule, we are proposing to add two new measures collected via claims to the ASCQR program measure set for the CY 2022 payment determination: (1) ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and (2) ASC-18: Hospital Visits after Urology Ambulatory

Surgical Center Procedures. As discussed in sections XIV.B.6.b. and c. of this proposed rule, data used to assess performance under these measures is collected via Part A and Part B Medicare administrative claims and Medicare enrollment data and therefore does not require facilities to report any additional data. Because these measures do not require facilities to submit any additional data, we do not believe there is any additional burden associated with these proposals.

We refer readers to the information collection requirements in section XVII.C. of this proposed rule for a detailed discussion of the financial and hourly burden of the ASCQR Program's current and proposed requirements.

We are inviting public comment on the burden associated with these proposals.

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 proposed rule would increase payments to small rural hospitals by less than 2 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 proposed rule 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. It has been determined that this proposed rule is a transfer rule that does not impose more than *de minimis* costs as described above and thus is not a regulatory action for the purposes of Executive Order 13771.

E. Conclusion

The changes we are proposing to make in this proposed rule would 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 would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2018. Table 38 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 1.9 percent increase in payments for all services paid under the OPPS in CY 2018, after considering all of the proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, proposed wage index changes, including the proposed frontier State wage index adjustment, proposed estimated payment for outliers, and proposed changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2018.

The proposed updates to the ASC payment system for CY 2018 would 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 39 demonstrates the estimated distributional impact among ASC surgical specialties of the proposed MFP-adjusted CPI-U update factor of 1.9 percent for CY 2018.

XX. 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 proposed rule 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 38 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 1.9 percent under this proposed rule. 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 proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would 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 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 proposing to amend 42 CFR chapter IV as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

■ 1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. 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

■ 3. 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, 1395(t), and 1395hh).

■ 4. 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.

* * * * *

■ 5. Section 419.46 is amended by—

■ a. Amending paragraph (a)(1) by removing the phrase “Web site” and adding in its place the term “website”;

■ b. Revising paragraph (a)(3);

■ c. Amending paragraphs (b) and (c)(2) by removing the phrase “Web site” and adding in its place the term “website”;

■ d. Revising paragraphs (c)(3)(i) and (ii) and (d);

■ e. Adding paragraph (e)(3); and

■ f. Amending paragraphs (f)(1) and (g)(2) by removing the phrase “Web site” and adding in its place the term “website” 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.

(a) * * *

(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). For Hospital OQR Program purposes, hospitals that share the same CCN are required to complete a single online participation form. Once a hospital has submitted a participation form, it is considered to be an active Hospital OQR Program participant until such time as it submits a withdrawal form to CMS or no longer has an effective Medicare provider agreement. Hospitals must submit the online participation form at any time prior to registering on the QualityNet Web site.

* * * * *

(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.

* * * * *

■ 6. 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: June 28, 2017.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: June 30, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

[FR Doc. 2017-14883 Filed 7-13-17; 4:15 pm]

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Part III

Environmental Protection Agency

40 CFR Part 702

Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act; Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act; Guidance To Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act; Notice of Availability; Final Rules and Notice

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 702

[EPA-HQ-OPPT-2016-0654; FRL-9964-38]

RIN 2070-AK20

Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: As required under section 6(b)(4) of the Toxic Substances Control Act (TSCA), EPA is issuing a rule that establishes a process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. This process incorporates the science requirements of the amended statute, including best available science and weight of the scientific evidence. Risk evaluation is the second step, after Prioritization, in a new process of existing chemical substance review and management established under recent amendments to TSCA. This rule identifies the steps of a risk evaluation process including: scope, hazard assessment, exposure assessment, risk characterization, and finally a risk determination. This process will be used for the first ten chemical substances undergoing evaluation from the 2014 update of the TSCA Work Plan for Chemical Assessments (to the maximum extent practicable). Chemical substances designated as High-Priority Substances during the prioritization process and those chemical substances for which EPA has initiated a risk evaluation in response to a manufacturer request, will always be subject to this process. The final rule also includes the required “form and criteria” applicable to such manufacturer requests.

DATES: This final rule is effective September 18, 2017.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0654, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington,

DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Susanna W. Blair, Immediate Office, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-4321; email address: blair.susanna@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

EPA is primarily establishing requirements on the Agency. However, this rule also includes the process and criteria that manufacturers (including importers) must follow when they request an Agency-conducted risk evaluation on a particular chemical substance. This action may, therefore, be of interest to entities that are manufacturing or importing, or may manufacture or import a chemical substance regulated under TSCA (e.g., entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. What action is the Agency taking?

EPA is establishing, by rule, the process by which the Agency will conduct risk evaluations on chemical substances under TSCA. The rule identifies the necessary components of a risk evaluation, including a scope (including a conceptual model and an analysis plan), a hazard assessment, an exposure assessment, a risk characterization, and a risk determination. The rule also establishes the process by which manufacturers would request an Agency-conducted risk evaluation, and the criteria by which the EPA will evaluate such requests. This rule also incorporates the

statutory science requirements, including best available science and weight of the scientific evidence.

C. What is the Agency's authority for taking this action?

EPA is issuing this rule pursuant to the authority in TSCA section 6(b)(4), as amended (15 U.S.C. 2605(b)(4)). See also the discussion in Units II.A. and B.

D. What are the estimated incremental impacts of this action?

The incremental impacts of this action are the result of the process and requirements that manufacturers (including importers) must perform if they elect to submit a chemical substance for a risk evaluation. EPA has estimated the potential burden and costs associated with the proposed requirements for submitting a request for an Agency-conducted risk evaluation on a particular chemical substance which is available in the docket, is discussed in Unit V. and is briefly summarized here. (Ref. 1).

The total estimated annual burden is 419.2 hours and \$282,861, which is based on an estimated per request burden of 83.8 hours.

In addition, EPA's evaluation of the potential costs associated with this action is discussed in Unit V. Since this rule focuses on the activities that a manufacturer must perform, the estimated incremental costs are expected to be *de minimis*.

II. Background

A. Statutory Requirements for Risk Evaluation

TSCA section 6(b)(4) requires EPA to establish, by rule, a process to conduct risk evaluations. Specifically, EPA is directed to use this process to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use.” 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that direct which chemical substances must undergo evaluation, the development of criteria for manufacturer-requested evaluations, the minimum components of an Agency risk evaluation, and the timelines for public comment and completion of the risk evaluation. The law also requires

that EPA operate in a manner that is consistent with the best available science and make decisions based on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i).

1. *Chemical substances to undergo risk evaluation.* TSCA section 6(b) identifies the chemical substances that are subject to this process; these are: (1) The ten chemical substances the Agency was required to identify from the 2014 update to the TSCA Work Plan within the first 180 calendar days after the signing of TSCA); (2) the chemical substances determined to be High-Priority Substances through the prioritization process published elsewhere in this **Federal Register**; and (3) chemicals selected in response to a manufacturer request that meets the criteria established by this rule. 15 U.S.C. 2605(b)(4)(C). Assuming EPA receives a sufficient number of compliant requests, the statute specifies that EPA shall ensure that the number of manufacturer-requested evaluations is not less than 25 percent and not more than 50 percent of the number of the ongoing “High Priority” risk evaluations. 15 U.S.C 2605(b)(4)(E). Since the number of manufacturer-requested evaluations is expressed as a percentage of the number of High-Priority Substance evaluations, not as a percentage of the total, the number of manufacturer-requested evaluations will likely comprise between 1/5 and 1/3 of the number of total ongoing evaluations, assuming a sufficient number of compliant requests are received. Any manufacturer requested risk evaluations for chemical substances on the 2014 update of the TSCA Work Plan (Ref. 2) will be granted at the discretion of the Administrator, and are exempt from the percentage limitations.

2. *Manufacturer-requested risk evaluations.* TSCA section 6(b)(4)(C) directs EPA to establish the “form and manner” and “criteria” that govern manufacturer requests that EPA conduct a risk evaluation on a substance that they manufacture. EPA has broad discretion to establish these criteria, but relatively less discretion over whether to grant requests that comply with EPA’s criteria. EPA must grant any request if it determines that it complies with EPA’s criteria, until the statutory minimum of 25 percent has been met. Assuming EPA receives requests in excess of this threshold, EPA interprets this provision to grant EPA discretion to determine whether to grant further requests, up to the maximum 50 percent level. In such circumstances, EPA is directed to give preference to manufacturer requests for which EPA determines that restrictions imposed by

one or more states have the potential to significantly impact interstate commerce, or health or the environment. 15 U.S.C. 2605(b)(4)(E)(iii).

3. *Components of a risk evaluation.* The statute identifies the minimum components EPA must include in all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation that EPA expects to conduct, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C 2605(b)(4)(D). The statute further provides that the scope of the risk evaluation must be published no later than six months after the initiation of the risk evaluation. Id.

Each risk evaluation must also: (1) Integrate and assess available information on hazards and exposure for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposure. 15 U.S.C. 2605(b)(4)(F)(i), and (iii)–(v). The risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(ii).

4. *Science requirements.* TSCA section 26 requires that, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, EPA must use scientific standards and base those decisions on the best available science and on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). TSCA does not however explicitly define either of these terms. Section 26(h) lists factors for the Agency to consider, as applicable, in employing best available science. These are: (1) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information; (2) the extent to which the information is relevant for the Administrator’s use in making a decision about a chemical substance or mixture; (3) the degree of clarity and completeness with which the data, assumptions, methods, quality

assurance, and analyses employed to generate the information are documented; (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models. As statutory requirements, they apply to EPA’s decisions under TSCA sections 4, 5, and 6.

5. *Timeframe.* TSCA requires that the risk evaluation process last no longer than three years, with a possible additional six-month extension. 15 U.S.C. 2605(b)(4)(G).

6. *Opportunities for public participation.* The statute requires that the Agency allow for no less than a 30-day public comment period on the draft risk evaluation, prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4)(H).

7. *Metals and metal compounds.* When evaluating metals or metal compounds, EPA must use the March 2007 Framework for Metals Risk Assessment of the Office of the Science Advisor (Ref. 3) or a successor document that addresses metals risk assessment and is peer-reviewed by the Science Advisory Board.

8. *Non-vertebrate testing.* Although not an explicit section 6 requirement, TSCA imposes new requirements on EPA regarding the reduction of vertebrate testing. Amendments to TSCA section 4 require EPA to “. . . reduce and replace, to the extent practicable, [. . .] the use of vertebrate animals in the testing of chemical substances . . .” and to develop a strategic plan to promote such alternative test methods. 15 U.S.C. 2603(h). Under the risk evaluation process, EPA may require development of new information relating to a chemical substance. Prior to developing this information EPA must first take into account reasonably available existing information, and additionally, must encourage and facilitate the use of test methods that reduce or replace the use of vertebrate animals, group chemicals into categories to reduce testing, and encourage the formation of industry consortia to jointly conduct testing and other data gathering to avoid unnecessary duplication of tests.

B. Overview of Final Rule

This final rule incorporates all the elements required by statute, as discussed in Unit II.A., some additional criteria the Agency plans to include and

consider, clarifications for greater transparency, and additional procedural steps to ensure effective and transparent implementation. In response to public comments on the proposal, EPA is, among other things: (1) Adding direct references in the final rule to acknowledge the Agency's commitment to implementing the best available science and weight of the scientific evidence provisions in TSCA, (2) codifying the Agency's commitment to interagency collaboration, (3) allowing manufacturers to limit their requests for EPA-conducted risk evaluations to one or more specified conditions of use, and (4) allowing for risk determinations to be made on individual conditions of use or categories of conditions of use at any time once the Final Scope is published.

EPA intends that the provisions of this rule be severable. In the event that any individual provision or part of this rule is invalidated, EPA intends that this would not render the entire rule invalid, and that any individual provisions that can continue to operate will be left in place.

III. Discussion of Final Rule and Response to Comments

A. Policy Objectives

The risk evaluation process under TSCA will provide the basis for the EPA's determination as to whether a chemical substance presents an unreasonable risk of injury to health or the environment. The overall objective of this action is to codify the process by which the Agency evaluates risks from chemical substances under TSCA section 6. In this rule, the Agency details those components of TSCA risk evaluation and key factors that EPA deems are necessary to consider in each risk evaluation to ensure that the public has a full understanding of how risk evaluations will be conducted and to provide predictability in how they will be conducted. However, EPA is not establishing highly detailed provisions that will address every eventuality or possible consideration that might arise. Due to the rapid advancement of the science of risk evaluation and the science and technology that inform risk evaluation, this rule seeks to balance the need for the risk evaluation procedures to be transparent, without unduly restricting the specific science that will be used to conduct the evaluations, allowing the Agency flexibility to adapt and keep current with changing science as it conducts TSCA evaluations into the future.

B. Scope of Evaluations

TSCA requires risk evaluations to determine whether or not a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, with conditions of use being defined as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. 2602(4).

In the proposed rule, EPA explained that it interpreted TSCA to require that risk evaluations encompass all manufacture, processing, distribution in commerce, use, and disposal activities that constitute the conditions of use within the meaning of TSCA section 3. EPA further proposed that the conditions of use would need to encompass all known, intended, and reasonably foreseen activities associated with the subject chemical substance. EPA also noted, however, that a use or other activity constitutes a condition of use under the definition only if EPA determines that it does, and that EPA has authority to exercise judgment in making its determination of whether a condition of use is known, intended, or reasonably foreseen.

This was one of the issues on which EPA received the most comments. Comments covered a number of considerations regarding conditions of use: How the Agency will define "the conditions of use", how the Agency will scope conditions of use (e.g., are there conditions of use which will not be included in the Scope of the risk evaluation for one reason or another), and finally how the Agency will treat the conditions of use identified in the scope, in the final risk determination. EPA discusses the first two considerations in this unit; the third consideration will be discussed in the risk determination Unit III.G.1.e.

In defining conditions of use, many commenters raised concern about EPA's interpretation that "the conditions of use" must include "all conditions of use." Concerns were raised in this regard was specifically about the ability of EPA to meet the statutory risk evaluation deadlines if all intended, known and reasonably foreseen activities must be considered conditions of use, and that attempting to identify every activity relating to the chemical substance was unnecessary and impractical. Concerns were also raised about ensuring that EPA can act promptly to address any unreasonable risks identified for particular conditions of use. Commenters who agreed with

the proposed interpretation of "all conditions of use" stated that the law in a number of locations signals the intent that EPA evaluate all activities associated with the chemical. The identified locations include the section on Final Agency Action which states that decisions will be on a "chemical substance" without mention of condition of use, indicating that EPA must consider all conditions of use (15 U.S.C. 2605(i)), and the requirement to account for the "likely duration, intensity, frequency, and number of exposures under the conditions, where relevant" (15 U.S.C. 2605(b)(4)(F)(iv)), which refers to the consideration of whether a combination of activities involving the chemical substance presents a risk, and therefore EPA must look at the full spectrum of the activities associated with a chemical (all intended, known, or reasonably foreseen manufacturing, processing, distribution, use and disposal).

As EPA acknowledged in the proposal, different interpretations of the statute are possible. Given the strength and variety of the concerns presented in the comments, EPA has reevaluated its proposal. Accordingly, EPA went back to the direction on risk evaluation provided in section 6(b) of the statute and legislative history, and developed an approach to the term, "the conditions of use" that is firmly grounded in the law, while accounting for the various policy considerations necessary for effective implementation of section 6. EPA's final approach is informed in part by the legislative history of the amended TSCA, which explicitly states that the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical, in order to ensure that the Agency's focus is on the conditions of use that raise the greatest potential for risk. See, June 7, 2016 Cong Rec, S3519-S3520.

In sum, EPA's overall objective of this rule is to ensure that it is able to focus on conducting a timely, relevant, high-quality, and scientifically credible evaluation of a chemical substance as a whole, and that it always includes an evaluation of the conditions of use that raise greatest potential for risk. EPA wants also to ensure that the Agency can effectively assess, and where necessary, regulate chemical substances, within the statutory deadlines. These same principles will also serve to guide EPA's implementation of the procedures.

To begin, EPA will identify the "circumstances" that constitute the "conditions of use" for each chemical substance on a case-by-case basis. TSCA

defines a chemical's "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. 2602(4). While EPA interprets this as largely a factual determination—*i.e.*, EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion. As EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk. In that regard, EPA will be guided by its best understanding, informed by legislative text and history, of the circumstances of manufacture, processing, distribution in commerce, use and disposal Congress intended EPA to consider in risk evaluations.

For most chemical substances EPA expects to make this determination primarily during the prioritization of a chemical substances. For chemicals that are the subject of a manufacturer request (which are not subject to prioritization), EPA intends to make this determination as part of the process for determining whether the request satisfies EPA's criteria, as discussed in greater detail in Unit III.G.

Although EPA intends this to primarily be a case-by-case determination, as discussed in greater detail in Unit III.B.1, based on legislative history, statutory structure and other evidence of Congressional intent, EPA has identified certain activities that may generally not be considered to be conditions of use. As EPA gains experience in conducting risk evaluations, EPA may determine that other activities do not constitute conditions of use, based on the same type of analysis of Congressional intent. Second, in developing the scope of the risk evaluation, TSCA section 6(b)(4)(D) requires EPA to identify "the conditions of use that the Agency expects to consider in a risk evaluation," suggesting that EPA is not required to consider all conditions of use. Consequently, EPA may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. For example, EPA may,

on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "*de minimis*" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks. EPA elaborates further on this step in Unit III.B.2.

EPA intends to identify any conditions of use excluded during these first and second steps in the draft scope, along with the basis for EPA's preliminary determination, to provide the public with an opportunity to comment on the exclusions. The final scope, which specifies the conditions of use that EPA expects to consider in the risk evaluation, will also identify whether particular conditions of use have been excluded as a result of this process, along with the Agency's rationale.

Finally, consistent with its original proposal, EPA may conduct its risk evaluations in stages. While the proposal only addressed the situation in which EPA determined that risk mitigation was necessary to address an unreasonable risk from a chemical substance under certain conditions of use, EPA has extended the logic in the final rule to apply whenever EPA has sufficient information to support a determination as to whether a chemical substance presents an unreasonable risk under particular conditions of use. Thus, at any point after EPA has issued its final scope document, in cases where EPA has sufficient information to determine whether or not the chemical substance presents an unreasonable risk under particular conditions of use, the Agency may issue an early determination for that subset of conditions of use, while EPA continues to evaluate the remaining conditions of use. All early determinations would be portions of the final, complete risk evaluation and would therefore be made using the procedures applicable to TSCA risk evaluations established in this rule. This would include the requirement that EPA publish a draft risk evaluation for no less than a 60-day public comment period, and the regulatory requirement for peer review. This may result in separate peer reviews for the separate determinations.

In the interest of efficiency, EPA envisions that, in general, it would attempt to identify the subset of conditions of use that are candidates for an early determination as part of the

draft scope document. In such cases, EPA may publish its draft risk evaluation for public comment along with the final Scope document. Depending on the information received during the comment period, EPA would either determine that it needed to continue to evaluate those conditions of use, or proceed to issue final determinations for those conditions of use.

1. *Exclusions from the Definition of Conditions of Use.* As noted, the statute grants EPA the discretion to determine the circumstances that are appropriately considered to be the chemical's "conditions of use." In exercising that discretion, for example, EPA would not generally consider that a single unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's "conditions of use." As a further example, although the definition could be read literally to include all intentional misuses (*e.g.*, inhalant abuse), as a "known" or "reasonably foreseen" activity in some circumstances, EPA does not generally intend to include such activities in either a chemical substance's prioritization or risk evaluation. EPA's judgment is supported by the legislative history, and public comment suggesting that "the term 'conditions of use' is not intended to include 'intentional misuse' of chemicals." See, for example Senate Report 114–67, page 7. Without these exclusions, the concept of "conditions of use" would likely result in no meaningful limitation on EPA risk evaluations, and risk evaluations could present unmanageable challenges—an outcome that EPA does not expect Congress intended.

Similarly, the statute is ambiguous as to whether the conditions of use identified by EPA should include the circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution, which EPA will refer to as "legacy uses." The statute is also ambiguous as to disposals from such uses (*e.g.*, the future disposal of insulation that contains a chemical substance that is no longer manufactured, processed, or distributed for use in insulation), which EPA will call "associated disposal," and disposals that have already occurred (*e.g.*, a chemical substance currently in a landfill or in groundwater), which EPA will call "legacy disposal." No statutory text expressly addresses these issues. The absence of express statutory

text on legacy use, associated disposal, and legacy disposal, as well as the plain language in “conditions of use” charging EPA to determine the circumstances appropriately considered to be the “conditions of use,” leads the Agency to resolve the statutory ambiguity by considering all the tools of statutory interpretation (e.g., reliance on legislative history, and general maxims of statutory construction).

EPA interprets the mandates under section 6(a)–(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of “conditions of use” in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation, where the manufacture, processing, or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. EPA believes the statute is better interpreted to focus on the prospective flow of the chemical substance. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses.

Overall, EPA has determined that the statutory text better supports a prospective interpretation. Section 3 defines the “conditions of use” as “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” (emphasis added). The “to be” phrasing suggests that the term is focused prospectively. Moreover, throughout the legislative history, there are a number of references to TSCA as a statute for the regulation of chemicals “in commerce,” suggesting the intent to focus on current activities

associated with chemicals rather than legacy issues. In addition, EPA notes that section 6(a) of TSCA does not authorize EPA to directly regulate non-commercial use, meaning that EPA would not have an effective tool to address risks found to arise from uses in consumer settings if there were no ongoing commercial manufacture, processing or distribution.

EPA’s interpretation finds support in the general presumption against construing a statute (or implementing regulation) to be retroactive or have retrospective effect. While Congress can make a law retroactive, absent clear intent from Congress, courts will not hold a statute to be retroactive, or uphold an agency regulation that seeks to have such an effect. *Republic of Iraq v. Beatty*, 556 U.S. 848 at 862 (2009) (citing to *Landgraf v. Usi Film Products*, 511 U.S. 244, 267–68 (1994)). See also, *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) (citing several sources). This general presumption also extends to statutes that affect “vested rights and past transactions,” which have been considered to be retroactive (or “retrospective”) in nature. E.g., *Landgraf*, 511 U.S. at 268–69, 296 (quotation marks and citations omitted) (citing several other Supreme Court cases using alternate formulations of this principle).

Finally, even if these activities were not excluded from the definition of conditions of use, EPA generally expects that it would exercise its discretion under section 6(b)(4)(D) to exclude them from the scope of risk evaluations, as discussed in section B.2., below.

2. *Conditions of use that may be excluded from the Scope of the risk evaluation.* In exercising its discretion under section 6(b)(4)(D), EPA believes it is important for the Agency to have the discretion to make reasonable, technically sound scoping decisions in light of the overall objective of determining whether chemical substances in commerce present an unreasonable risk. For example, EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping. In some instances, it may be most appropriate from a technical and policy perspective to evaluate the potential risks arising from a chemical impurity within the scope of the risk evaluations for the impurity itself. In other cases, it may be more appropriate to evaluate such risks within the scope of the risk evaluation for the separate chemical substances that bear the impurity. (EPA

has previously taken an analogous approach, in requiring chemical testing of certain chemical substances under 40 CFR part 766, based on the potential for the chemical substance to be manufactured in such a manner as to be contaminated with dioxins.) In still other cases, EPA may choose not to include a particular impurity within the Scope of any risk evaluation, where EPA has a basis to foresee that the risk from the presence of the impurity would be ‘*de minimis*’ or otherwise insignificant. Finally, as stated, EPA received a number of comments offering ideas regarding conditions of use that should not be considered in a risk evaluation, for example, on the ground that certain uses are not “reasonably foreseen.” Some of the many uses that commenters asked to be excluded from a risk evaluation include: Uses where other agencies hold jurisdiction, misuse, illegal use, speculative future conditions of use, uses that are inconsistent with labeling requirements or PPE requirements, chemicals used in articles or replacement parts, uses that are inconsistent with manufacturers’ instructions, accidental conditions of use of a chemical, or uses where residuals from an industrial process are completely destroyed. In connection with these suggestions, several of these commenters also requested that EPA clearly define precisely how the Agency will determine whether a condition of use is “known or reasonably foreseen.”

At this stage of EPA’s implementation, EPA believes that it would be premature to definitively exclude a priori specific conditions of use from risk evaluation. For the same reason, EPA believes that it would be premature to establish a specific test or restrictive definition to determine whether a condition of use is “reasonably foreseen.” The Agency is committed to exercising its discretion to determine the conditions of use in a reasonable manner and will not base this determination upon hypotheticals or conjecture. The identification of “reasonably foreseen” conditions of use will necessarily be a case by case determination, and will be highly fact-specific. Sources of facts to support such determinations may include known activities associated with similar chemicals, knowledge of a chemical’s properties that may allow it to replace a function currently being performed by non-chemical means, or information on research and development activities applying a chemical substance to a particular new use. It is reasonable to foresee a condition of use, for example, where facts suggest the activity is not

only possible but, over time under proper conditions, probable.

As EPA gains experience in conducting risk evaluations, it will likely develop additional scoping principles, consistent with the discussion in this preamble. EPA has issued Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluation Under the Toxic Substances Control Act and section 26(l) requires EPA to reevaluate guidance every 5 years. This document may be the appropriate venue for EPA to provide additional transparency regarding conditions of use included/excluded as a part of scoping as the Agency becomes better versed in this process.

C. General Provisions

The general provisions of the final rule outline the purpose, scope, applicability and enforcement of this rule.

D. Definitions

TSCA defines a number of key terms necessary for interpretation of the new law, and the statutory definitions apply to this rule. To increase clarity and transparency, EPA has included a number of additional definitions in the rule. In the proposed rule, EPA asked for comments specifically on whether to codify definitions of terms including “best available science,” “weight-of-the-scientific evidence,” “sufficiency of information,” “unreasonable risk,” and “reasonably available information,” among others. EPA identified the sources of possible definitions, and in some instances provided extensive discussion of its current interpretation of the terms. EPA also encouraged commenters to suggest alternative definitions the Agency should consider for codification in this rule.

EPA received a number of comments on this subject; in general, many comments acknowledged that there are numerous ways these phrases can be defined and ultimately implemented. Many also acknowledged that the science is changing and the Agency must maintain flexibility to implement advancing and novel science. Some commenters agreed with EPA’s proposed conclusion that not defining the terms allows for flexibility to change as the science changes and that strict definitions may impede TSCA implementation. A number of comments discussed the legislative history behind these terms, specifically the fact that previous versions of the statute did include some of these definitions and that they were removed in the final version. Other commenters argued that

since these terms are not defined in the statute and there is no requirement in the statute to define them by rule, there was no Congressional intent to codify definition of these terms in this rule. Additionally, it was reasoned that any codified definitions would apply not only to TSCA section 6 actions and rules, but also to TSCA sections 4 and 5, and potentially other applications outside of TSCA. They argued this makes it much more difficult to develop and implement universally appropriate definitions.

A significant number of commenters did encourage EPA to define, or at the very least, to provide additional principles and concepts that will be applied to implement these terms, arguing that this will add transparency and better articulate how EPA will implement the scientific criteria of the statute. Some commenters stated that the definitions of these terms have not changed with changing science, only the data sets used to inform the definitions. Other commenters, who agreed these terms do have a number of different meanings believed it was therefore more important to define them in this rule so the public knew which definition would be applied. Commenters also stated these terms are the “cornerstones” of risk evaluations under TSCA, and definitions were necessary to alleviate potential confusion in implementation of these requirements. Many commenters who believed it is necessary for EPA to define these terms did include proposed definitions and/or descriptions.

EPA has chosen to only define terms in this final rule that appear in the statute, including best available science, reasonably available information, and weight of the scientific evidence, among others. EPA agrees with many of the public comments that the definitions of these terms in the final rule will instill confidence, increase transparency, and provide the public with assurance that EPA will adhere to the requirements of the statute. Based on review of the public comments received, EPA has also revised the proposed definitions to increase their clarity, while also adding additional discussion in the preamble.

EPA will first discuss definitions included in the regulation (in the order they appear in the regulation), and then will discuss additional terms that have not been codified, but are important components of the risk evaluation process.

1. *Aggregate exposure.* TSCA requires EPA, as a part of the risk evaluation, to document whether the Agency has considered aggregate exposure, and the basis for that decision. 15 U.S.C.

2605(b)(4)(F)(ii). This term is not statutorily defined; however, EPA has defined aggregate exposure to be consistent with current Agency policies and practices. “Aggregate exposure” means the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (Ref.4). This is consistent with the proposed rule and consistent with agency policy.

2. *Best available science.* Section 26(h) of amended TSCA requires that “in carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science.” As stated, many commenters encouraged EPA to codify a definition of the “best available science.” In response to these comments, EPA determined that ‘best available science’ is an integral component of section 6 risk evaluations, and has incorporated a definition of ‘best available science’ into the regulatory text. The first part of the definition originates from the Safe Drinking Water Act (SDWA) (42 U.S.C. 300f *et seq.*) and is also included in the EPA’s Information Quality Guidance (Ref. 5). The SDWA definition was cited by a number of commenters, and EPA agrees this definition, already in use at the Agency, is appropriate. The second part of the definition is taken directly from TSCA section 26(h), which identifies mandatory approaches to fulfilling the science standards under TSCA. By basing its definition of ‘best available science’ on these two sources, EPA believes that the Agency is remaining consistent with the current approach already used Agency-wide, while also acknowledging the specific standards under TSCA.

The final rule defines “best available science” as science that is reliable and unbiased. This involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). Additionally, EPA will consider as applicable:—

—The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are

- reasonable for and consistent with the intended use of the information;
- The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
- The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
- The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and;
- The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.

3. *Conditions of use* as defined in 15 U.S.C. 2602(4), means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. This definition was not included in the proposed rule, but has been added for clarity. Additional discussion of conditions of use can be found in Unit B.

4. *Pathways*. Pathways of exposure refers to the mode through which one is exposed to a chemical substance, including but not limited to: Food, water, soil, and air (Ref. 4). This definition is consistent with EPA's policies and practices, and did not change from the proposed rule.

5. *Potentially exposed or susceptible subpopulations*. TSCA requires EPA to evaluate risk to "potentially exposed or susceptible subpopulation[s]" identified as relevant to the risk evaluation by the Administrator, under the conditions of use. 15 U.S.C. 2605(b)(4)(A). TSCA defines this as "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." 15 U.S.C. 2602(12). EPA proposed a definition to clarify how the Agency interprets this provision. Specifically, EPA proposed to substitute the phrase "including but is not limited to" for the statutory phrase "such as," to clarify that the statutory list of potential subpopulations is not

exclusive. EPA also proposed to include additional examples of subpopulations that have been previously considered. In response to comments, the final rule simply codifies the statutory definition without revision.

EPA received a number of comments regarding this definition. Some stated that EPA was correct in expanding and clarifying the definition in the proposed rule, while others stated that EPA should use the statutory definition. Many comments that supported the proposed definition also identified other subpopulations that EPA should include. EPA's view of the interpretation of the statutory definition has not changed since proposal—EPA interprets the statutory definition broadly and believes it does not prevent EPA from including any subpopulation that may be at greater risk due to greater susceptibility or exposure, or from identifying additional subpopulations other than those listed in the statute, where warranted. The definition in the final rule uses the statutory definition because, due to EPA's broad interpretation, EPA does not think that it limits any consideration of a particular subpopulation. Also, regarding EPA's proposed inclusion of more examples than those provided by the statute (*e.g.*, life-stage, age, gender, geography), and in reading public comments, which listed numerous other important subpopulations EPA should consider, it was clear that it would be difficult for the Agency to list all the potential subpopulations that the Agency might have reason to include in a risk evaluation. Codification of the statutory definition does not limit the subpopulations that may be evaluated and ensures there is no misconception that a partial list was intended as a deliberate exclusion of other subpopulations.

6. *Reasonably available information*. TSCA section 26(k) (15 U.S.C. 2625(k)) states that in carrying out risk evaluations, EPA shall consider information that is "reasonably available," but the statute does not further define this phrase. EPA is defining "reasonably available information" to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. However, there is a preference for reasonably available information that is consistent with the required quality standards. Information that meets the terms of the preceding sentence is reasonably available information whether or not it is claimed as confidential business

information. This definition is slightly revised from the proposed definition.

First, EPA deleted the word "existing" to address concerns that this would prevent the Agency from considering (or requiring) data generated in response to EPA data gathering, including testing, authorities. Several commenters encouraged EPA to take full advantage of its new information gathering authorities and not limit the basis of its decisions to "existing" information. EPA agrees that it makes sense to view information that can be obtained through testing as "reasonably available" in some instances—especially information that can be obtained through short-term testing, where it can be obtained within the relevant statutory deadlines and the information would be of sufficient value to merit the testing. As discussed in a related rulemaking on prioritization under TSCA, EPA will seek to generally ensure that sufficient information to complete a risk evaluation exists and is available to the Agency prior to initiating the evaluation. The proposed definition was drafted to reflect that intention. However, EPA also recognizes that there may be circumstances where additional information may need to be developed within the time frames of the risk evaluation process. This may include information developed through the use of novel and advancing chemical assessment procedures, measures, methods, protocols, methodologies, or models (*e.g.*, high-throughput chemical assessment techniques). While EPA disagrees that its original definition would have precluded the generation of additional data, to avoid any confusion, EPA has modified the definition to clarify the point. Note that EPA will, as appropriate, also require longer-term testing, and at times will need to do so to address data gaps. However, EPA does not think information that could be generated through such testing should be viewed as "reasonably available". EPA will tailor its information gathering efforts as appropriate.

Second, EPA added a statement regarding CBI to clarify to the public that EPA does consider CBI under section 14 of TSCA to be "reasonably available," and will utilize it in risk evaluations where relevant.

7. *Routes*. The final rule defines routes of exposure to mean the particular manner which a chemical substance may contact the body, including absorption via ingestion, inhalation, or dermally (Ref. 4). This definition is consistent with EPA's policies and practices and with the proposed definition.

8. *Sentinel exposure.* The final rule defines sentinel exposure to mean the exposure to a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures. As mentioned in the proposed rule, this term previously had not been defined by the Agency. In light of the comments received, many of which requested revisions to the proposed definition, EPA believes it most appropriate to revise the definition in the proposed rule. The majority of comments explained that the concept of sentinel exposures is narrower than the definition EPA had proposed (“the exposure of greatest significance, which may be the plausible maximum exposure”); rather, as one comment explained, sentinel exposures are employed to represent broad categories of use so that the assessor does not have to go into each specific subcategory of use. While sentinel exposures do represent upper-bound exposures—which is part of what EPA proposed—it is the upper bound within those broad use categories. Under this approach, because the exposures are expected to be much greater than other sources or pathways, if the margin of exposure is at an acceptable level, there is no need to specifically evaluate the other individual exposure pathways in the category. A number of commenters also suggested that EPA adopt the approach to ‘sentinel exposure’ used by the European Union’s (EU) European Chemicals Agency (ECHA) Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) program and Health Canada (Ref. 6 and 7). The final definition, although not the same as the one used by ECHA and Health Canada, more closely tracks their approach. Specifically, the definition seeks to address situations including but not limited to: (1) The same chemical substance is added to a number of related products, and EPA is evaluating exposure to the chemical substance in these related products under the same exposure scenario (e.g., adults who could use these products for the same task). If EPA identifies and evaluates the product associated with the upper bound of exposure from use of these products, then EPA could reach risk conclusions for the chemical substance in the entire category of these products, because the range of potential exposures is no greater than the magnitude of the exposure to the chemical substance in the upper-bound product. (2) A number of different workers are exposed to the same chemical substance. If EPA

identifies or evaluates the worker whose exposure represents the upper bound of exposure, EPA would have confidence that the other workers exposed would be less exposed than the worker with the upper bound or “sentinel” exposure.

In the proposed rule, EPA used the phrase “maximum exposure” in defining sentinel exposure. This phrase has been changed to “upper bound of exposure” in the final rule. This change was a result of public comment that suggested that the term “maximum” could indicate that EPA intended to use only the 99.99th percentile exposure. This was not EPA’s intent, and so EPA has substituted the phrase “upper-bound of exposure,” which is consistent with EPA’s existing practice, and allows EPA the flexibility to consider the available data and its quality in determining the appropriate exposure scenario (e.g., sentinel exposure scenarios).

9. *Uncertainty and variability.* The statute requires EPA to consider “the extent to which the variability and uncertainty . . . are evaluated and characterized.” 15 U.S.C. 2625(h). EPA proposed definitions for both “variability” and “uncertainty” based on existing Agency guidance (Framework for Human Health Risk Assessment). The final rule adopts the proposed definition of “uncertainty” with minor modification. EPA added the phrase “the real world” to exactly reflect the definition in Agency guidance. In the final rule, uncertainty means the imperfect knowledge of the real world or lack of precise knowledge of the real world either for specific values of interest or in the description of the system (Ref. 8). The final rule adopts the proposed definition of “variability” without modification. The regulation thus states: “Variability” means the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population (Ref. 8). Both definitions are consistent with EPA’s policies and practices.

10. *Weight of the scientific evidence.* The Agency is required by the statute to use a weight of scientific evidence approach in a risk evaluation and the Agency is codifying a definition of this term in this final rule. In responding to public comment, EPA notes that inclusion of the definition will provide the much requested transparency to the public regarding the processes for how the Agency reviews scientific information used in risk evaluations without stifling scientific advances. In the preamble to the proposed rule, EPA provided an extensive discussion of how the weight of the scientific

evidence is applied by EPA and the National Toxicology Program of the National Institutes of Environmental Health. This discussion formed part of the basis for the definition EPA is promulgating in this final rule.

The application of weight of the scientific evidence has generated much discussion in the scientific community, and EPA agrees with the National Academies who stated “because scientific evidence use in weight of the scientific evidence (WoSE) evaluations varies greatly among chemical and other hazardous agents in type, quantity and quality, it is not possible to describe the WoSE evaluation in other than relative general terms” (Ref. 9). Application of weight of the scientific evidence analysis is an integrative and interpretive process. It is more than a simply tallying of the number of positive and negative studies. It also is applicable to both human health and ecological risk evaluations.

There are certain principles of weight of the scientific evidence that are universal, including foundational considerations, such as objectivity and transparency, and the general process. This process starts with assembling the relevant information, evaluating the information for quality and relevance, and synthesizing and integrating the different lines of evidence to support conclusions (Ref. 10). Given these overarching and inclusive principles, EPA does not think that providing a general definition restricts flexibility or scientific advancement. For the purposes of this rule the definition EPA is adopting states: “Weight of the scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.” This definition was suggested by a few public commenters, it is consistent with practices under TSCA before it was amended, and was generally outlined in the lengthy discussion in the proposal. The bulk of the definition, aside from the phrase “applied manner suited to the nature of the evidence or decision” clarification, is taken directly from TSCA’s legislative history. See Congressional Record at S3519, June 7, 2016. The additional phrase was added to be consistent with the concept (also discussed in the proposal) that the components of its risk evaluations will

be “fit-for-purpose.” As explained in the proposed rule at 82 FR 7566, all conditions of use will not warrant the same level of evaluation, and EPA expects that it may, in some cases, be able to reach conclusions without extensive or quantitative evaluations of risk. The addition of this phrase to the definition is intended to clarify that different weight of the scientific evidence review methods may be appropriate for different information, types of evaluations, or decisions. Specifically, fit-for-purpose means that while EPA will always apply the principles contained in the definition, the depth or extent of the analysis will be commensurate with the nature and significance of the decision.

11. *Systematic Review.* EPA requested comment on the need for regulatory text prescribing a specific systematic review approach for hazard identification, including the appropriateness of elements that might be included or concerns about codifying an approach. Commenters both supported and opposed the inclusion of systematic review in the rule text. Those opposing the codification of systematic review argued that EPA should retain flexibility and the ability to change the process as improved methods for systematic review are developed. Some commenters did encourage a description of the intended approach in the preamble, but suggested that EPA reserve the specific process for guidance. Those in support of codifying a description of systematic review in the rule text stated that inclusion would increase transparency and would provide the public with an indication of how the statutory requirement of weight of the scientific evidence, requirements of sections 6 and 26, and an integral component of systematic review, will be applied.

EPA intends to use the systematic review approach, described in the proposed rule, but is not codifying a definition in the regulatory text. To be clear, although EPA asked for comment on the need for regulatory text for systematic review on hazard identification specifically, EPA will not limit the use of this approach solely to the hazard assessment, but will use it throughout the risk evaluation process. The inclusion of a description of systematic review in the preamble is the most appropriate approach in light of public comment and the requirements of the statute. First, systematic review is not required under the statute, only a weight of the scientific evidence analysis. The definition the Agency is adopting for “weight of the scientific evidence” uses the phrase “systematic

review,” which addresses to some extent the commenters who favored including the concept in this regulation.

EPA sees weight of the scientific evidence approach as an interrelated part of systematic review, and further believes that integrating systematic review into the TSCA risk evaluations is critical to meet the statutory requirements of TSCA. Although, as EPA discusses elsewhere in this preamble, there are universal components of systematic review that EPA intends to apply in conducting risk evaluations, this is one area where EPA concluded it would be premature to codify specific methods and criteria that may change as the Agency gains more experience conducting TSCA risk evaluations. As requested by commenters, EPA does believe the addition of discussion of the systematic review approach the Agency intends on utilizing is necessary for transparency, and so provides the description herein. Section 26(l) also requires EPA to develop and revise Agency guidance. The Agency intends to provide further details on systematic review and weight of scientific evidence approaches under TSCA in future guidance documents.

As defined by the Institute of Medicine (Ref. 11) systematic review “is a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. The goal of systematic review methods is to ensure that the review is complete, unbiased, reproducible, and transparent” (Ref. 11).

The principles of systematic review have been well developed in the context of evidence-based medicine (*e.g.*, evaluating efficacy of medical interventions tested in multiple clinical trials) (Ref. 12) and are being adapted for use across a more diverse array of systematic review questions, through the use of a variety of computational tools. For instance, the National Academies’ National Research Council (NRC) has encouraged EPA to move towards systematic review processes to enhance the transparency of scientific literature review that support chemical-specific risk assessments to inform regulatory decision making (Ref. 13). Key elements of systematic review include:

- A clearly stated set of objectives (defining the question);
- Developing a protocol which describes the specific criteria and approaches that will be used throughout the process;
- Applying the search strategy criteria in a literature search;

- Selecting the relevant papers using predefined criteria;
- Assessing the quality of the studies using predefined criteria;
- Analyzing and synthesizing the data using the predefined methodology;
- Interpreting the results and presenting a summary of findings (Ref. 14)

12. *Sufficiency of information.* EPA did not propose to codify this phrase, but discussed it in the context of having “enough” information to conduct a risk evaluation within the statutory timeframe. However, EPA also specifically requested comment on whether to define sufficiency of information. Commenters who opposed codifying a definition stated that the phrase was “vague” and could have a number of definitions and that the information needs for chemical risk evaluations can vary significantly, so not one definition would be appropriate. Commenters who supported codifying a definition of this phrase stated that, specifically for risk evaluation conducted and submitted by third parties, knowledge of what constitutes sufficient information is necessary. Consistent with the proposed rule, the final rule does not codify this term because EPA agrees that the information required for chemical risk evaluations can be highly variable, and that given the case-by-case nature of the hazard and exposure scenarios, it is difficult to have an overarching definition of “sufficient information” applicable to all evaluations. EPA does not believe that the definitions offered by the commenters would provide any greater clarity that would effectively inform third party risk evaluations and expansion of this concept is more appropriate for the statutorily required guidance documents.

13. *Unreasonable risk.* In the proposed rule, EPA said that the Agency did not think it was appropriate to define “unreasonable risk” because each risk evaluation will be unique. For example, defining specific risk measures for use in all risk evaluations would be inappropriate to capture the broad set of health and environmental risk measures and information that might be relevant to chemical substances. In the preamble to the proposed rule, EPA did discuss some of the considerations the Agency will use in making a risk determination. The public overwhelmingly agreed with the proposed approach. EPA did take public comment on this approach and the public agreed that a definition was not appropriate, but appreciated EPA’s approach to including considerations.

For the final rule, the Agency will be taking the same approach, and has

identified, a revised list of some of the considerations that the Agency will use in making a risk determination. This is not intended as an exhaustive list, but merely identifies some of the considerations that are likely to be among the most commonly used. However, the list of considerations has changed slightly in response to public comment. In the proposed rule preamble a few considerations were too specific and were not expected to be widely applicable to TSCA risk evaluations. For example, the proposed rule included the specific mention of margin of exposure (MOE), which is just one approach for risk characterization. EPA acknowledges that MOE is just one of several approaches to risk characterization, and agrees that it does not make sense to single out this one particular approach. There will be risk scenarios where one approach may be better than another and, as commenters correctly pointed out, the science of risk characterization is still evolving, particularly for non-cancer hazards. The proposed preamble had also included the consideration of cumulative exposure in making a risk determination. A number of commenters pointed out, this is not a requirement under the statute; EPA agrees that this may not be widely applicable to many TSCA risk assessments, and so EPA has not included it in the list below. Additionally, commenters correctly pointed out that EPA did not mention environmental risks in the proposed definition. Considerations of environmental hazards and exposures have been added.

To account for the number of different risk characterization approaches and for changing science, EPA will not include any specific definition in this final rule. To make a risk determination, EPA may weigh a variety of factors in determining unreasonable risk. The Administrator will consider relevant factors including, but not limited to: The effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any susceptible populations), the severity of hazard (the nature of the hazard, the irreversibility of hazard), and uncertainties.

E. Timing of Risk Evaluations

A risk evaluation is initiated upon the final designation of a high priority substance at the completion of the

prioritization process or through the completed manufacturer request process. A risk evaluation is complete upon the publication of the final risk evaluation, which includes the final risk determination for all the conditions of use identified in the Scope document. As indicated, the statute requires EPA to complete risk evaluations within three years, with the possibility of a single six-month extension. This rule adopts these timeframes without modification or elaboration.

F. Chemical Substances for Risk Evaluation

As identified previously, chemical substances that will undergo risk evaluation can be put into three groups: (1) The first ten chemical substances the Agency is required to identify within the first 180 calendar days of enacting the amendments to TSCA (15 U.S.C. 2605(b)(2)); (2) the chemical substances determined as High-Priority Substances through the prioritization process proposed in a separate rulemaking; and (3) chemical substances requested by manufacturers, when the requests meet the criteria for EPA to conduct an Agency risk evaluation.

Public comment requested that EPA be explicit about what constitutes a chemical substance under TSCA. The statute defines a chemical substance to mean any organic or inorganic substance of a particular molecular identity, including: (1) Any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring nature, and (2) and element or uncombined radical. Chemical substances do not include: (1) Any mixture, (2) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide, (3) tobacco or any tobacco product, (4) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act), (5) any article the sale of which is subsequent to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code), and (6) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. 15 U.S.C. 2602(2)(B). The list constitutes what is commonly referred to as “non-

TSCA uses.” It may be appropriate for EPA to consider potential risk from non-TSCA uses (as identified above) in evaluating whether a chemical substance presents an unreasonable risk, although these uses would not be within the scope of the risk evaluation. EPA would explain the basis for such consideration in any risk evaluation. EPA may not in a risk management rule under section 6(a) regulate non-TSCA uses. TSCA § 6(a) generally provides that if EPA determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Agency must apply certain regulatory requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. The potential risks of non-TSCA uses may help inform the Agency’s risk determination for the exposures from uses that are covered under TSCA (e.g., as background exposures that would be accounted for, should EPA decide to evaluate aggregate exposures).

G. Process and Criteria for Manufacturer Requested Risk Evaluations.

TSCA allows a manufacturer or group of manufacturers to request that the Agency conduct a risk evaluation of a chemical substance (or group of substances) that they manufacture. The statute further directs EPA to establish the “form . . . manner and . . . criteria” for such requests as part of this rule.

1. *Scope of request.* In the proposed rule, EPA required the manufacturers submitting the request to include all information necessary to conduct a risk evaluation on all conditions of use. EPA received numerous public comments on this provision. EPA did receive comments that supported the proposed approach, indicating that the approach was consistent with EPA’s own process for evaluating high priority chemicals, and because the chemicals evaluated as the result of a manufacturer request will have not gone through the Prioritization process, where the bulk of information may be gathered, it was appropriate to have manufacturers submit all information necessary to conduct a risk evaluation for all conditions of use. Those opposed to the proposed approach stated that manufacturers are not always privy to every downstream use, and therefore would find it very difficult to obtain all the required information. Commenters also expressed concern that the bar set in the proposed rule overall was too high and

would make it extremely difficult for manufacturers to submit a compliant request, and that the extensive requirements EPA had proposed could create a disincentive to submit requests for risk evaluation.

EPA agrees with many of these concerns in opposition to the proposed approach. EPA believes that Congress intended for EPA to establish a process under which the 25%–50% target would most likely be met. The law instructs EPA to “ensure” that that target is met. Section 6(b)(4)(E)(i). While this is conditioned on EPA’s receipt of a sufficient number of compliant requests, EPA believes it signals an intent that the criteria for requests make it reasonably likely that the target will be met. Legislative history supports this reading. See S3516 (June 7, 2016) (“The Administrator should set up a system to ensure that those percentages are met and not exceeded in each fiscal year.”)

Upon consideration of these comments, among others, EPA is modifying its proposal in several ways. First, the final rule allows manufacturers to submit requests for risk evaluation on only the conditions of use of the chemical substances that are of interest to the manufacturer.

Although manufacturers may request that EPA conduct a risk evaluation based on a subset of the conditions of use, EPA intends to conduct the risk evaluation in the same manner as any other risk evaluation conducted under section 6(b)(4)(A). This is clear from subsections (A) and (C), and from section 6(b)(4)(E)(ii), which expressly directs that the Administrator shall not expedite or otherwise provide special treatment to manufacturer-requested risk evaluations. As such, EPA intends to conduct a full risk evaluation that encompasses both the conditions of use that formed the basis for the manufacturer request, and any additional conditions of use that EPA identifies, just as EPA would if EPA had determined the chemical to be high priority. However, rather than require the manufacturer to identify any additional conditions of use that EPA will evaluate, EPA will determine the additional conditions of use during the process of determining whether to grant or deny the manufacturer request. From receipt of a compliant request to initiation of a risk evaluation EPA anticipates 195 days. This includes: (1) Public notification of request within 15 days of receipt; (2) Within 60 days after receipt of the request, EPA will publish the request in the **Federal Register**; (3) EPA will open a docket to facilitate a no less than 45-day public comment period; (4) Within 60 days of the end of

the comment period EPA will issue the decision to grant or deny the request; (5) Upon a decision to grant a request, the requester has 30 days to withdraw the request or EPA will move to initiate the risk evaluation.

Upon receipt of a request, EPA will evaluate whether the circumstances of manufacture, processing, distribution in commerce, use, and/or disposal identified by the submitter constitute conditions of use that warrant risk evaluation and whether additional conditions of use need to be included in the risk evaluation. EPA will apply the same criteria in the same manner outlined earlier in this preamble in making these evaluations.

EPA must complete the full risk evaluation that encompasses both the conditions of use that formed the basis for the manufacturer request, and any additional conditions of use that the Administrator determines under section 15 U.S.C. 2605(b)(4)(A), within the statutory three-year deadline. However, as discussed elsewhere in this preamble, EPA may make an early risk determination on any condition of use included in the Agency’s scope, after peer review of the risk evaluation for that condition of use. Thus, since manufacturers are required to submit all of the information necessary to complete risk evaluation for the identified conditions of use, EPA expects these conditions of use may be good candidates for an early determination.

2. Information that must be submitted as part of request. Consistent with the proposal, a request must include the chemical identity—all known names, CAS number, and molecular structure. Manufacturers may also submit requests for categories of chemical substances, and such requests must include an explanation of why the category is appropriate under 15 U.S.C. 2625(c). EPA will grant such request only upon determining that the requested category is appropriate for risk evaluation. As described above, manufacturers may now request a risk evaluation based on a subset of conditions of use. The manufacturer’s request must include all of the information necessary for EPA to conduct the evaluation for the requested conditions of use, consistent with the requirements in sections 15 U.S.C. 2605(b)(4)(A), and 15 U.S.C. 2625(h). This includes all of the necessary information, as relevant to the requested conditions of use, on the chemical substance’s hazard and exposure potential; the chemical substance’s persistence and bioaccumulation; any relevant potentially exposed or susceptible subpopulation; whether

there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and nearby drinking source; the chemical substance’s production volume or significant changes in production volume; and any other information relevant to the risks potentially presented by the chemical substance. The requesting manufacturer does not need to supply a copy of the information if it is publicly available, but must list all references. These are the same requirements EPA listed in the proposed rule; however, the scope of the request may be narrower, specifically regarding the conditions of use requested. Some comments argued that it would be exceedingly difficult to obtain information for uses that the requesting manufacturer may have no knowledge of. EPA agrees with that, and that is a large part of the motivation behind EPA’s decision to allow manufacturers to request risk evaluations on limited conditions of use. However, for those conditions of use requested, the manufacturer must provide all the information EPA needs for risk evaluation.

Any information submitted by a manufacturer must be consistent with the scientific standards in 15 U.S.C. 2625(h). Although the judgement of consistency is ultimately EPA’s, holding the requester to the statutory standard helps to ensure that if EPA grants the request, the Agency can effectively utilize the information provided. Additionally, any information submitted that is claimed as CBI must be accompanied by a redacted version of the information, including as necessary an accession number and a structurally descriptive generic name. Instructions for submitting CBI are also included in this rule. Consistent with EPA’s general interpretation of section 14, the rule requires upfront substantiation of non-exempt CBI claims.

The final rule also includes a number of other revisions to the information that must be submitted for the request to be considered. In the proposed rule, EPA required manufacturers to submit in the request any risk assessment or evaluation that they might possess. This was added to the proposed rule to provide the Agency with additional information, specifically, as it relates to the hazard assessment. The Agency’s intent was to use this as purely another source of information, not base any decision solely on the information in this document. Commenters argued that these risk assessments or evaluations may have been conducted under a different statute or for a particular purpose, and therefore may not be

useful or appropriate under TSCA. Additionally, commenters stated that a risk evaluation may have been conducted in response to litigation and therefore would be protected under attorney client privilege. In response to public comments, EPA is removing the requirement that the manufacturer must commit to providing EPA existing risk assessments on the chemical. EPA believes that all relevant risk assessments would be required to be provided pursuant to TSCA section 8(e), and/or would be submitted in response to the regulatory provision that requires that the requesters provide any information relevant to the potential risks of the chemical substance under the circumstances identified in the request.

Many commenters also requested that EPA rephrase the certification statement. Commenters stated that the content of the certification was overly aggressive and unnecessary given the enforcement provision at the beginning of the regulation and the enforcement that applies to all of TSCA.

3. Process for evaluating requests.

Upon receipt of the request, EPA will verify that the request appears to be valid, *i.e.*, that information has been submitted that is consistent with the regulatory requirements. Within 15 business days of receiving a facially valid request, EPA will publish a public notice of the receipt, which will include the manufacturer request. This notice is intended to give the public early notice of the chemical substance that may be under evaluation from a manufacturer request. Due to the 15 day turn around on this public notice this will not be a **Federal Register** Notice, but an announcement on the Agency's Web site and/or an email announcement. Between receipt of the request and the subsequent end of public comment period (discussed in this next part), EPA will work to identify any additional conditions of use, if any, of the chemical requested. Within 60 days from receipt, EPA will submit for publication an announcement of the receipt of the request in the **Federal Register**, open a docket for the request, make available the information that has been submitted (taking into account any valid CBI claims), and provide no less than a 45-day comment period. This notice will include the manufacturer request and EPA's proposed determinations as to whether the activities identified in the request are conditions of use that warrant risk evaluation, and whether there are additional conditions of use that need to be included in the risk evaluation. This public comment period will allow the public to comment on

EPA's proposed determinations and to identify and/or submit any reasonably available information regarding hazard, exposure, potentially exposed populations and subpopulations, and conditions of use that may help inform a risk evaluation. The requesting manufacturer may also submit any additional material during this time.

Chemical substances that EPA has prioritized through the prioritization process (the subject of separate rulemaking (EPA-HQ-OPPT-2016-0636)), are subject to two separate public comment periods prior to the completion of the prioritization process. These comment periods are designed to ensure that EPA has the necessary information to evaluate the chemical substances, including, in particular, information on the relevant conditions of use. EPA is adopting the similar structure described here for manufacturer requests, under which EPA will solicit input from the public prior to the decision on whether to grant the request, as part of the method by which EPA will identify and gather information on the additional conditions of use to be addressed in the final risk evaluation. Since manufacturers are required to submit all the information necessary to complete risk evaluation on the identified conditions of use, EPA generally expects that the submitted information would include reasonably complete toxicity information on the chemical, even though it would likely not include exposure information relevant to the other conditions of use. While this pre-risk evaluation process for manufacturer request differs from the process of high-priority substances and compresses the period in which EPA will identify conditions of use and supporting information, EPA believes that some differences are necessary in order to effectuate Congress' intent to create a workable process for manufacturer requests that is reasonably likely to hit the numerical target in the statute. Through this mechanism, EPA expects that in many cases, the available information will be comparable to what EPA will identify or generate through the measures identified in the prioritization framework rule. During the public comment period associated with each manufacturer request, EPA encourages public commenters to identify additional information to inform a risk evaluation that was not in the manufacturer request, including any additional conditions of use.

At any time prior to the end of the comment period, the manufacturer may supplement the original request with new information they receive or obtain.

At any point prior to the completion of a risk evaluation conducted on a chemical substance at the request of a manufacturer(s), manufacturer(s) are required to supplement the original request upon receipt of information that meets the criteria in 15 U.S.C. 2607(e) and 40 CFR 702.37, or other information that has the potential to change EPA's risk evaluation for the requested conditions of use.

Within 60 days after the end of the comment period, EPA will review the request along with any additional information received during the comment period to determine whether the request meets the regulatory criteria and will notify the manufacturer(s) accordingly. If EPA determines that the request is compliant (*i.e.*, that the activities for which risk evaluation is requested constitute "conditions of use" as EPA interprets the term, and are conditions of use that EPA concludes warrant inclusion in the scope of a risk evaluation for the chemical, and that EPA has the required information necessary for conducting a risk evaluation on the condition(s) of use requested), EPA will grant the request. Otherwise, EPA will deny the request. Requesters may resubmit any denied request. Within 30 days of the notice that EPA will grant the request, the requestor may withdraw the request for any other reason after the Agency has notified the requester of the decision to grant or deny. For EPA to proceed with a risk evaluation on the chemical requested, it would have to go through the Prioritization process. The process for conducting the risk evaluation will follow the regulatory requirements applicable to high-priority chemical risk evaluations and will not be expedited or otherwise afforded special treatment. EPA will initiate the risk evaluation consistent with TSCA section 6(b)(4)(E)(i) upon payment of required fees requirements as established in the Fees Rule. EPA is not addressing in this rulemaking the fee amount for manufacturer requested evaluations. The fee amount will be addressed in a separate rulemaking process.

Consistent with TSCA section 6(b)(4)(E)(iii), EPA will give preference to requests where there is evidence that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment, and is therefore proposing to allow (but not require) manufacturers to include any evidence to support such a finding. Following this required initial preference, EPA will give further preference to requests in the order in which a request is received. This last

provision regarding preference is a change from the proposed rule, where EPA indicated that preference would be given to chemicals where EPA determined that there were relatively high estimates of hazard and/or exposure for the chemical substance. EPA received a number of comments arguing that this was not an appropriate way to order chemicals to be evaluated. First, comments asked for a definition of "high estimates of hazard or exposure." Other commenters suggested that manufacturers may submit a request for a low hazard or exposure chemical to get the EPA determination of no unreasonable risk. There were also a few comments that stated that the proposed preference scheme was appropriate in addressing the worst chemicals first. While EPA agrees that this is the best way to approach the identification of high priority substances, EPA does not believe this is necessarily the best approach for selecting among manufacturer-requested evaluations. EPA believes, on reflection, that Congress intentionally established the process for industry requests, to operate outside of the prioritization process, under which lower risk chemicals might be identified for risk evaluation. Therefore, EPA has dropped this proposed preference. EPA also acknowledges it is possible that manufacturers could request an evaluation seeking to get an Agency determination of no unreasonable risk.

H. Interagency Collaboration

In the proposed rule, EPA committed to ensuring there will be interagency engagement and dialogue throughout its risk evaluation process; however, EPA chose not limit the potential interagency collaboration by proposing to codify any particular process. EPA requested specific public comment on whether codifying this collaboration at a specific point regulation was appropriate. Overwhelmingly, commenters were supportive of collaboration with other agencies, and some comments encouraged additional collaboration with state and local agencies, global partners, and tribes. There were mixed comments regarding the codification of interagency collaboration at a particular point in the risk evaluation process. Those in support of the collaboration stated that other agencies, such as the Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Safety and Health (NIOSH), may have additional information on worker exposure that will undoubtedly be useful for EPA in conducting the risk evaluation. Those opposing the

codification argued that this would be overly bureaucratic and a waste of resources, as not all agencies would have an interest/information on every chemical so there would not always be the necessity to consult with them.

EPA has codified collaboration to give the public confidence that EPA will work with other agencies to gain appropriate information on chemical substances. As stated a number of times in this preamble, EPA is committed to transparency and communication with the public. Codification of interagency collaboration is just one more example of this commitment. Through this interagency process, EPA expects to gain additional information into uses and exposure scenarios, with which other agencies may be more familiar. Additionally, during interagency meetings (under the Office of Management and Budget process of reviewing the proposed rule), other federal agencies expressed significant interest in early and frequent collaboration. Agencies such as NIOSH and OSHA have resources available and information for assessing exposure to workers that EPA may not have. Communication with the Small Business Administration (SBA) Office of Advocacy was requested by a number of commenters. Collaboration with Consumer Product Safety Commission (CPSC), which some commenters argued will be necessary, was requested as EPA evaluates chemicals commonly found in consumer products. There are a number of other agencies that have information and expertise that will undoubtedly be useful to the EPA, and codified collaboration, along with mechanisms already in place, further guarantees that this information will be utilized.

By mandating consultation at any particular stage, EPA does not intend to imply that collaboration with agencies will solely occur at this step of the process, but including this collaboration upon initiation gives other agencies sufficient time to work with the EPA to identify any information that will be useful for EPA risk evaluation (*e.g.*, existing regulations or mission critical uses) of the chemical substance. EPA anticipates that this collaboration would include agencies that may also regulate the chemical substance or the environment in which the chemical substance may be present, as well as agencies that may have critical operations that require the chemical being evaluated, or may otherwise be affected by regulation of the chemical substance. EPA will also consult with the SBA Office of Advocacy and other federal agencies, as appropriate, to help

facilitate outreach to the small business sector.

This provision also is not intended to suggest that EPA will not collaborate with federal agencies prior to the initiation of the risk evaluation. EPA has a number of existing mechanisms already in place to facilitate collaboration between EPA's federal partners and will continue to utilize them. Collaboration with other agencies is an important step in identifying chemicals prior to prioritization, as well as during the risk management phase, if a chemical use is determined to present an unreasonable risk.

As requested in the comments, EPA also plans to engage with state and local agencies where they may have information to inform risk evaluations. Similarly, EPA looks to increase collaboration with tribes, as they can be impacted by chemical substances differently due to unique traditional activities and lifestyles, as discussed in comments.

H. Risk Evaluation Requirements

1. Considerations. This subpart identifies and discusses what EPA will consider in conducting a risk evaluation. The first subpart identifies the necessary components of the risk evaluation process—a scope, which will include a Conceptual Model and Analysis Plan, a hazard assessment, an exposure assessment, a risk characterization, and a risk determination.

a. Agency guidance. EPA has a number of existing guidance documents that inform Agency risk assessment. EPA has been using risk assessments as a tool to characterize the nature and magnitude of health risks to humans and ecological receptors from chemical contaminants and other stressors that may be present in the environment since its inception. Over the years, EPA has worked with the scientific community and other stakeholders to develop a variety of guidance, guidelines, methods and models for use in conducting different kinds of assessments. A compendium of existing Agency guidance related to risk assessments is maintained on EPA's Web site (Ref. 15). Additionally, on EPA's Web site is a compendium of guidance, databases and models used for assessing pesticide risks (Ref. 16) and information about available predictive models and tools for assessing chemicals under TSCA (Ref. 17). Each of these Web sites identify and link to a number of written guidance documents, tools and models.

In the proposed rule, EPA made it clear that the Agency would be taking

advantage of existing guidance, tools and models that are relevant and available for use in conducting a risk evaluation under this program. Since each risk evaluation is based on the specific circumstances surrounding the chemical being assessed, EPA did not propose to mandate the use of any specific guidance, method or model, to ensure that there is flexibility. EPA asked for comments about this approach.

The majority of the commenters did not think the Agency should mandate the use of or otherwise codify a list of guidance documents. Many public comments mentioned that many of the guidance documents were potentially outdated and were in need of updates. These commenters asserted that codifying these outdated documents would not be appropriate, nor accurately indicate to the public how risk evaluations will be conducted. Additionally, many commenters pointed out the provision in section 26(l) of TSCA that requires EPA to develop and to regularly review and update, the necessary policies, procedures, and guidance. This cuts against mandating use of particular guidance documents in regulation. Other commenters expressed concern that existing guidance did not take into account new science requirements in TSCA. By contrast, some expressed the view that the list should be codified, as it would result in added transparency to the process.

EPA is not codifying a list of guidance (with the exception of the Metals Framework as mandated by TSCA), but states in the regulation that guidance may be used if it constitutes the best available science, and consistent with the weight of the scientific evidence. This approach is consistent with the proposed rule, and in line with the majority of the comments received on this subject. Rather than starting anew, EPA intends to take advantage of existing guidance, tools and models that are relevant and available for use in conducting a risk evaluation under this program. EPA added a new clause regarding the use of best available science and weight of the scientific evidence to the regulation; this addition of the clause regarding the use of best available science and weight of the scientific evidence was done to ensure that while the documents may have been developed under another statute, EPA will take care to ensure their use would be compliant with the various requirements of section 26 of TSCA. While EPA does think many of the current guidance documents can be utilized effectively under the statute, the

Agency agrees with many of the comments that it will be necessary to modify some documents to further adhere to the amendments in the statute, as well as to reflect changing science and technology. Additionally, section 26(l) requires the development of any policies, procedures, and guidance that may be necessary to carry out the amendments of the law, and to routinely review and revise them as necessary to reflect scientific developments. Codifying documents that may be changed, while not codifying others that have yet to be developed, could potentially lead to long processes to change the rule language.

The scope of each risk evaluation will identify those guidance documents that the Agency expects to utilize to inform the risk evaluation. EPA will use the guidance only to the degree that it represents the best available science appropriate for the particular risk evaluation. EPA recognizes that some guidance may be outdated and may rely on defaults where no data exists currently to replace those defaults.

b. Categories of chemical substances. TSCA provides EPA with authority to take action on categories of chemical substances: Groups of chemical substances which are, for example, similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment. Although the rule most often references “chemical substances,” EPA includes a clear statement in the final regulation that nothing in the rule shall be construed as a limitation on EPA’s authority to take action with respect to categories of chemical substances, and that, where appropriate, EPA can evaluate categories of chemical substances. This is the same provision that EPA included in the proposal, but EPA has removed the statement regarding the Agency’s consideration of hazards and exposures associated with the category of chemicals, and the populations likely exposed. EPA believed that this was duplicative, because EPA is required to treat categories of chemicals in the same manner as individual chemical substances.

c. Science requirements. EPA has incorporated into the regulatory text the statutory requirements regarding best available science and weight of the scientific evidence. Definitions of those terms have also been added. While EPA prefers high quality data, where available, EPA recognizes that data is not always necessary to reach a scientifically grounded conclusion on

the potential risks of a chemical substance, within the timeframes dictated by the statute.

As a matter of practice, EPA has been, and will continue to be, committed to basing its decisions on the best available science and the weight of the scientific evidence. In response to public comments on the proposal, EPA has determined to make a number of additions to the final rule to ensure that the science standards in TSCA are more explicitly incorporated into the risk evaluation process. Specifically, EPA has added specific language to the final rule stating that EPA will evaluate hazard and exposure data in a manner consistent with the section 26 science standards including documenting the use of the standards in 15 U.S.C. 2625(h) and the weight of the scientific evidence in 15 U.S.C. 2625(i). These changes clarify that EPA’s risk evaluations will be consistent with TSCA’s new requirements in section 26 related to best available science and weight of the scientific evidence.

d. Fit-for-purpose risk evaluations. As described in the proposed rule and in Unit III.D.10, each risk evaluation will be fit-for-purpose—that is to say, the level of refinement will vary as necessary to determine whether the chemical substance presents an unreasonable risk, given the nature of the evidence, for the conditions of use of a specific chemical substance. A number of the public comments received stated their support for this approach, as it conserves the Agency’s resources to focus on the most important components of a given risk evaluation.

EPA introduced the idea that risk evaluations would be conducted in a fit-for-purpose manner in the proposed rule. Specifically, EPA stated that all conditions of use evaluated will not warrant the same level of evaluation, and that EPA expects, that in some cases, it may be able to reach conclusions without extensive or quantitative evaluations of risk. For example, a lower-volume or less dispersive (those uses that do not spread as far in the environment, either indoors or outdoors as compared to a different use) condition of use might require a less quantitative, data-driven evaluations to credibly characterize the risks than uses with more extensive or complicated exposure patterns. Consistent with EPA’s current practice in conducting risk assessments, technically sound risk determinations can be made, consistent with the best available science, through a combination of different types of information and methods approaches.

EPA will continue to utilize this approach and has retained it in the final rule. The concept of fit-for-purpose risk evaluation is further explained in the regulation as follows: EPA will refine, as necessary, its evaluations for one or more conditions of use in any risk evaluation and when information and analysis are sufficient to make a risk determination using assumptions, uncertainty factors, and models or screening methodologies, EPA may decide not to refine its analysis further. Both of these provisions give EPA the flexibility to conduct risk evaluations in a manner that best suits the available information and the decisions that will be made. These are generally consistent with the proposed text, however some changes have been made, namely the exclusion of the phrase "accepted science policies." A number of commenters expressed concern regarding the lack of clarity of this language. Commenters asked for specific examples of science policies and some commenters expressed concern that the Agency would confuse science with regulatory policy, and specifically encouraged separation between the two, to ensure that EPA's decisions would be science-based. To address these concerns EPA has deleted the reference to "science policies" from the rule text.

Many commenters suggested that this fit-for-purpose approach would be necessary to evaluate chemical substances within the statutory timeframe, and agreed that this is appropriate because due to the nature of some uses, some will not necessitate the same level of evaluation as others. By contrast, some commenters were concerned that the fit-for-purpose approach is not scientifically sound and can never be objective. To clarify, EPA will not sacrifice best available science in implementing this approach. The speed of an evaluation does not equate to less rigorous science. EPA will always be transparent about the data and assumptions used.

e. Timing of a risk determinations. In the proposed rule, EPA explicitly allowed for the expedited evaluation for a particular condition of use to, if necessary, move more rapidly to risk management under TSCA section 6(a) (15 U.S.C. 2605(a)). This could include a situation in which a single use presented an unreasonable risk of injury for the population as a whole or for a susceptible subpopulation (e.g., one use results in risks that EPA would determine unreasonable regardless of the risk posed by other uses). A number of commenters raised concern about the apparent one-sided nature of this provision, arguing that this appeared to

preclude a similar determination that a chemical substance did not present an unreasonable risk. EPA agrees that logically such determinations could be appropriate in either case, and has revised its approach to apply more generally. Accordingly, the final regulation at 720.41(a)(7) has been revised to clarify that EPA may make early risk determinations that a chemical substance does or does not present an unreasonable risk under particular conditions of use. The final rule also makes clear that any expedited determination may be issued at any point after the final scope is published. As discussed previously, all early determinations would be portions of the final, complete risk evaluation and would therefore be made using the procedures applicable to TSCA risk evaluations established in this rule. TSCA is very clear that unreasonable risk determinations cannot be made until after a risk evaluation that meets the requirements of section 6(b)(4) is complete. Any risk evaluation for a chemical under particular conditions of use will therefore be consistent with all statutory requirements as well as the procedures established in this regulation. This would also include the requirement that EPA publish a draft risk evaluation for no less than a 60-day public comment period, and the regulatory requirement for peer review.

The final regulation also continues to explicitly state that in any case where EPA would find it necessary to issue an early risk determination for a chemical substance under particular conditions of use of a chemical, the Agency will still complete a risk evaluation on all conditions of use identified in the final scope, within the statutory 3-year deadline. In sum, the final rule explicitly recognizes that EPA may make early risk determinations, to either to manage unreasonable risks as they are identified, through the issuance of a regulation under TSCA section 6(a) or to notify the public as soon as possible of the safety of a chemical substance under a particular condition of use.

f. Metals or metal compounds. As required by the statute, when evaluating metals or metal compounds, EPA must use the March 2007 Framework for Metals Risk Assessment of the Office of the Science Advisor (Ref. 3) or a successor document that addresses metals risk assessment and is peer-reviewed by the Science Advisory Board. The final rule, consistent with the proposal, merely reiterates this statutory mandate.

2. Information and information sources. For those chemical substances designated as high priority for risk

evaluation, EPA expects to initiate the process when EPA has determined that most of the information necessary to complete the evaluation is reasonably available, which in most cases means the information already exists. In the proposal, EPA had stated that the goal would be to "only" initiate the process once most of the information necessary to complete the evaluation was reasonably available. In the final rule the word "only" has been deleted to account for the fact that EPA may use its regulatory authorities to obtain or require the generation of additional information even after the risk evaluation has been initiated.

For manufacturer requested risk evaluations, EPA acknowledges it may potentially be difficult to gather all of the necessary information prior to risk evaluation, as these chemicals will not have gone through the prioritization process. Nevertheless, EPA generally expects that it will be feasible to obtain the necessary information to complete a risk evaluation within the statutory timeframe. As discussed previously, the final rule requires a manufacturer to submit all of the necessary hazard information for EPA to complete a risk evaluation on the one or more conditions of use that have been requested. Although there may be other hazards associated with other conditions of use that present different routes of exposure, EPA expects that the majority of the necessary hazard information will be obtained through the request. EPA has then allotted 195 days from receipt of request to gather additional information required to assess both requested uses and any additional conditions of use EPA has determined warrant evaluation. For both EPA- and manufacturer-initiated risk evaluations, EPA may also rely on information developed through the use of novel and advancing chemical assessment procedures, measures, methods, protocols, methodologies, or models (e.g., high-throughput chemical assessment techniques).

For identified data needs, EPA may issue a voluntary call to the public for relevant information or otherwise engage directly with stakeholders, followed, as necessary, by exercise of EPA's authorities under TSCA to require submission or generation of new data. Accordingly, as appropriate, EPA will exercise its TSCA information collection, testing, and subpoena authorities, including those under TSCA sections 4, 8, and 11(c) to obtain the information needed for a risk evaluation. EPA notes as well that TSCA section 8(e) requires that any person who manufacturers, processes, or

distributes in commerce a chemical substance or mixture and who obtains information which supports the conclusion that this substance or mixture presents a substantial risk of injury to health or the environment, shall immediately inform the Agency, and EPA may obtain some information through this route.

EPA also expects to obtain scientific advice from the Science Advisory Committee on Chemicals (SACC), which the Agency is required to develop and convene under TSCA section 26(o).

When conducting a risk evaluation, EPA will ensure that risk evaluations are consistent with the scientific standards in section 26(h) and (i), including reliance on the best available science and the weight of the scientific evidence. EPA will rely on data, models, and screening methods, as needed. The use of these methods will be balanced by the quality of the information (consistent with standards in section 26(h) and (i)) and the statutory deadlines for completing a risk evaluation. In the final rule, EPA will use the scope to focus on the reasonably available information and science approaches, and reserve uncertainty considerations specifically for the remainder of the risk evaluation.

EPA does not intend to preclude the generation of new scientific information to inform risk evaluations, however, as mentioned in the discussion of reasonably available information, the extent to which EPA will consider any newly generated information in a risk evaluation will depend on the statutory deadlines.

In compliance with the statute, EPA will work to reduce and replace, to the extent practicable, the use of vertebrate animals in testing chemical substances as outlined in TSCA section 4(h). The intent to reduce testing on animals was in the proposed text, however comments suggested the language was not exactly as the statute intended, and that it should refer to the development of new information, not all existing information, as it could have been interpreted. The final rule text has been amended to more closely hew to the statute.

I. Risk Evaluation Steps

1. Scope. The first step of a risk evaluation is the development of the scope. The scope of each risk evaluation will include the following components. The conditions of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation will be included in the scope. This is amended from the proposed rule to address the approach to conditions of use as

explained in Unit III.B. The EPA will identify the potentially exposed or susceptible subpopulations EPA expects to consider, the ecological receptors, and the hazards to human health and the environment the Agency plans to evaluate will also be included. From the proposed rule, EPA changed “ecological characteristics” to “ecological receptors.” This was done to clarify that the Agency will be evaluating specifically the impact of the chemical stressor, and EPA believes that characteristics was too broad, and receptors more closely hew a chemical risk assessment. The scope will include a description of the reasonably available information and the science approaches that the Agency plans to use. In the proposed rule EPA had included that the reasonably available information would include “accepted science policies (e.g., defaults and uncertainty factors), models, and screening methodologies.” As already discussed, a number of commenters expressed their concern with this language and in response EPA removed this provision. Under the final rule, the scope will focus on the reasonably available information and science approaches, and reserve uncertainty considerations specifically for the remainder of the risk evaluation.

EPA will include a conceptual model that will describe the actual or predicted relationships between the chemical substance and the receptors, either human or environmental, with consideration of potential hazards throughout the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, use, to release or disposal.

Also included will be an analysis plan, which will identify the approaches and methods EPA plans to use to assess exposure, hazards, which will include dose-response, and risk, including associated uncertainty and variability. The analysis plan will also include a description of the reasonably available information and science approaches the EPA plans to use.

As requested by a number of commenters, the scope will also include the plan for peer review the Agency expects to consider. This may include the plan for peer review for those conditions of use that EPA expects to make early risk determinations on. This plan may also include the Agency’s plan to have any methods or models peer reviewed, along with the risk evaluation, as well as the EPA’s anticipated use of the SACC or another peer review body or whether the Agency anticipates a letter peer review or a committee consensus peer review. The

Peer Review Handbook walks through the numerous options the Agency can use, and the plan will give the public an idea of what the Agency intends to use for a particular risk evaluation.”

EPA will publish a notice in the **Federal Register**, announcing the availability of the final scope within six months of the initiation of the risk evaluation. Although not required under the statute, EPA will publish a draft scope and provide for no less than a 45 calendar day public comment period during this six-month period. As a number of commenters pointed out, there was a mistake in the proposed rule—the length of the commenter period on the draft scope was 30 days in the preamble, but 45 days in the regulatory text. EPA has corrected this mistake. EPA welcomes all public participation, but specifically encourages commenters to provide information they believe might be missing or may further inform the risk evaluation. That said, the prioritization process requires two public comment opportunities, and EPA expects this will reduce the likelihood of significant comments on the draft scope for those High-priority chemicals.

EPA has deleted the issue preclusion clause included in the proposed rule stating that “any issues related to the scope not raised in the comments at that time cannot form the basis for an objection or challenge in a future administrative or judicial hearing” in response to a significant number of comments. However, under general principles of administrative law, commenters are required to identify relevant available information and raise objections that could be raised during established comment periods, and courts generally will require commenters to have done so as a matter of exhaustion of administrative remedies. EPA has concluded that these principles provide sufficient assurance that commenters will raise timely objections and provide timely information and has therefore decided to strike the proposed regulatory text.

2. Hazard assessment. In compliance with TSCA section 6(b)(4)(F), EPA will conduct a hazard assessment on each chemical substance or category, under the conditions of use as identified in the scope. A hazard assessment identifies the types of adverse health or environmental effects or hazards that can be caused by exposure to the chemical substance in question, and to characterize the quality and weight of the scientific evidence supporting this identification. Hazard identification is the process of determining whether exposure to a chemical stressor can

cause an increase in the incidence of specific adverse health or environmental effects (e.g., cancer, developmental toxicity). All information used in this assessment will be reviewed in a manner consistent with reliance on the best available science and a weight of the scientific evidence approach.

As the rule text indicates, EPA will present the hazard information, as identified in the scope, for the identified exposure scenarios, and including any identified potentially exposed or susceptible subpopulation. From the proposed rule, EPA changed the word “endpoints” to “hazards,” as hazards is more general and inclusive.

The hazard assessment will identify the types of hazards to human health and the environment. The information will be reviewed in a manner consistent with use of the best available science and with the weight of scientific evidence. This will include the identification, evaluation, and synthesis of information to describe the potential health and environmental hazards of the chemical, under the conditions of use, and all assessment methods will be documented. This hazard assessment may include, but may not be limited to, evaluation of the potential toxicity of the chemical substance with respect to cancer, mutation, reproductive, developmental, respiratory, immune, and cardiovascular impacts, and neurological impairments. The assessment may evaluate effects at life stage(s) most appropriate for a receptor target.

A hazard assessment also will include a dose-response assessment. A dose-response relationship describes how the likelihood and severity of adverse health effects (the responses) are related to the amount and condition of exposure to an agent (the dose provided). The same principles generally apply for studies where the exposure is to a concentration of the agent (e.g., airborne concentrations applied in inhalation exposure studies or water or other media concentrations for ecological exposure studies), and the resulting information is referred to as the concentration-response.

Potential information sources that may support the hazard assessment include but are not limited to: Population based epidemiological studies that identify risk factors and susceptible subpopulations; information related to geographic location of subpopulations; models that represent health effects of relevant subpopulation; *in vivo* and/or *in vitro* laboratory studies; mechanistic or kinetic studies in a variety of test systems, including

but not limited to toxicokinetics and toxicodynamics, and computational toxicology, which the final rule makes clear may include high-throughput assays, genomic response assays, data from structure-activity relationships, and ecological field data. The hazard identification will also include an evaluation of the strength, limitations, and uncertainties associated with the reasonably available information. The final rule was amended to include uncertainties as commenters encouraged EPA to further discuss how uncertainties will be addressed in this process.

Specifically, for human health hazards, the assessment will consider all potentially exposed or susceptible subpopulation(s) identified in the scope. EPA will use an appropriate combination, if available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing health effects to the population, and any other information or methodology consistent with scientific standards.

An environmental hazard assessment will evaluate the relationship between the chemical substance and the occurrence of an ecological response. This assessment may be conducted using reasonably available information from field or laboratory data, modeling strategies, and species extrapolations, if needed.

Changes from the proposed rule include the addition of EPA’s commitment to using the best available science and a weight of the evidence approach. Some specific details regarding the available information that may be used in hazard assessments have been moved to this preamble. The proposal stated that EPA “may include” followed by a list of types of information, and although the phrase “may include” provides flexibility, EPA believes that it is more appropriate to not codify this level of specific detail in the regulation. Many public comments encouraged transparency in the Agency’s risk evaluation process, but because this rule must cover the process for all risk evaluations, which by nature will necessitate the consideration of many types of information sources, EPA believes the better (and ultimately more accurate) approach is to ensure that it provides full transparency in the individual risk evaluations.

3. *Exposure assessment.* Pursuant to TSCA section 6(b)(4)(F), EPA, “where relevant, will take into account the likely duration, intensity, frequency, and number of exposures under the conditions of use in an exposure

assessment.” An exposure assessment will include information on chemical-specific factors, including but not limited to: Physical-chemical properties and environmental fate and transport parameters. These considerations were included in the proposed rule; however “transport” has been added to the final text. Fate and transport in environmental media are commonly assessed together, and this is more consistent with EPA’s current practices. EPA has also added a statement in the rule text regarding the use of best available science and weight of scientific evidence approaches. As stated elsewhere in the preamble, EPA is committed to upholding these statutory requirements.

An exposure assessment includes some discussion of the size, nature, and types of individuals or populations exposed to the agent, as well as discussion of the uncertainties in this information. Exposure can be measured directly, but when data is unavailable it is estimated indirectly through consideration of measured concentrations in the environment, consideration of models of chemical transport and fate in the environment, and estimates of human intake or environmental exposure over time. A number of commenters encouraged the use of probabilistic approaches as they provide better estimates of exposure when compared to specific “bright line” approaches. In response EPA will strive to utilize probabilistic approaches for exposure assessments included in a risk evaluation but has not revised the proposed regulation, consistent with its approach to other provisions, where EPA has moved many of the specific approaches that appeared in the proposed rule text into the final preamble. EPA believes that this level of detail regarding the specific information types used in risk evaluation is more appropriate for guidance. Commenters had also suggested that guidance is more appropriate for specific methods and approaches because it can be amended easily to adopt to changing science. Codifying specific methods could unnecessarily restrict the Agency’s ability to review all pertinent information.

Using reasonably available information, exposures will be estimated (usually quantitatively) for the identified conditions of use. For human health exposure, the assessment would consider all potentially exposed or susceptible subpopulation(s) identified in the scope and utilize any combination, as available, of population-based epidemiological studies, information related to

geographic location of susceptible subpopulations, models representing exposures to the population, measurements in human tissues or relevant environmental or exposure media, and any other relevant, scientifically valid information or methodology. In an environmental health exposure assessment the interaction of the chemical substance with any ecological characteristics identified in the scope will be characterized and evaluated. As with the hazard assessment, specific details on the source of information EPA will use have been moved to this preamble to allow for flexibility in identifying the appropriate sources of information.

4. *Risk characterization.* TSCA requires that a risk evaluation “integrate and assess available information on hazards and exposures.” (15 U.S.C. 2605(b)(4)(F)). A risk characterization conveys the risk assessor’s judgment as to the nature and presence or absence of risks, along with information about how the risk was assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made. Risk characterization takes place for both human health risk assessments and ecological risk assessments. The proposed text only included the necessity for EPA to describe whether aggregate or sentinel exposures were considered during the risk evaluation and the basis for that consideration. The final rule text was amended to include all of the statutory requirements of the risk evaluation process, including: Not considering costs or other non-risk factors; taking into account the likely duration, intensity, frequency, and number of exposures under the condition(s) of use; and a description of the weight of scientific evidence for the identified hazards and exposures. The statute requires a risk evaluation to include all of these components, so EPA believed it was necessary to codify them all, rather than to single out just one of the requirements.

In the risk characterization summary, EPA will further carry out the obligations under TSCA section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review. 15 U.S.C. 2625(h). EPA may include a discussion of alternative interpretations, where these interpretations are plausible, of

results generated from the risk evaluation. EPA amended the regulation text to include the phrase “where these interpretations are plausible,” because EPA believes, in agreement with a commenter, that through the use of best available science and weight of scientific evidence approaches, it is feasible that not every risk evaluation will have alternative interpretations. EPA wants to be clear that alternative interpretations will be presented in the risk characterization on a case-by-case basis, but may not be the norm, as requested by another commenter.

For environmental evaluations specifically, EPA plans to include a discussion of the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the species, population, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance. A few commenters suggested that when conducting an ecological risk assessment, it is important to consider the population level, as this was not included in the proposed rule. The commenters’ suggestion more accurately reflects EPA’s general practices for ecological risk assessments and this change has been made in the final rule.

In practice, each component of the risk assessment (e.g., hazard assessment, dose-response assessment, exposure assessment) has an individual characterization written to carry forward the key findings, assumptions, limitations, and uncertainties. The set of these individual characterizations provide the information basis to write an integrative risk characterization analysis. The final, overall risk characterization thus consists of the individual component characterizations plus an integrative analysis. Each risk evaluation will quantitatively and/or qualitatively estimate and characterize risk for the identified populations and ecological characteristics under the conditions of use.

EPA has historically used a MOE approach in risk characterization of TSCA risk assessments. The proposed rule asked the public to comment on the strengths and weaknesses of the MOE approach. EPA received many comments with thoughtful reasoning both for and against using this approach. As discussed by commenters, the benefits of the MOE approach include the assertion that the approach is more transparent than other approaches, such as a hazard index or hazard quotient, because the application of uncertainty factors is transparent, and that the MOE approach can incorporate data from multiple pathways and endpoints. Some supporters of the MOE

approach did encourage EPA to not prescribe a single value that would be used for all risk evaluations, but to select a MOE value that is fit-for-purpose and specifically associated with the evidence of the evaluation.

Commenters that were not supportive of this approach expressed their concern for this “bright line” approach, in that it does not reflect knowledge about what the potential risks are above or below the ‘line,’ and that it assumes a safe level of exposure below which harm will not occur. Others commented that the MOE approach is not always easily communicated to the public. Many commenters suggested alternatives, including the use of probabilistic approaches, arguing that they better account for variability and uncertainty. Finally, others commented that it was not appropriate to call out specific methods, as this is more appropriate for guidance.

Agreeing with the consensus from the comments, EPA acknowledges that MOE is just one of many ways to characterize risk. There will be risk scenarios where one approach may be better than another, and as commenters correctly pointed out, the science of risk characterization is still evolving, particularly for non-cancer hazards. To account for the number of different approaches and for changing science, EPA will not codify any specific method in this final rule.

Finally, EPA will utilize EPA’s Information Quality Guidelines in the risk characterization section of the risk evaluation, as it provides guidance for presenting risk information (Ref. 5). As explained in that document, EPA should identify: (1) Each population addressed by an estimate of applicable risk effects; (2) the expected risk or central estimate of risk for the potentially exposed or susceptible subpopulations affected; (3) each appropriate upper-bound or lower-bound estimate of risk; (4) each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) peer-reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

5. *Peer review.* For each risk evaluation conducted on chemicals identified pursuant to TSCA section 6(b)(4)(A), EPA will conduct a peer review using the guidance provided in executive branch peer review directives, including in the Office of Management and Budget Final Information Quality

Bulletin for Peer Review (OMB Bulletin) (Ref. 18) and in the EPA Peer Review Handbook (2015) (Ref. 19) or its updates. For those conditions of use that may receive an early determination of no unreasonable risk, EPA will ensure that the risk assessments underlying these determinations are reviewed in a manner consistent with the OMB Bulletin and the EPA Peer Review Handbook. These documents do provide some latitude for the type of peer review that EPA can conduct, which EPA will take advantage of. For example, in determining the appropriate type of peer review, EPA can consider the complexity of the information and any prior peer review of underlying information. EPA may also utilize the SACC in reviewing the science that underlies these determinations.

As discussed in the proposed rule, EPA will identify aspects of the analysis on which peer review will be conducted, and the planned methodologies, as part of the draft scoping document that will undergo public comment for each chemical substance that undergoes risk evaluation. These may include novel models or analyses that warrant an in-depth peer review. In addition to any targeted peer review of specific aspects of the analysis, the entire risk assessment will also undergo peer review, as it is important for peer reviewers to consider how the various underlying analyses fit together to produce an integrated risk characterization, which will form the basis of an unreasonable risk determination. A number of commenters argued for involvement of the public into the peer review process. To respond to this, EPA plans to take public comment on the charge questions given to peer reviewers.

The peer review will address aspects of the science underlying the assessment, including, but not limited to hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. Consistent with the proposed rule, EPA will not seek review of any determination as to whether the risks are “unreasonable,” which is an Agency policy determination. EPA did receive public comment requesting that the risk determination also be subject to peer review; however, EPA strongly believes that the purpose of peer review is for the independent review of the science underlying the risk assessment, not an evaluation of EPA’s policy determinations. TSCA expressly reserves to the Agency the final determination of whether risk posed by a chemical substance is “unreasonable.”

15 U.S.C. 2605(i). EPA nevertheless will include its risk determination as part of the risk evaluation that is subject to public review and comment.

EPA specifically requested public comment on whether there are circumstances where conducting peer review may not be warranted, (e.g., what circumstances may require peer review and if there are others that may not) and whether the regulatory text should be adjusted to require EPA to make a case by case determination of whether and to what extent, consistent with the EPA Peer Review Handbook, peer review is warranted for the chemical substance undergoing a risk evaluation. The comments received were generally very supportive of conducting a peer review on all risk evaluations. There were some comments that encouraged discretion as to whether peer review had to be conducted on a particular risk evaluation (e.g., determinations of no unreasonable risk, or on evaluations where the result was consistent with other national or international conclusions). Commenters also raised issues regarding the timing of peer review in the risk evaluation process (e.g., after public comment), what should and should not be included in peer review (e.g., the risk determination), and views on what type of peer review should be conducted (e.g., full panel review). EPA’s responses to specific comments are addressed in the response to comment document.

Accordingly, EPA has retained the provision from the proposed rule requiring peer review on all risk evaluations. Guidance on how peer review will be conducted will remain consistent with the EPA Peer Review Handbook. For clarity, EPA did move the peer review provision to its own section of the rule, as suggested by a commenter. EPA agrees with comments that peer reviewed evaluations will instill greater confidence and provide transparency to the process. EPA postulated in the proposed rule that there may be circumstances that may not necessitate peer review (e.g., where a chemical substance is found to not present an unreasonable risk or that findings are similar or the same as other jurisdictions (states or countries) that have reached similar conclusions based on the same information). Public comment presented arguments to why this is not appropriate. Although a substance may not present an unreasonable risk, the consequence of a ‘false negative’ could be extremely problematic. For the second scenario where EPA’s results may be similar to another jurisdiction’s, commenters argued that it will also be necessary to

peer review the evaluation. It would be necessary to make certain the best available science and weight of the scientific evidence approaches were used properly, as they may not have been required under the process by which the comparable evaluation was conducted. As such, EPA will require peer review on all risk evaluations.

6. Unreasonable risk determination.
The final step of a risk evaluation is for EPA to determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment. EPA will make individual risk determinations for all uses identified in the scope. This part of the regulation is slightly amended from the proposed rule, to clarify that the risk determination is part of the risk evaluation, as well as to account for the revised approach to that ensures each condition of use covered by the risk evaluation receives a risk determination. Due to EPA’s decision to allow for early determinations on one or more conditions of use, where appropriate, risk determinations may be published in multiple documents or in a single document containing all risk determinations for all identified uses. If the determinations are published in multiple documents, the final determination will be a composite document of all determinations made. EPA’s determinations will specify whether each condition of use identified for a chemical substance does or does not present an unreasonable risk of injury to health or the environment. A determination that a condition of use does not present an unreasonable risk is considered to be a final EPA action. If EPA determines that the chemical substance, under one or more condition of use, does present an unreasonable risk, EPA must initiate a rulemaking pursuant to TSCA section 6(a) to impose requirements to the extent necessary so that the substance no longer presents such risk. 15 U.S.C. 2605(a). Any rule would apply only to the condition(s) of use that present an unreasonable risk, and those that do not present an unreasonable risk will not be subject to risk management. A number of commenters asked EPA to communicate clearly which uses may go to risk management following the evaluation. EPA will clarify in the draft and final risk evaluation documents specifically which condition(s) of use warrant risk management and which do not.

7. Reassessment of unreasonable risk determination. EPA stated in the proposed rule that it may reassess determinations of unreasonable risk. A number of commenters requested clarification on when and how this

might happen. Following review of the comments, EPA has deleted the provision as it was unnecessary. Generally, agencies are authorized to revisit determinations they are charged by statute to make, and nothing in TSCA prevents EPA from doing that. EPA is also concerned that the provision could have been read as an effort to limit, expand, or otherwise alter the statutory authority.

8. *Additional publicly available information.* Pursuant to TSCA section 26(j), and subject to TSCA section 14, the final regulation specifies that EPA will make available: (1) The draft scope, final scope, draft risk evaluation, and final risk evaluation; (2) All notices, determinations, findings, consent agreements, and orders; (3) Any information required to be provided to the Agency under 15 U.S.C. 2603; (4) A nontechnical summary of the risk evaluation; (5) A list of the studies, with the results of the studies, considered in carrying out each risk evaluation; (6) Each determination as to whether the chemical substance presents an unreasonable risk under one or more conditions of use, along with an identification of the information, analysis, and basis used to make the designation; (7) The final peer review report, including the response to peer review and public comments received during peer review; and (8) Response to public comments received on the draft scope and the draft risk evaluation. In this final rule there are a few slight changes from the proposed regulation, largely to conform to changes made to other sections of the rule. The final rule now includes number 6, which has been slightly amended from the statute to make clear that EPA will be making public its risk determinations (the statute uses the term “designations”). In addition, the final regulation now specifies and that these determinations will be made for the chemical under the one or more conditions of use identified in the risk evaluation.

IV. Summary of Request for Specific Public Comment on the Proposed Rule

In the Proposed Risk Evaluation Rule, EPA requested specific public input on a number of subjects. These subjects are listed below along with reference of the particular section where EPA has discussed the public comment.

1. *Redefining scientific terms.* Unit III.D.
2. *Margin of Exposure.* Unit III.D.13.
3. *Systematic Review.* Unit III.D.12.
4. *Manufacturer requests.* Unit II.A.2.
5. *Peer Review.* Unit III.G.5.

6. *Reliance on existing guidance and procedures for conducting risk evaluations.* Unit III.G.1.a.

7. *Interagency collaboration.* Unit III.H.

V. Cost Analysis

Industry costs for this rule are limited to activities a manufacturer must perform in order to meet the requirements outlined in previous sections. Manufacturers are not required to submit a chemical substance for risk evaluation, therefore these costs will only be experienced when a given manufacturer chooses to make a submission to the Agency. The fully loaded wage rate of a technical professional (*i.e.*, toxicologist) of \$78.40 was used to calculate the cost of labor burden.

A. Number of Entities Affected

EPA developed estimates for the number of manufacturers who are likely to elect to submit a chemical substance for risk evaluation. Since submissions of this nature have never been collected by the Agency before, the actual number of expected submittals is relatively unknown. However, EPA assumes 5 chemical manufacturers may submit requests to the Agency in any given year. The Agency will not be required to perform 20 risk evaluations at any given time until 2 years after rule finalization. Based on this, assuming 25 percent of total risk evaluations coming from manufacturer submissions was considered a best estimate with the lack of actual data. The total number of entities affected by the recordkeeping and reporting requirements of the rule, therefore, is estimated to be 5 chemical manufacturers per year.

B. Rule Familiarization Burden

EPA assumes that each manufacturer who elects to submit a chemical substance for risk evaluation consideration is assumed to spend one hour becoming familiar with the requirements of the rule and developing an understanding of what actions are necessary to complete the forms and submission package. This is separate from the time it takes to create the submission package itself.

The total cost of rule familiarization is estimated to be \$392 per year ($5 \times 1 \times 78.40 = 392$).

C. CDX Electronic Reporting Burden

Manufacturers requesting a chemical substance be considered by EPA for risk evaluation are required to provide the submission package to the Agency via the CDX electronic system. While several manufacturers may be familiar

with the CDX system and are registered users because the same system is used for new chemical submissions to the Agency (*e.g.*, pre-manufacture notice, significant new use notice, low volume exemptions) there is no way to estimate which manufacturers submitting risk evaluation requests are familiar with CDX and which are new to the system. Therefore, EPA assumes submissions under this rule are performed by new users of CDX which may result in an overestimate of burden.

The CDX electronic reporting burden includes registration to CDX, familiarization with the subscriber agreements, potential use of the help desk, and problem resolution. The burden estimates used in this rule are based off of estimates in EPA ICR No. 2502.02, resulting in a burden of 2.83 hours per respondent.

The total cost of CDX electronic reporting burden is estimated to be \$1,109 per year ($5 \times 2.83 \times 78.40 = 1,109$).

D. Submission Package Burden

Chemical manufacturers electing to request EPA consider a chemical substance for risk evaluation must provide a submission package including the following information: Contact information of requesting entity(s), full chemical identity information, complete list of reasonably available information consistent with TSCA section 26(h) standards that is relevant to an unreasonable risk determination, addresses all the circumstances that constitute conditions of use, of interest to the manufacturer, within the meaning of TSCA section 3, contain a commitment to provide EPA any referenced information upon request of the Agency, and provide a signed certification that all information in the submission is accurate and complete.

While submissions of this nature have never been required or requested by EPA in the past, the Agency has performed similar tasks internally while conducting previous Risk Evaluations. The average contractor expense and labor time the Agency spends on the types of activities required to prepared the submission package covered by this rule were used to develop the burden and cost estimates.

EPA estimates the cost of having a contractor conduct an in-depth literature review and screen the literature found for relevance costs an average of \$50,000 per chemical. This includes the cost of using literature review databases and the contractor labor time involved in performing the review and screening activities. In addition to the contractor cost, the

manufacturer is expected to spend an average of 80 hours per chemical reviewing the data found during the literature, refining the searches as needed, and preparing the submission package. Therefore, the estimated burden for developing and submitting a risk evaluation request is 80 hours per respondent with an additional direct cost of \$50,000 per submission package.

Total cost for submission package burden is estimated to be \$281,360 per year ($5 \times 50,000 \times 80 \times 78.40 = 281,360$).

E. Total Cost

The total annual cost for this rule is estimated to be \$282,861 per year ($392 + 1,109 + 281,360 = 282,861$) under the assumption EPA receives 5 manufacturer requests per year. Manufacturers choosing to submit a chemical substance for risk evaluation may be a small entity. Due to the low cost (\$56,572) of a single submission package, the cost of the voluntary submission is expected to impact less than 1% of the small business at greater than 3% of average revenue in the estimated universe of small businesses.

VI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

- USEPA. Information Collection Request (ICR) for the Proposed Rule: Procedures for Chemical Risk Evaluation Under TSCA. EPA ICR No.: 2559.01 and OMB No. 2070—[NEW].
- EPA. TSCA Work Plan Chemical Assessments: 2014 Update-Final. Office of Pollution Prevention and Toxics. October 2014. <https://www.epa.gov/sites/production/files/2015-01/documents/tscaworkplanchemicals2014update-final.pdf>.
- EPA. Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum. Washington, DC. March 2007.
- USEPA. Exposure Factors Handbook. EPA/600/R-090/052F. Office of Research and Development, National Center for Environmental Assessment. Washington, DC. 2011. <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252>.
- Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency. EPA/260R-02-008. Washington, DC. 2002. <https://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf>.
- European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC). Targeted Risk Assessment User Guide. version 3.1. June 2014. http://www.ecetoc.org/wp-content/uploads/2014/06/Ecetoc_Tra_Standalone_Consumer_Tool_User_Guide_Jun2014.pdf.
- Toxicology Excellence for Risk Assessment (TERA). Complex Exposure Tool (ComET) Meeting Materials. 2009. <http://www.tera.org/Peer/Exposure/ExposureMeetingMaterials.htm>.
- USEPA. Framework for Human Health Risk Assessment to Inform Decision Making. EPA/100/R-14/001 Office of the Science Advisor, Risk Assessment Forum. 2014. <https://archive.epa.gov/raf/web/pdf/hhra-framework-final-2014.pdf>.
- National Research Council. Science and Decisions: Advancing Risk Assessment. The National Academies Press. Washington, DC. 2009.
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- Institute of Medicine. Finding What works in Health Care: Standards for Systematic Reviews. p. 13–34. The National Academies Press. Washington, DC. 2011.
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- Stephens, M.F., Betts, K., Beck, N.B., Cogliano, V., Dickersin, K., Fitzpatrick S., Freeman, J., Gray, G., Hartung T., McPartland, J., Rooney A.A., Scherer R.W., Verloo, D., Hoffmann, S. The Emergence of Systematic Review in Toxicology. *Toxicological Sciences*. 152 (1): 10–16. 2016. DOI: <https://doi.org/10.1093/toxsci/kfw059>.
- USEPA. Risk Assessment Guidelines. <https://www.epa.gov/risk/risk-assessment-guidelines>.
- USEPA. Pesticide Science and Assessing Pesticide Risks. <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks>.
- USEPA. Predictive Models and Tools for Assessing Chemicals under the Toxic Substances Control Act (TSCA). <https://www.epa.gov/tscascreening-tools>.
- Office of Management and Budget Final Information Quality Bulletin for Peer Review. Washington, DC. 2004. https://19january2017snapshot.epa.gov/sites/production/files/2015-01/documents/omb_final_info_quality_bulletin_peer_review_2004_1.pdf.
- USEPA. Peer Review Handbook. 3rd ed. EPA/100/B-06/002. Science Policy Council. Washington, DC. 2006. <https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015>.

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations are documented in the docket. EPA conducted an analysis of the potential costs associated with this action. This analysis, can be found in Unit V. This action is not subject to the requirements of Executive Order 13771, entitled “Reducing Regulation and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017) because this rule results in no more than *de minimis* costs.

B. Paperwork Reduction Act (PRA)

The information collection activities associated with this rule have been submitted to OMB for review and approval under the PRA, 44 U.S.C. 3501 *et seq.* Specifically, EPA has prepared an ICR to estimate the potential burden and costs associated with the requirements for submitting a request for an Agency-conducted risk evaluation on a particular chemical substance. The ICR, which is available in the docket, has been assigned the EPA ICR number 2559.01. You can find a copy of the ICR in the docket for this rule (Ref. [Insert reference #]), and it is briefly summarized here.

Respondents/Affected Entities: Manufacturers (including importers).

Respondent's Obligation to Respond: Optional, *i.e.*, needed only if they are requesting an EPA-conducted risk evaluation for a particular chemical substance.

Estimated Number of Respondents: 5.
Frequency of Response: On occasion.
Total Estimated Annual Burden: 419.2 hours. Burden is defined in 5 CFR 1320.3(b).

Total Estimated Annual Cost: \$282,861 for burden hours. There are no O&M costs.

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. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act (RFA)

EPA certifies under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, that this action will not have a significant economic impact on a substantial number of small entities. Although this rule primarily addresses internal EPA procedures and activities associated with conducting risk evaluations for chemical substances as required by TSCA, EPA is also including the process and content requirements for a manufacturer (including importer) to request that EPA conduct a risk evaluation on particular uses of interest of a chemical substance. EPA has determined that the process and content requirements proposed will have minimal impact on an entity, regardless of size, because there is no mandate for them to make such a request, and the information they must provide should they decide to make such a request, which involves basic information about the chemical substance and the manufacturer's reasons for requesting the EPA-conducted risk evaluation on that chemical substance, should be readily available to the manufacturer. Estimated potential burden and costs are presented in the ICR (Ref. 1).

EPA developed estimates for the number of manufacturers likely to submit a request for a chemical substance to be considered for a risk evaluation. EPA has never collected submissions of this nature in the past, so the actual number of expected submissions is unknown. EPA estimates five manufacturer-requested submissions may be sent to EPA in any given year. Based on the average number of manufacturers (and small businesses) per chemical for the ten chemicals initially identified by EPA for risk evaluation, EPA estimates an average of 35 manufacturers will be involved with the five manufacturer-requested submissions for risk evaluations each year. Of the 35 affected manufacturers, 15 are estimated to be small businesses. Based on the ten chemicals initially identified by EPA for risk evaluations, there are an average of seven manufacturers per chemical. Assuming that submission costs are shared equally within a consortium of seven manufacturers, the one-time respondent cost of \$56,572 per submission would be \$8,082 per manufacturer.

Based on revenue data from U.S. Census Statistics of US Business and an estimated cost of \$8,082 per manufacturer, EPA estimated the proportion of small manufacturer firms that could have a cost impact of less than 1%; between 1% and 3%; and

more than 3% of the average revenues. The proportion of small business firms which may incur a cost impact of less than 1% of the average revenues is 76% of the small firms (approximately 11 of the 15 affected small manufacturers). The proportion of small business firms which may incur a cost impact between 1% and 3% of the average revenues is 23% of the small firms (approximately 3 of the 15 affected small manufacturers). The proportion of small business firms which may incur a cost impact greater than 3% of the average revenues is 1% of the small firms (approximately 1 of the 15 small manufacturers).

The decision to request a risk assessment for a chemical is voluntary and manufacturers may decide not to make such a request. But if such a request is made, the burden for the needed paperwork still does not result in a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

This Action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will 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. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental

health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–201 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not establish an environmental health or safety standard, and is therefore not subject to environmental justice considerations under Executive Order 12898 (59 FR 7629, February 16, 1994). This is a procedural rule that will not affect the level of protection provided to human health or the environment.

K. Congressional Review Act (CRA)

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

List of Subjects in 40 CFR Part 702

Environmental protection, Chemicals, Chemical substances, Hazardous substances, Health and safety, Risk evaluation.

Dated: June 22, 2017.

E. Scott Pruitt,
Administrator.

Therefore, 40 CFR chapter I, subchapter R, is amended as follows:

PART 702—[AMENDED]

■ 1. The authority citation for part 702 is revised to read as follows:

Authority: 15 U.S.C. 2605 and 2619.

■ 2. Add subpart B to read as follows:

Subpart B—Procedures for Chemical Substance Risk Evaluations

Sec.

- 702.31 General provisions.
- 702.33 Definitions.
- 702.35 Chemical substances designated for risk evaluation.
- 702.37 Submission of manufacturer requests for risk evaluations.
- 702.39 Interagency collaboration.
- 702.41 Evaluation requirements.
- 702.43 Risk Characterization.
- 702.45 Peer review.
- 702.47 Unreasonable risk determination.
- 702.49 Risk evaluation timeframes and actions.
- 702.51 Publically available information.

§ 702.31 General provisions.

(a) *Purpose.* This subpart establishes the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B) (15 U.S.C. 2605(b)(4)(B)).

(b) *Scope.* These regulations establish the general procedures, key definitions, and timelines EPA will use in a risk evaluation conducted pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)).

(c) *Applicability.* The requirements of this part apply to all chemical substance risk evaluations initiated pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)).

(d) *Enforcement.* Submission to EPA of inaccurate, incomplete, or misleading information pursuant to a risk evaluation conducted pursuant to 15 U.S.C. 2605(b)(4)(B) is a prohibited act under 15 U.S.C. 2614, subject to penalties under 15 U.S.C. 2615 and Title 18 of the U.S. Code.

§ 702.33 Definitions.

All definitions in TSCA apply to this subpart. In addition, the following definitions apply:

Act means the Toxic Substances Control Act, as amended (15 U.S.C. 2601 *et seq.*).

Aggregate exposure means the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways.

Best available science means science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). Additionally, EPA will consider as applicable:

(1) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(2) The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

(3) The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(4) The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(5) The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.

Conditions of use means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

EPA means the U.S. Environmental Protection Agency.

Pathways means the mode through which one is exposed to a chemical substance, including but not limited to: Food, water, soil, and air.

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by the Agency who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

Reasonably available information means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation. Information that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14.

Routes means the particular manner by which a chemical substance may contact the body, including absorption

via ingestion, inhalation, or dermally (integument).

Sentinel exposure means the exposure from a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures.

Uncertainty means the imperfect knowledge or lack of precise knowledge of the real world either for specific values of interest or in the description of the system.

Variability means the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population.

Weight of scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

§ 702.35 Chemical substances designated for risk evaluation.

(a) *Chemical substances undergoing risk evaluation.* A risk evaluation for a chemical substance designated by the Agency as a High-Priority Substance pursuant to the prioritization process described in subpart A, identified under 15 U.S.C. 2605(b)(2)(A), or initiated at the request of a manufacturer or manufacturers under § 702.37, will be conducted in accordance with this part, except that risk evaluations that are initiated prior to the effective date of this rule will be conducted in accordance with this part to the maximum extent practicable.

(b) *Percentage requirements.* The Agency will ensure that, of the number of chemical substances that undergo risk evaluation under 15 U.S.C. 2605(b)(4)(C)(i), the number of chemical substances undergoing risk evaluation under 15 U.S.C. 2605(b)(4)(C)(ii) is not less than 25%, if sufficient requests that comply with 702.37, and not more than 50%.

(c) *Manufacturer requests for work plan chemical substances.* Manufacturer requests for risk evaluations, described in paragraph (a) of this section, for chemical substances that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments will be granted at the discretion of the Agency. Such evaluations are not subject to the percentage requirements in paragraph (b) of this section.

§ 702.37 Submission of manufacturer requests for risk evaluations.

(a) *General provision.* Any request that EPA conduct a risk evaluation pursuant to this part must comply with all the procedures and criteria in this section to be eligible to be granted by EPA.

(b) *Method for submission.* One or more manufacturers of a chemical substance may request that EPA conduct a risk evaluation. All requests submitted to EPA under this subpart must be submitted via the EPA Central Data Exchange (CDX) found at <http://cdx.epa.gov>. Requests must include all of the following information:

(1) Name, mailing address, and contact information of the entity (or entities) submitting the request. If more than one manufacturer submits the request, all individual manufacturers must provide their contact information.

(2) The chemical identity of the chemical substance that is the subject of the request. At a minimum, this includes, all known names of the chemical substance, including common or trades names, CAS number, and molecular structure of the chemical substance. A request for risk evaluations of a category of chemical substances must include an explanation of why the category is appropriate under 15 U.S.C. 2625(c), and EPA will grant such request only upon determining that the requested category is appropriate for risk evaluation.

(3) The manufacturer must identify the circumstances on which they are requesting that EPA conduct a risk evaluation and include a rationale for why these circumstances constitute conditions of use under § 702.33.

(4) The request must also include a list of all the existing information that is relevant to whether the chemical substance, under the circumstances identified by the manufacturer(s), presents an unreasonable risk of injury to health or the environment. The list must be accompanied by an explanation as to why such information is adequate to permit EPA to complete a risk evaluation addressing the circumstances identified by the manufacturer(s). The request need not include copies of the information; citations are sufficient, if the information is publicly available. The request must include or reference all available information on the health and environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s), as relevant to the circumstances identified in the request. At a minimum, this must include all the following, as relevant to the circumstances identified:

(i) The chemical substance's hazard and exposure potential;

(ii) The chemical substance's persistence and bioaccumulation;

(iii) Potentially exposed or susceptible subpopulations which the manufacturer(s) believes to be relevant to the EPA risk evaluation;

(iv) Whether there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and the nearby drinking water source(s);

(v) The chemical substance's production volume or significant changes in production volume; and

(vi) Any other information relevant to the potential risks of the chemical substance under the circumstances identified in the request.

(5) The request must include a commitment to provide to EPA any referenced information upon request.

(6) Scientific information submitted must be consistent with the scientific standards in 15 U.S.C. 2625(h).

(7) A signed certification that all information contained in the request is accurate and complete, as follows:

(i) I certify that to the best of my knowledge and belief:

(A) The company named in this request manufacturers the chemical substance identified for risk evaluation.

(B) All information provided in the notice is complete and accurate as of the date of the request.

(C) I have either identified or am submitting all information in my possession, control, and a description of all other data known to or reasonably ascertainable by me as required for this request under this part. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information in this request and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

(ii) [Reserved]

(c) *Optional elements.* A manufacturer may provide information that will inform EPA's determination as to whether restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment, and that as a consequence the request is entitled to preference pursuant to 15 U.S.C. 2605(b)(4)(E)(iii).

(d) *Confidential business information.*

(1) Persons submitting a request under this subpart are subject to EPA confidentiality regulations at 40 CFR part 2, subpart B.

(2) In submitting a claim of confidentiality, a person must certify the accuracy of the following statements concerning all information claimed as confidential:

(i) I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that:

(A) My company has taken reasonable measures to protect the confidentiality of the information;

(B) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(C) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(D) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(ii) [Reserved]

(3) Each claim of confidentiality, other than a claim pertaining to information described in TSCA section 14(c)(2), must be accompanied by a substantiation in accordance with 15 U.S.C. 2613.

(4) Manufacturers must supply a structurally descriptive generic name where specific chemical identity is claimed as CBI.

(5) Any knowing and willful misrepresentation, under this section, is subject to criminal penalty pursuant to 18 U.S.C. 1001.

(e) *EPA process for evaluating manufacturer requests*—(1) *Review for completeness.* Upon receipt of the request, EPA will verify that the request is facially complete, *i.e.*, that information has been submitted that appears to be consistent with the requirements in paragraphs (b) through (d) of this section. EPA will inform the submitting manufacturer(s) if EPA has determined that the request is incomplete, and cannot be processed. Facially complete requests will be processed as described in this subpart.

(2) *Public notification of receipt of request.* Within 15 business days of receipt of a facially complete submission, EPA will notify the public of receipt of the manufacturer request. This notification will include any information submitted by the manufacturer that is not CBI, including the condition(s) of use for which the evaluation is requested.

(3) *Conditions of use to be evaluated.* EPA will assess whether the circumstances identified in the request constitute condition of use under

§ 702.33, and whether those conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will also assess what, if any, additional conditions of use that warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will conduct these assessments and make proposed determinations based on the same considerations applied in the same manner as it would for a risk evaluation for a high-priority substance.

(4) *Public notice and comment.* No later than 60 business days of receiving a request that EPA has determined to be complete under paragraph (e)(1) of this section, EPA will submit for publication the receipt of the request in the **Federal Register**, open a docket for that request and provide no less than a 45 calendar day public comment period. The docket will contain the manufacturer request (excluding information claimed as CBI) and EPA's proposed additions of conditions of use as described in paragraph (e)(3) of this section, and the basis for these proposed additions. During the comment period the public may submit comments and information relevant to the requested risk evaluation, in particular, commenters are encouraged to identify any information not included in the request or the proposed determinations that the commenters believe would be needed to conduct a risk evaluation, and to provide any other information relevant to EPA's proposed determinations of the conditions of use, such as information on other conditions of use of the chemical than those included in the request or in EPA's proposed determinations.

(5) *Supplementation of original request.* (i) At any time prior to the end of the comment period, the requesting manufacturer(s) may supplement the original request with any new information it receives.

(ii) At any point prior to the completion of a risk evaluation pursuant to this section, manufacturer(s) must supplement the original request with any information that meets the criteria in 15 U.S.C. 2607(e) and this section, or with any other information that has the potential to change EPA's risk evaluation with respect to the conditions of use as requested by the manufacturer. Such information must be submitted consistent with section 8(e) if the information is subject to that section or otherwise within 30 calendar days of the manufacturer's obtaining the information.

(6) *EPA's decision.* (i) Within 60 days of the end of the comment period provided in paragraph (e)(4) of this

section, EPA will review the request along with any additional information received during the comment period to determine whether the request meets the criteria and requirements of this section.

(ii) EPA will grant the request if it determines that all of the following have been met:

(A) That the circumstances identified in the request constitute conditions of use that warrant inclusion in a risk evaluation for the chemical substance;

(B) That EPA has all of the information needed to conduct such risk evaluation on the conditions of use that were the subject of the request; and

(C) All other criteria and requirements of this section have been met.

(iii) At the end of this 60-day period, EPA will notify the submitting manufacturer(s) of its decision and include the basis for granting or denying the request. Bases for a denial, include the manufacturer has not provided sufficient information to complete the risk evaluation on the condition(s) of use requested, or that the circumstances identified in the request either do not constitute conditions of use, or the conditions of use do not warrant inclusion in a risk evaluation for the chemical substance. This notification will also identify any additional conditions of use, as determined by the Administrator, that will be included in this risk evaluation.

(iv) Within 30 days of receipt of EPA's notification the requester(s) may withdraw the request.

(7) *Public notice of decision.* EPA will make public EPA's decision to grant or deny the request at the time that EPA notifies the manufacturer.

(8) *Compliant request.* EPA will initiate a risk evaluation for all requests for non-TSCA Work Plan Chemicals that meet the criteria in this subpart, until EPA determines that the number of manufacturer-requested chemical substances undergoing risk evaluation is equal to 25% of the High-Priority Substances identified in subpart A as undergoing risk evaluation. Once that level has been reached, EPA will initiate at least one new manufacturer-requested risk evaluation for each manufacturer-requested risk evaluation completed so long as there are sufficient requests that meet the criteria of this subpart, as needed to ensure that the number of manufacturer-requested risk evaluations is equal to at least 25% of the High-Priority substances risk evaluation and not more than 50%.

(9) *Preferences.* In conformance with § 702.35(c), in evaluating requests for TSCA Work Plan Chemicals and requests for non-TSCA Work Plan

chemicals in excess of the 25% threshold in § 702.35(b), EPA will first give preference to requests for risk evaluations on chemical substances:

(i) First, for which the Agency determines that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce, health or the environment; and then

(ii) Second, based on the order in which the requests are received.

(10) *No preferential treatment.* Once granted, EPA will initiate the risk evaluation and thereafter will conduct the risk evaluation following the procedures in §§ 702.39 through 702.51. EPA will not expedite or otherwise provide special treatment to a risk evaluation conducted as a result of a manufacturer's request.

(11) *Fees.* Manufacturers must pay fees to support risk evaluations as specified under 15 U.S.C. 2605(b)(4)(E)(ii).

§ 702.39 Interagency collaboration.

During the risk evaluation process, not to preclude any additional, prior, or subsequent collaboration, EPA will consult with other relevant Federal agencies.

§ 702.41 Evaluation requirements.

(a) *Considerations.* (1) Each risk evaluation will include all of the following components:

(i) A Scope, including a Conceptual Model and an Analysis Plan;

(ii) A Hazard Assessment;

(iii) An Exposure Assessment;

(iv) A Risk Characterization; and

(v) A Risk Determination.

(2) EPA guidance will be used, as applicable where it represents the best available science appropriate for the particular risk evaluation.

(3) Where appropriate, a risk evaluation will be conducted on a category of chemical substances. EPA will determine whether to conduct an evaluation on a category of chemical substances, and the composition of the category based on the considerations listed in 15 U.S.C. 2625(c).

(4) EPA will document that it has used the best available science and weight of scientific evidence approaches in the risk evaluation process.

(5) EPA will ensure that all supporting analyses and components of the risk evaluation are suitable for their intended purpose, and well-tailored to the problems and decision at hand, in order to inform the development of a technically sound determination as to whether a chemical substance presents an unreasonable risk of injury to health or the environment under the

conditions of use within the scope of the risk evaluation, based on the weight of the scientific evidence.

(6) The extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment.

(7) To the extent a determination as to the level of risk presented by a condition of use can be made, for example, using assumptions, uncertainty factors, and models or screening methodologies, EPA may determine that no further information or analysis is needed to complete its risk evaluation of the condition(s) of use.

(8) In general, EPA intends to determine whether a chemical substance does or does not present an unreasonable risk under all of the conditions of use within the scope of the risk evaluations, and intends to identify the individual conditions of use or categories of conditions of use that are responsible for such determinations.

(9) Within the time frame in § 702.43(d), EPA will complete the risk evaluation of the chemical substance addressing all of the conditions of use within the scope of the evaluation. However, EPA may complete its evaluation of the chemical substance under specific conditions of use or categories of conditions of use at any point following the issuance of the final scope document, and issue its determination as to whether the chemical substance under those conditions of use does or does not present an unreasonable risk to health or the environment under those conditions of use. EPA will follow all of the requirements and procedures in this Subpart when it conducts its evaluation of the chemical substance under any individual or specific conditions of use.

(10) EPA will evaluate chemical substances that are metals or metal compounds in accordance with 15 U.S.C. 2605(b)(2)(E).

(b) *Information and information sources.* (1) EPA will base each risk evaluation on reasonably available information.

(2) EPA generally expects to initiate a risk evaluation for a chemical substance when EPA believes that all or most of the information necessary to perform the risk evaluation is reasonably available. EPA expects to use its authorities under the Act, and other information gathering authorities, when necessary to obtain the information needed to perform a risk evaluation for a chemical substance before initiating the risk evaluation for such substance.

EPA will use such authorities on a case-by-case basis during the performance of a risk evaluation to obtain information as needed to ensure that EPA has adequate, reasonably available information to perform the evaluation.

(3) Among other sources of information, the Agency will consider information and advice provided by the Science Advisory Committee on Chemicals established pursuant to 15 U.S.C. 2625.

(4) In conducting risk evaluations, EPA will utilize reasonably available information including information, models, and screening methodologies, as appropriate. The approaches used will be determined by the quality of the information, the deadlines specified in TSCA section 6(b)(4)(G) for completing the risk evaluation, and the extent to which the information reduces uncertainty.

(5) Where appropriate, to the extent practicable, and scientifically justified, EPA will require the development of information generated without the use of new testing on vertebrates in performing risk evaluation.

(c) *Scope of the risk evaluation.* The scope of the risk evaluation will include all the following:

(1) The condition(s) of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation.

(2) The potentially exposed populations, including any potentially exposed or susceptible subpopulations as identified as relevant to the risk evaluation by the Agency under the conditions of use, that EPA plans to evaluate; the ecological receptors that EPA plans to evaluate; and the hazards to health and the environment that EPA plans to evaluate.

(3) A description of the reasonably available information and science approaches EPA plans to use in the risk evaluation.

(4) A conceptual model:

(i) The scope documents will include a Conceptual Model that describes actual or predicted relationships between the chemical substance, the conditions of use within the scope of the evaluation and human and environmental receptors.

(ii) The conceptual model will identify human and ecological health hazards the EPA plans to evaluate for the exposure scenarios EPA plans to evaluate.

(iii) Conceptual model development will consider the life cycle of the chemical substance, including manufacture, processing, distribution in commerce, storage, use, and disposal,

relevant to the conditions of use within the scope of the evaluation

(5) An analysis plan:

(i) The scope documents will include an analysis plan that identifies the approaches, methods, and/or metrics that EPA plans to use to assess exposures, effects, and risk, including associated uncertainty and variability for each risk evaluation. The analysis plan will also identify the strategy for using information, accepted science policies, models, and screening methodologies.

(ii) Hypotheses about the relationships identified in the conceptual model will be described. The relative strengths of alternative hypotheses if any will be evaluated to determine the appropriate risk assessment approaches.

(6) The Agency's plan for peer review.

(7) Developing the scope.

(i) *Draft scope.* For each risk evaluation to be conducted EPA will publish a document in the **Federal Register** that specifies the draft scope of the risk evaluation the Agency plans to conduct. The document will address the elements in paragraphs (c)(1) through (6) of this section.

(ii) *Timeframes.* EPA generally expects to publish the draft scope no later than 3 months from the initiation of the risk evaluation process for the chemical substance.

(iii) *Public comments.* EPA will allow a public comment period of no less than 45 calendar days during which interested persons may submit comment on EPA's draft risk evaluation scope. EPA will open a docket to facilitate receipt of public comments.

(8) Final scope:

(i) The Agency will, no later than 6 months after the initiation of a risk evaluation, publish a document in the **Federal Register** that specifies the final scope of the risk evaluation the Agency plans to conduct. The document shall address the elements in paragraphs (c)(1) through (6) of this section.

(ii) For a chemical substance designated as a High-Priority Substance under subpart A of this part, EPA will not publish the final scope of the risk evaluation until at least 12 months have elapsed from the initiation of the prioritization process for the chemical substance.

(d) *Hazard assessment.* (1) The hazard information relevant to the chemical substance will be evaluated using hazards identified in the final scope document published pursuant to paragraph (c)(8) of this section, for the identified exposure scenarios, including any identified potentially exposed or susceptible subpopulation(s).

(2) The hazard assessment process will identify the types of hazards to health or the environment posed by the chemical substance under the condition(s) of use within the scope of the risk evaluation. Hazard information related to potential health and environmental hazards of the chemical substance will be reviewed in a manner consistent with best available science and weight of scientific evidence as defined in § 702.33 and all assessment methods will be documented. This process includes the identification, evaluation, and synthesis of information to describe the potential health and environmental hazards of the chemical substance.

(3) Relevant potential human and environmental hazards will be evaluated.

(4) The relationship between the dose of the chemical substance and the occurrence of health and environmental effects or outcomes will be evaluated.

(5) Studies evaluated may include, but would not be limited to: Human epidemiological studies, in vivo and/or in vitro laboratory studies, biomonitoring studies, mechanistic and/or kinetic studies in a variety of test systems, including but not limited to toxicokinetics and toxicodynamics, computational toxicology such as high-throughput assays, genomic response assays, data from structure-activity relationships, and ecological field data.

(6) Hazard identification will include an evaluation of the strengths, limitations, and uncertainties associated with the reasonably available information.

(7) The human health hazard assessment will consider all potentially exposed and susceptible subpopulation(s) determined to be relevant, as identified in the final scope document published pursuant to paragraph (c)(8) of this section.

(8) The environmental health hazard assessment will consider the relationship between the chemical substance and the occurrence of an ecological hazard elicited.

(e) *Exposure assessment.* (1) Where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use will be considered.

(2) Chemical-specific factors including, but not limited to: Physical-chemical properties and environmental fate and transport parameters will be examined.

(3) Exposure information related to potential human health or ecological hazards of the chemical substance will be reviewed in a manner consistent with the description of best available science

and weight of scientific evidence in § 702.33 and all methods will be documented.

(4) The human health exposure assessment will consider all potentially exposed and susceptible subpopulation(s) determined to be relevant, as identified in the final scope document published pursuant to paragraph (c)(8) of this section.

(5) Environmental health exposure assessment:

(i) The environmental health exposure assessment will characterize and evaluate the interaction of the chemical substance with the ecological receptors identified in the final scope document published pursuant to paragraph (c)(8) of this section.

(ii) Exposures considered will include populations and communities, depending on the chemical substance and the ecological characteristic involved.

§ 702.43 Risk Characterization.

(a) *Risk Characterization considerations.* EPA will:

(1) Integrate the hazard and exposure assessments into quantitative and/or qualitative estimates of risk for the identified populations (including any potentially exposed or susceptible subpopulation(s)) identified in the final scope document published pursuant to § 702.41(c)(8) and ecological characteristics for the conditions of use within the scope of the risk evaluation;

(2) Describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for their consideration;

(3) Not consider costs or other nonrisk factors;

(4) Take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the condition(s) of use of the chemical substance; and

(5) Describe the weight of the scientific evidence for the identified hazards and exposures.

(b) *Risk Characterization summary.*

The Risk Characterization will summarize, as applicable, the considerations addressed throughout the evaluation components, in carrying out the obligations under 15 U.S.C. 2625(h). This summary will include, as appropriate, a discussion of:

(1) *Considerations regarding uncertainty and variability.* Information about uncertainty and variability in each step of the risk evaluation (e.g., use of default assumptions, scenarios, choice of models, and information used for quantitative analysis) will be integrated into an overall characterization and/or analysis of the

impact of the uncertainty and variability on estimated risks. EPA may describe the uncertainty using a qualitative assessment of the overall strength and limitations of the data used in the assessment.

(2) *Considerations of data quality.* A discussion of data quality (e.g., reliability, relevance, and whether methods employed to generate the information are reasonable for and consistent with the intended use of the information), as well as assumptions used, will be included to the extent necessary. EPA also expects to include a discussion of the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models used in the risk evaluation.

(3) *Considerations of alternative interpretations.* If appropriate and relevant, where alternative interpretations are plausible, a discussion of alternative interpretations of the data and analyses will be included.

(4) *Considerations for environmental risk evaluations.* For environmental risk evaluations, it may be necessary to discuss the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the individual, species, population, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance.

§ 702.45 Peer review.

The *EPA Peer Review Handbook* (2015), the Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin), and other available, relevant and applicable methods consistent with 15 U.S.C. 2625, will serve as the guidance for peer review activities. Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A).

§ 702.47 Unreasonable risk determination.

As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses within the scope of the risk evaluation, either in a single decision document or in multiple decision documents.

§ 702.49 Risk evaluation timeframes and actions.

(a) *Draft risk evaluation timeframe.* EPA will publish a draft risk evaluation in the **Federal Register**, open a docket to facilitate receipt of public comment,

and provide no less than a 60-day comment period, during which time the public may submit comment on EPA's draft risk evaluation.

(b) *Final risk evaluation.* (1) EPA will complete a risk evaluation for the chemical substance under the conditions of use within the scope of the risk evaluation as soon as practicable, but not later than 3 years after the date on which the Agency initiates the risk evaluation.

(2) The Agency may extend the deadline for a risk evaluation for not more than 6 months. The total time elapsed between initiation of the risk evaluation and completion of the risk evaluation may not exceed 3 and one half years.

(3) EPA will publish the final risk evaluation in the **Federal Register**.

(c) *Final determination of unreasonable risk.* Upon determination by the EPA that a chemical substance under one or more of the conditions of use within the scope of the risk evaluation presents an unreasonable risk of injury to health or the environment as described in § 702.47, the Agency will initiate action as required pursuant to 15 U.S.C. 2605(a).

(d) *Final determination of no unreasonable risk.* A determination by EPA that the chemical substance, under one or more of the conditions of use within the scope of the risk evaluation, does not present an unreasonable risk of injury to health or the environment will be issued by order and considered to be a final Agency action, effective on the date of issuance of the order.

§ 702.51 Publicly available information.

For each risk evaluation, EPA will maintain a public docket at <http://www.regulations.gov> to provide public access to the following information, as applicable for that risk evaluation:

(a) The draft scope, final scope, draft risk evaluation, and final risk evaluation;

(b) All notices, determinations, findings, consent agreements, and orders;

(c) Any information required to be provided to the Agency under 15 U.S.C. 2603;

(d) A nontechnical summary of the risk evaluation;

(e) A list of the studies, with the results of the studies, considered in carrying out each risk evaluation;

(f) The final peer review report, including the response to peer review and public comments received during peer review; and

(g) Response to public comments received on the draft scope and the draft risk evaluation.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 702

[EPA-HQ-OPPT-2016-0636; FRL-9964-24]

RIN 2070-AK23

Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: As required under section 6(b)(1) of the Toxic Substances Control Act (TSCA), EPA is issuing a final rule that establishes the process and criteria that EPA will use to identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at the time. The final rule describes the processes for formally initiating the prioritization process on a selected candidate, providing opportunities for public comment, screening the candidate against certain criteria, and proposing and finalizing designations of priority. Prioritization is the initial step in a new process of existing chemical substance review and risk management activity established under TSCA.

DATES: This final rule is effective September 18, 2017.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0636, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Susanna W. Blair, Immediate Office, Office of Pollution Prevention and

Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-4321; email address: blair.susanna@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

EPA is promulgating this final rule to establish the process and criteria by which EPA will identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at the time.

B. Does this action apply to me?

This final rule does not establish any requirements on persons or entities outside of the Agency. This action may, however, be of interest to entities that are manufacturing or may manufacture or import a chemical substance regulated under TSCA (e.g., entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

C. Why is the Agency taking this action?

This rulemaking is required by TSCA section 6(b)(1)(A), 15 U.S.C. 2605(b)(1)(A). Prioritization of chemical substances for further evaluation will help to ensure that the Agency's limited resources are conserved for those chemical substances most likely to present risks, thereby furthering EPA's overall mission to protect health and the environment.

D. What is the Agency's authority for taking this action?

This final rule is issued pursuant to the authority in TSCA section 6(b), 15 U.S.C. 2605(b).

E. What are the estimated incremental impacts of this action?

This final rule establishes the processes by which EPA intends to designate chemical substances as either High or Low-Priority Substances for risk evaluation. It does not establish any requirements on persons or entities outside of the Agency. No incremental

impacts are therefore anticipated, and consequently EPA did not estimate potential incremental impacts from this action.

II. Background

A. Statutory Requirements for Prioritization

TSCA section 6(b)(1), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114–182), requires EPA to establish, by rule, a process for prioritizing chemical substances for risk evaluation. Specifically, the law requires EPA to establish “a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time.” 15 U.S.C. 2605(b)(1)(A). TSCA sections 6(b)(1) through (3) provide further specificity on both the process and criteria, including preferences for certain chemical substances that EPA must apply, procedural steps, definitions of High-Priority Substances and Low-Priority Substances, and screening criteria that EPA must consider in designating a chemical substance as either a High-Priority Substance or a Low-Priority Substance. 15 U.S.C. 2605(b)(1)–(3).

EPA published a proposed rule on January 17, 2017 setting forth the draft process and criteria (Ref. 1). A detailed summary of the statutory requirements for prioritization, EPA’s methodology for prioritizing existing chemicals for assessment under the TSCA Work Plan before enactment of the TSCA amendments in 2016, and pre-proposal stakeholder involvement activities and feedback was presented in the proposed rule.

B. Interagency Collaboration

EPA is committed to engaging and collaborating with partner federal agencies prior to and during the prioritization process. TSCA specifically authorizes other federal agencies, at EPA’s request, to: (1) Make their services, personnel, and facilities available to the Agency, (2) provide information, data, estimates, and statistics to the Agency, and (3) grant EPA access to all information in its possession as the Agency may reasonably determine to be necessary for the administration of the Act. 15 U.S.C. 2625(a). EPA has a number of existing mechanisms already in place to facilitate collaboration with the Agency’s federal partners and will continue to utilize them. Collaboration

with other federal agencies is an important step in identifying chemicals for prioritization, evaluating risks from chemicals, and during the risk management phase, if a chemical use is determined to present an unreasonable risk.

EPA’s collaboration with other federal agencies prior to and during the risk-based prioritization process gives other agencies sufficient time to work with the EPA in identifying any information about a particular chemical substance that may be useful for formulating a priority designation for that substance (e.g., conditions of use, exposure scenarios, etc.). The Agency anticipates that it will at times collaborate with the other statutory member agencies of the TSCA Interagency Testing Committee (ITC), *i.e.*, the Consumer Product Safety Commission (CPSC), the Council on Environmental Quality (CEQ), Department of Commerce, the Food and Drug Administration (FDA), the National Cancer Institute (NCI), the National Institute of Environmental Health Sciences (NIEHS), the National Institute for Occupational Safety and Health (NIOSH), the National Science Foundation (NSF); and the Occupational Safety and Health Administration (OSHA). 15 U.S.C. 2603(e)(2)(A). EPA also expects that such collaboration will extend, when appropriate, to other federal agency partners not specifically identified in TSCA as ITC members, such as the Agency for Toxic Substances Disease Registry (ATSDR), the Department of Defense, the National Aeronautics and Space Administration (NASA), and the Office of Management and Budget (OMB). Finally, EPA anticipates that its collaboration with other federal agencies may include, when appropriate, the Small Business Administration’s Office of Advocacy and various other agencies to help facilitate outreach to the business sector.

III. Overview of the Final Rule

This final rule incorporates all of the elements required by statute, some additional criteria the Agency expects to consider, clarifications for greater transparency, and additional procedural steps to ensure effective implementation. In response to public comments on the proposal, EPA is, among other things: (1) Deleting the pre-prioritization provisions, and committing to further public comment on how the Agency will identify candidates for prioritization, (2) adding direct references in the final regulation to acknowledge the Agency’s commitment to implementing the best available science and weight of the

scientific evidence provisions in TSCA, and (3) adding a number of provisions to clarify the limited meaning of a priority designation, and committing the Agency to clear and effective communication throughout the process.

EPA intends that the provisions of this rule be severable. In the event that any individual provision or part of this rule is invalidated, EPA intends that this would not render the entire rule invalid, and that any individual provisions that can continue to operate will be left in place.

IV. Detailed Discussion of Final Rule and Response to Comments

This unit provides a more in-depth discussion of the provisions in the final rule, public comments received on the proposal, and revisions made to the rule in response. A separate document that summarizes all comments submitted on the proposal and EPA’s responses to those comments has been prepared and is available in the docket for this rulemaking (Ref. 2).

A. Policy Objective

The final rule adopts the proposed codification of the policy objective without revision. The prioritization process serves a limited, but important, purpose in the new pipeline of existing chemical review and management to help the Agency identify priorities for further risk evaluation, to ensure that those priorities are grounded in risk-based considerations (which may include, among other considerations, the nature and extent of any existing regulation that is intended to mitigate the hazards of a chemical substance), and to provide the public and interested stakeholders with notice and an opportunity to engage with the Agency and provide relevant information prior to the start of the risk evaluation process on a particular chemical. Through the process of prioritization, EPA is ultimately making a judgment as to whether or not a particular chemical substance warrants further assessment. As a general matter, the primary objective of the process should be to guide the Agency towards identifying the High-Priority Substances that have the greatest hazard and exposure potential first. The prioritization process is not intended to be an exact scoring or ranking exercise and, consistent with the proposed rule, EPA is not adopting such a system in this rule. The precise order (e.g., ranking or ordering chemicals based on their hazard and exposure potential) in which EPA identifies High-Priority Substances (all of which must meet the same statutory definition) should not be allowed to

slow the Agency's progress towards evaluating the risks from those chemical substances. EPA intends to conserve its resources and the Agency's deeper analytic efforts for the actual risk evaluation.

Low-Priority Substance designations serve the same policy objectives. Chemical substances with low hazard and/or exposure potential that meet the definition of Low-Priority Substances are taken out of consideration for further assessment. This gives the public notice of chemical substances for which the hazard and/or exposure potential is anticipated to be low or nonexistent, and provides some insight into which chemical substances are likely not to need additional evaluation and risk management under TSCA. As a policy matter, EPA is committed to making Low-Priority designations on an ongoing basis beyond the statutory minimum.

B. Scope of Designations

Consistent with the proposed rule, EPA will designate the priority of a "chemical substance," as a whole, under this established process, and will not limit its designation to a specific use or subset of uses of a chemical substance. The statute is clear that EPA is to designate the priority of the "chemical substance"—not a condition of use for a chemical substance. See, e.g., 15 U.S.C. 2605(b)(1)(A) ("the Administrator shall establish, by rule, a risk-based screening process, including criteria for *designating chemical substances as high-priority substances for risk evaluations*") (emphasis added); 2605(b)(1)(B) (definitions of high and low priority chemical substances.)

Public comments on the proposed rule were split with respect to this issue. Some commenters suggested that EPA should designate a specific use of a chemical substance as High-Priority or a Low-Priority. In general, these commenters argued that EPA should focus only on chemical "uses of greatest concern," in order to conserve EPA resources, raising concern that EPA would be unable to meet its statutory deadlines by focusing so broadly. These commenters argue that nothing in the statute would foreclose this interpretation, and that EPA's reading of the statute to require designation of "chemical substances" as either High or Low-Priority is strained. One commenter pointed to the "sentinel exposure" provision in the risk evaluation context as evidence that Congress envisioned such a partial, use-based approach.

EPA disagrees that the statutory text would support such an interpretation for purposes of prioritization. The

statute directs EPA to make prioritization determinations on a "chemical substance" or "substance," not on "uses," see, e.g., 15 U.S.C. 2605(b)(1)(A)–(C), and in most cases, without reference to "the conditions of use." Had Congress intended EPA to designate individual uses as high or low priority, the statute would have used a different phrase or would have otherwise clearly directed EPA to make determinations on high or low priority "uses." The clearest support for EPA's interpretation is found in the statutory definitions of a High and Low Priority Substance. Note, first, that these are definitions of high and low priority "substances." More critically, the definitions themselves make clear that Congress intended EPA to prioritize the chemical as a whole, rather than to prioritize particular uses or subsets of uses. A High Priority substance is one that presents "*a potential hazard and a potential route of exposure under the conditions of use;*" in other words, the statute directs that the *substance* is High Priority based on a potential risk from a single one of the chemical's various conditions of use. Similarly, the statute directs that EPA can only designate a substance as low priority if "*such substance does not meet the standard . . . for designating a chemical substance a high-priority substance.*"

More generally, EPA believes the addition of the phrase "*the conditions of use*" (emphasis added) was intended to move the Agency away from its past practice of assessing only narrow uses of a chemical substance, towards a more inclusive approach to chemical substance management. Note that the phrase is plural, rather than singular (conditions, not condition). While under the definition of "conditions of use," the Administrator retains some discretion to "determine" the conditions of use for each chemical substance, that discretion is not unfettered. As EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of determining in a risk evaluation whether a chemical substance—not just individual uses or other individual activities—presents an unreasonable risk. In that regard, EPA will be guided by its best understanding, based on legislative text and history, of the circumstances of manufacture, processing, distribution in commerce, use and disposal Congress intended EPA to consider in risk evaluations.

However, this does not mean that in prioritization, EPA will necessarily consider every activity involving the chemical substance to be a "condition of use." TSCA defines a chemical's

"conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. 2602(4). As discussed at greater length in the final rule addressing procedures for chemical risk evaluation under TSCA (RIN 2070–AK20), published elsewhere in this issue of **Federal Register**, based on legislative history, statutory structure and other evidence of Congressional intent, EPA has determined that certain activities generally should not be considered to be "conditions of use."¹ Thus early in the prioritization process, EPA will identify the "circumstances" that constitute the "conditions of use" for each chemical substance. A proposed determination would be presented for public comment as part of the proposed designation of the substance as High- or Low-Priority.

Accordingly, those activities that the Administrator determines fall within the definition of "conditions of use" will be considered during prioritization. When publishing proposed and final priority designations pursuant to 40 CFR 702.9 and 40 CFR 702.11, the Agency expects to identify the information, analysis and basis used to support the designations, as well as the specific condition(s) of use that were the basis for a High- or Low-Priority designation. A chemical substance can only be designated as a Low-Priority if the "conditions of use" (as determined by the Administrator) do not meet the standard for High-Priority designation.

C. Timeframe

TSCA section 6(b)(1)(C) requires that the prioritization process be completed in no fewer than 9 months and no greater than 12 months. Accordingly, the final rule specifies that the process—from initiation to final designation—shall last between 9 and 12 months. EPA received no significant comments on these timeframes, which are statutorily mandated. However, some commenters requested that EPA clarify the points of initiation and completion. Consistent with the proposal, initiation of the prioritization process, for purposes of this timeframe, begins upon publication of a notice in the **Federal Register** that identifies a chemical substance for prioritization. Similarly, the prioritization process is complete upon publication of a notice

¹ In the Risk Evaluation rule published elsewhere in this issue of the **Federal Register**, EPA is adopting other revisions that are applicable solely to the risk evaluation process, based on statutory provisions that are exclusive to risk evaluations.

in the **Federal Register** announcing a final priority designation. The publication of a notice announcing a final designation of a chemical as a High-Priority Substance simultaneously initiates a risk evaluation pursuant to TSCA section 6(b)(4).

As indicated in the proposed rule, this timeframe serves dual purposes. The minimum 9-month timeframe ensures that the general public; potentially-affected industries; state, tribal, and local governments; environmental and health non-governmental organizations; and others have ample notice of upcoming federal action on a given chemical substance, and opportunity to engage with EPA early in the process. The 12-month maximum timeframe keeps the existing chemical substances review pipeline in a forward motion, and prevents EPA from getting mired in analysis before ever reaching the risk evaluation step.

D. Categories of Chemical Substances

TSCA section 26 provides EPA with authority to take action on categories of chemical substances. 15 U.S.C. 2625(c). “Category of Chemical Substances” is defined at 15 U.S.C. 2625(c)(2)(A). EPA is including in the final rule several provisions from the proposal with respect to categories of chemical substances, without revision. EPA is including, as proposed, a statement in the regulation that nothing in the subpart shall be construed as a limitation on EPA’s authority to take action with respect to categories of chemical substances. Finally, several commenters asked for clarification with respect to how EPA might define a category of chemical substances. EPA is not adopting a regulatory definition of a category, as the term is defined in TSCA at 15 U.S.C. 2625(c)(2)(A). However, should EPA determine to prioritize a category of chemical substances, EPA would describe the basis for such a determination in the **Federal Register** notice published to initiate prioritization. As discussed elsewhere in this preamble, EPA has revised the regulation at 40 CFR 702.7(b) to state that as part of the initiation notice, EPA will provide an explanation of the rationale for initiating the process on the chemical substance, thus ensuring the public has notice and an opportunity to comment on any decision to prioritize a category of chemical substances.

As defined in 15 U.S.C. 2625(c), a category of chemical substances means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical or biological properties, in

use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

EPA proposed to include a consideration of substitutes at the candidate selection phase. This consideration was deleted from the final rule for the reasons discussed in Unit IV(J).

E. Metals and Metal Compounds

A number of commenters expressed concern that EPA may choose not to apply the March 2007 Framework for Metals Risk Assessment when prioritizing metals or metal compounds. The commenters were concerned that metals and metal compounds have unique attributes that are different from organic and organometallic substances, which necessitate special considerations when assessing their human health and ecological risks. TSCA mandates use of the “Framework for Metals Risk Assessment” to account for these attributes. Commenters’ concerns stem from a statement in EPA’s proposed rule that it would consider “relevant considerations” from this document “as appropriate” when prioritizing chemicals.

EPA fully recognizes the special attributes and behaviors of metals and metal compounds, and the mandate to use the Framework document. EPA did not intend the words “as appropriate” and “relevant considerations” to suggest that EPA was seeking to avoid that mandate or to otherwise diminish the significance of those considerations. Accordingly, EPA revised the final rule to strike those words and eliminate the confusion.

However, EPA notes that TSCA does not contemplate completion of a full risk assessment during the prioritization phase. As the Metals Framework is intended to guide EPA in conducting a risk assessment on a metal or metal compound, the phrase “as appropriate” was merely intended to reflect that no risk assessment would be conducted at this phase, and thus certain sections of the Framework specific to conducting risk assessments would not be relevant. In the context of prioritization, EPA interprets the Metals Framework provision in TSCA to require EPA to take into account the special attributes and behaviors of metals and metal compounds as described in the Framework document. For example, the document’s Key Principles discuss the

differences between inorganic metals and organic and organometallic compounds, and the unique attributes, properties, issues, and processes associated with metals and metal compounds. Nevertheless, to avoid confusion, EPA has deleted the phrase “as appropriate” from the regulation.

F. Chemicals Subject to Prioritization

EPA is adopting these provisions from the proposal without revision. Some commenters encouraged EPA to exclude certain groups of chemicals from prioritization altogether, such as new chemicals recently reviewed under TSCA section 5 and “inactive” chemicals. Congress intended prioritization to be a public and transparent process of determining which chemicals on the TSCA Inventory deserve further evaluation. EPA does not believe TSCA allows EPA to simply exclude chemical substances from this process. Chemical substances that do not warrant risk evaluation would instead be proposed as Low-Priority Substances, and the public given an opportunity to comment on that determination through the procedures in this final rule.

With respect to chemical substances newly added to the TSCA Inventory following EPA’s completion of pre-manufacture review under section 5 of TSCA (15 U.S.C. 2604), EPA expects that such chemical substances are not likely to be selected as early High-Priority candidates in light of the risk-related determination that the Agency must make pursuant to TSCA section 5(a)(3). Chemicals that are designated as “inactive” pursuant to the Active/Inactive Inventory rule (RIN 2070–AK24) are still chemical substances on the TSCA Inventory, and therefore subject to prioritization. Nothing in TSCA prohibits EPA from initiating the prioritization process on an “inactive” chemical substance and ultimately from designating the priority of that chemical substance. However, similar to chemical substances newly added to the TSCA Inventory, such chemicals may be less likely to be selected as early High-Priority candidates. Whether or not a chemical substance is actively manufactured would generally be relevant to informing EPA’s exposure judgments during the prioritization process.

G. Section 26 Scientific Standards

The proposed rule explained that EPA did not need to specifically reference or incorporate statutory requirements in the proposed rule in order for them to have effect. A number of commenters opined on EPA’s lack of reference to the

new scientific standards in section 26 of TSCA. Some encouraged EPA to broadly address how the new scientific terms apply to prioritization decisions/process, and to acknowledge the role of section 26 in the prioritization process. Commenters were split on whether and how EPA should further define some of these terms.

As a matter of practice, EPA has been, and will continue to be, committed to basing its decisions on the best available science and the weight of the scientific evidence. In response to public comments on the proposal, EPA has determined to make a number of additions to the final rule to ensure that the science standards in TSCA are more explicitly incorporated into the prioritization process. Specifically, the final rule states that EPA's proposed priority designations under 40 CFR 702.9 and final priority designations under 40 CFR 702.11 will be consistent with the scientific standards in 15 U.S.C. 2625(h) and the weight of the scientific evidence in 15 U.S.C. 2625(i). These changes clarify that EPA's proposed and final designations for both High- and Low-Priority Substances will be consistent with TSCA's new requirements in section 26 related to best available science and weight of the scientific evidence.

H. Definitions

The final rule incorporates a number of key definitions. As in the proposed rule, the final rule includes a definition of High-Priority Substances and Low-Priority Substances. High-Priority Substance means a chemical substance that EPA determines, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA. A Low-Priority Substance means a chemical substance that EPA concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, does not meet the standard for a High-Priority Substance.

EPA also incorporated the statutory definition of conditions of use at 15 U.S.C. 2602(4). Conditions of use means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

EPA further incorporated the statutory definition of potentially exposed or

susceptible subpopulation at 15 U.S.C. 2602(12). Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

Finally, in response to comments that favored a definition of "reasonably available information," EPA incorporated the definition proposed in EPA's risk evaluation rule with some modifications to be consistent with the definition in the final risk evaluation rule. In the final rule, reasonably available information means information that EPA possesses or can reasonably generate, obtain and synthesize for use, considering the deadlines specified in TSCA section 6(b) for prioritization and risk evaluation. Reasonably available information includes information in EPA's possession that is confidential business information under 15 U.S.C. 2613. Several commenters encouraged EPA to take full advantage of its new information gathering authorities and not limit the basis of its decisions to "existing" information. EPA agrees that it makes sense to view information that can be obtained through testing as "reasonably available" in some instances—especially information that can be generated through short-term testing, where it can be obtained within the relevant statutory deadlines and the information would be of sufficient value to merit the testing. Thus, the final rule modifies the definition of "reasonably available information" to delete the word "existing." Note that EPA will, as appropriate, also require longer-term testing, and at times will need to do so to more completely consider the hazard characteristics and exposure pathways of a chemical substance. However, EPA does not think information that could be generated through such testing should be viewed as "reasonably available". Ultimately, EPA will tailor its information gathering efforts. Further, the addition of the reference to confidential business information was intended to clarify that information in EPA's possession that is confidential business information under 15 U.S.C. 2613 is also "reasonably available."

I. Pre-Prioritization Considerations

EPA received a significant number of comments regarding the pre-prioritization phase (§ 702.5 in the

proposed rule) included in the proposed rule. As EPA noted in the proposal, TSCA does not require EPA to articulate in the prioritization rulemaking its expected activities before prioritization, including those related to information gathering or putting chemicals into some type of queue for input into the prioritization pipeline. However, in an attempt to be more transparent about these expected activities, EPA included in the proposal some considerations for identifying both potential High- and Low-Priority candidates, and general hazard and exposure considerations.

While commenters generally supported the concept and importance of pre-prioritization activities, most took issue with the level of detail and criteria in EPA's proposed rule and the expected lack of transparency with respect to EPA's implementation, and most expressed a strong desire to increase public participation and opportunities for comment during the pre-prioritization phase. A number of commenters stated that the Agency's proposed pre-prioritization process was lacking sufficient detail, and that they were not able to provide meaningful comment. In short, the details of implementing pre-prioritization activities were the subject of widely differing, and often irreconcilable views by commenters.

For these reasons, EPA does not believe it would be appropriate to attempt to finalize a pre-prioritization process without further discussions with interested stakeholders. As such, EPA has determined to defer a final decision on the proposed pre-prioritization provisions as part of this rule, and finalize at this time only the prioritization process required under TSCA. The Agency will promptly initiate an additional stakeholder process, to include an additional public comment opportunity addressing EPA pre-prioritization activities. EPA is fully committed to further dialogue on best practices for pre-prioritization activities, and to carrying out these activities in a transparent, science based manner, to ensure successful implementation of the prioritization and risk evaluation processes.

Further, EPA appreciates the time commenters spent developing and sharing their views on this particular subject. Commenters should rest assured that these comments have been informative to the Agency and will be considered as EPA continues to implement the recent amendments to TSCA. EPA expects to re-engage the public on this matter as early as Fall 2017, and these comments will serve as a solid foundation for those discussions.

Following the additional stakeholder process, and in consideration of public comments received, EPA will issue an appropriate final action. While it is premature to determine the outcome of this future process, it could foreseeably result in EPA formally establishing pre-prioritization procedures in a final rule—either by first re-proposing, or by finalizing based on the proposed rule. Alternatively, for example, EPA may issue a guidance document that further describes the pre-prioritization process. EPA will promptly evaluate public comments received in response to the additional stakeholder process and take the appropriate next steps. In the interim, the Agency fully expects to move forward with prioritizing chemicals in accordance with the procedures of the final rule. Indeed, TSCA compels the Agency to proceed with designating a certain number of chemicals as High- or Low-Priority by December of 2019. 15 U.S.C. 2605(b)(2)(B). Pre-prioritization is not statutorily mandated, and, as a legal matter, not a necessary precursor to the designation of High- and Low-Priority substances. Pre-prioritization was intended to be a phase of expected activities (e.g., potential candidate identification, information gathering/review, etc.) to ensure a smooth process of moving chemicals through the new pipeline of prioritization, risk evaluation, and (where warranted) risk management. To illustrate, the Agency could, as a general matter, draw potential candidates for prioritization from existing Agency resources (including but not limited to, the 2014 update of the TSCA Work Plan for Chemical Assessments (Ref. 3) and the Safer Chemicals Ingredients List (Ref. 4)). However, until EPA takes final action on pre-prioritization as discussed above, the Agency will not follow a formal process that identifies a chemical as being “in pre-prioritization.”

J. Information Availability

EPA expects to consider the existence and availability of risk-related information on a candidate chemical substance before initiating the prioritization process. EPA must complete its prioritization process within 12 months once prioritization has been initiated for a chemical substance, and then immediately initiate a risk evaluation for a High-Priority Substance, and complete the risk evaluation within three years of initiation. As a general practice, EPA intends to resolve any concerns it may have about the sufficiency of information about a given chemical substance for purposes of prioritization,

relative to the considerations in § 702.9(a), before subjecting that chemical substance to the prioritization process. Should EPA identify a critical data need after the prioritization process has already begun, it may be difficult or impossible for the Agency to develop or acquire the necessary information, consistent with statutory deadlines for prioritization. Although EPA will not establish or implement a minimum information requirement of broader applicability, the Agency anticipates that the types of information that are helpful to inform and support prioritization decisions will become clearer as the Agency gains experience with the prioritization process while also allowing for advances in science and information gathering.

Commenters argued that EPA should not overuse its information gathering authorities for a particular chemical before that chemical has been identified as a High-Priority Substance for risk evaluation. To avoid confusion, EPA has deleted several references to ensuring sufficient information for purposes of risk evaluation at the prioritization stage. While EPA has broad authorities to gather and require generation of information, EPA did not intend to suggest that it will routinely use its information gathering authorities for a particular chemical without first evaluating the available information to determine whether this is necessary. EPA expects to review and consider the reasonably available existing hazard and exposure-related information, and evaluate whether that information would be sufficient to allow EPA to complete the prioritization process within the statutory deadlines. To the extent the information is not currently available or is insufficient, EPA will determine on a case-by-case basis how to best proceed to ensure that information can be developed and collected, reviewed and incorporated into analyses and decisions in a timely manner.

To further clarify this intent, EPA has modified the final rule to indicate that EPA generally expects to use a tiered approach to information gathering. As a general matter, a tiered approach to data gathering first involves a review of existing literature and available information by EPA to determine data needs. EPA is also mindful of its requirements with respect to the reduction of testing on vertebrate animals under 15 U.S.C. 2603(h). For identified data needs, EPA may issue a voluntary call to the public for relevant information or otherwise engage directly with stakeholders, followed, as necessary, by exercise of EPA's

authorities under TSCA to require submission or generation of new data.

K. Candidate Selection

TSCA requires that EPA give preference to chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are persistent and bioaccumulative; known human carcinogens; and/or highly toxic. TSCA section 6(b)(2)(B) further requires that 50 percent of all ongoing risk evaluations be drawn from the 2014 Update to the TSCA Work Plan for Chemical Assessments, meaning that EPA will need to draw at least 50 percent of High-Priority Substance candidates from the same list. By operation of this statutory directive, all TSCA Work Plan chemical substances will eventually be prioritized. These preferences are incorporated into the final rule during candidate selection at 40 CFR 702.5(c), without revision from the proposal. Aside from these statutory preferences, however, TSCA does not specifically limit how EPA must ultimately select a chemical substance to put into the prioritization process.

As described in the proposed rule, in practice, EPA expects to select for High-Priority Substances those chemicals with the greatest hazard and exposure potential first, consistent with the policy objectives codified in 40 CFR 702.5(a). EPA has not revised the regulatory text at 40 CFR 702.5(c) to include additional preferences.

The proposed rule included a statement that EPA is not required to select candidates or initiate prioritization pursuant to 40 CFR 702.9 in any ranked or hierarchical order. EPA is striking this statement. Some commenters encouraged EPA to adopt such a system and EPA is retaining the discretion to do so by rule in the future. EPA does not believe the statement in the proposed rule was necessary or had any legal effect, since nothing in the rule or TSCA requires EPA to implement an ordering or ranking system in selecting candidate chemical substances for prioritization.

The proposed rule included a general objective for identifying candidates for High-Priority Substances. In response to comments that EPA more explicitly recognize Low-Priority designations as part of the process, the final rule now includes a general objective for selecting candidates for Low-Priority, consistent with the statutory definition for Low-Priority Substances. As defined in TSCA, Low-Priority Substances are those for which risk evaluation is not warranted at this time. 15 U.S.C. 2605(b)(1)(A). As described in the final rule, EPA will seek to identify

candidates for Low-Priority designation where the information on hazard and exposure under the conditions of use for the chemical substance is sufficient to establish that a risk evaluation is not warranted to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

EPA included in its proposed rule a general statement that EPA “may consider the relative hazard and exposure of potential candidate’s substitutes” in selecting a chemical for prioritization. Some commenters believe strongly that EPA should not consider substitutes as part of the prioritization phase because it is a consideration more appropriate for the risk management phase. Others had concern that considering the relative risk of substitutes had the potential to lead to unlawful consideration of the availability of substitutes at this phase—a non-risk factor the commenters assert is expressly excluded from consideration during the prioritization process. Several commenters expressed general support for consideration of substitutes to the extent that it could help to avoid regrettable substitution, and conserve both Agency and industry time and resources that would result from inappropriate switches to other dangerous chemicals. EPA has stricken the provision in question from the final rule. EPA agrees that the consideration of alternatives is most appropriately considered as part of any risk management rule.

L. Initiation of Prioritization

The prioritization process officially begins, for purposes of triggering the 9 to 12-month statutory timeframe, when EPA publishes a notice in the **Federal Register** identifying a chemical substance for prioritization. The final rule includes a new provision clarifying that EPA generally expects to provide an explanation in this notice for why it chose to initiate the process for the particular chemical substance (e.g., whether EPA views this as a potential candidate for High or Low priority). This was in response to commenters’ concerns that initiation of the prioritization process could send strong signals to the public regarding potential risks, even if certain uses of that chemical did not prompt the initiation of prioritization. Note that a proposed priority designation, as EPA clarified in the final rule, is not a finding of unreasonable risk by the Agency.

Publication of the notice in the **Federal Register** also initiates a 90-day public comment period. For each chemical substance, EPA will open a docket to facilitate receipt of public comments and access to publicly available information throughout this process. Interested persons are welcome and encouraged during this time to submit information relevant to the chemical substance. Because TSCA specifically requires the prioritization process to be risk-based and EPA’s determinations to exclude non-risk factors, relevant information at this stage is limited to that which is risk-related.

Although the proposed rule specified that EPA would publish the results of the screening review in this same notice, EPA’s final rule shifts the timing of the screening review, which will now occur after the close of this initial 90-day public comment period. A number of commenters expressed concern that the proposed rule did not guarantee any opportunity for public comment prior to the screening review, and many felt strongly that the Agency needed to engage the public to inform prioritization decisions. The shift in timing puts the screening review squarely within the prioritization process and affords the public an opportunity to inform EPA’s screening review before that review. Thus, commenters are encouraged to submit relevant information that may inform EPA’s screening review. EPA will consider all relevant information received during this comment period.

M. Screening Review

Following completion of the initial 90-day public comment period, EPA will screen the selected candidate against the specific criteria and considerations in TSCA section 6(b)(1)(A). Those criteria and considerations are: (1) The chemical substance’s hazard and exposure potential; (2) the chemical substance’s persistence and bioaccumulation; (3) potentially exposed or susceptible subpopulations; (4) storage of the chemical substance near significant sources of drinking water; (5) the chemical substance’s conditions of use or significant changes in conditions of use; and (6) the chemical substance’s production volume or significant changes in production volume. The Agency will develop guidance, consistent with OMB’s *Final Bulletin for Agency Good Guidance Practices* (72 FR 3432, January 25, 2007), to describe the implications of the criteria and considerations and to explain how EPA

generally expects to apply them during the screening review step.

The final rule also includes an additional criterion, consistent with the proposal: (7) Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance’s priority. As explained in the proposal, this final criterion allows the screening review to adapt with future changes in our understanding of science and chemical risks. Should EPA rely on this criterion to support a proposed designation, EPA would describe in the publication of proposed designation the specific factors considered for such designation, thereby affording the public notice and an opportunity to comment on the basis for the proposed designation under this criterion. The screening review is not a risk evaluation, but rather a review of reasonably available information on the chemical substance that relates to the screening criteria. EPA expects to review all sources of relevant information, consistent with the scientific standards in 15 U.S.C. 2625(h), while conducting the screening review.

N. Proposed Designation

Based on the results of the screening review, EPA will propose to designate the chemical substance as either a High-Priority Substance or Low-Priority Substance, as those terms are defined in 40 CFR 702.3. In making this proposed designation, as directed by the statute, EPA will not consider costs or other non-risk factors.

The final rule provides that EPA will publish the proposed designation in the **Federal Register**, along with an identification of the information, analysis and basis used to support a proposed designation. Pursuant to 15 U.S.C. 2625(j), EPA shall make this information available to the public in the docket, subject to 15 U.S.C. 2613. Publication of this notice begins a second period of public comment for 90 days, during which time the public may submit comments on EPA’s proposed designation. EPA will reopen the same docket opened upon initiation of the prioritization process to facilitate receipt of comments and information. Because the supporting documentation for a proposed High-Priority Substance designation is likely to foreshadow what will go into a scoping document for risk evaluation, EPA will be particularly interested in comments on the accuracy of science-related information such as the chemical’s “conditions of use,” at this step.

In the event of insufficient information at the proposed designation

step, the proposed rule required EPA to propose to designate the chemical as a High-Priority Substance. A number of commenters felt that a “default” to High-Priority Substance would be an unfair result for affected industries and/or irresponsible action by the Agency. This provision has largely been stricken from the final rule, except for the circumstance that is explicitly required in 15 U.S.C. 2505(b)(1), which is now described in 40 CFR 702.9(e). TSCA requires that the prioritization process lead to one of two outcomes by the end of the 12-month deadline: A High-Priority Substance designation or a Low-Priority Substance designation. 15 U.S.C. 2605(b)(1)(B). On further consideration, EPA believes the Agency is charged by the statute, and will be able, to determine which of these priority categories each chemical falls into during the prioritization process, and therefore it is not necessary or appropriate to establish a default. EPA notes that the statute specifically prohibits a default to Low-Priority, requiring that a Low-Priority Substance designation be based on “information sufficient to establish” that a chemical substance meets the definition. 15 U.S.C. 2605(b)(1)(B)(ii). There is no comparable statutory requirement for High-Priority Substance designations. 15 U.S.C. 2605(b)(1)(B)(i).

In response to a number of concerns raised by public commenters, EPA is striking the “issue preclusion” provision related to proposed designations as Low-Priority Substances, which stated that all comments that could be raised on the issues in the proposed designation must be presented during the comment period, or would be considered waived and could not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding. Under general principles of administrative law, commenters are required to identify relevant available information and raise objections that could be raised during established comment periods, and courts generally will require commenters to have done so as a matter of exhaustion of administrative remedies. EPA has concluded that these principles provide sufficient assurance that commenters will raise timely objections and provide timely information and has therefore decided to strike the proposed regulatory text.

Although the final rule makes other clarifications to the “Proposed Priority Designation” provision, the standard for designating High- and Low-Priority Substances has not changed from the proposed rule. EPA will prioritize a

“chemical substance,” and the standard for a High-Priority Substance (“ . . . may present an unreasonable risk [. . .] because of a potential hazard and a potential route of exposure . . .”) can be met by identification of one or more condition of use that meet that standard. Conversely, in designating a Low-Priority Substance (“ . . . based on sufficient information, such substance does not meet the standard for [. . .] a high-priority substance . . .”), TSCA requires EPA to determine that under none of the conditions of use, as determined by the Administrator, does the chemical substance meet the definition of a High-Priority Substance.

O. Final Priority Designation

The last step in the prioritization process is for EPA to finalize its designation of a chemical substance as either a High-Priority Substance or a Low-Priority Substance. EPA will consider additional relevant information received during the proposed designation step before finalizing a priority designation, excluding any consideration of costs or other non-risk factors. The final rule specifies that EPA will publish a notice of the final priority designation in the **Federal Register**, using the same docket that was used for the initiation and proposal steps.

EPA has included additional regulatory text in the final rule, clarifying that EPA would publish an identification of information, analysis, and basis used to support the final designation, as required under TSCA. Additionally, EPA amended the proposed rule to provide that EPA generally expects to identify which condition(s) of use were the primary bases for the priority designation. This was made in response to some concerns that a priority designation for a chemical substance could send strong signals to the public regarding potential risks.

P. Repopulation of High-Priority Substances

TSCA requires EPA to finalize a designation for at least one new High-Priority Substance upon completion of a risk evaluation for another chemical substance, other than a risk evaluation that was requested by a manufacturer. Because the timing for the completion of risk evaluation and/or the prioritization process will be difficult to predict, EPA intends to satisfy this 1-off, 1-on replacement obligation as follows: In the notice published in the **Federal Register** finalizing the designation of a new High-Priority Substance, EPA generally expects to identify the complete or near-complete risk evaluation that the new

High-Priority Substance will replace. So long as the designation occurs within a reasonable time before or after the completion of the risk evaluation, this will satisfy Congress’ intent while avoiding unnecessary delay and the logistical challenges that would be associated with more perfectly aligning a High-Priority Substance designation with the completion of a risk evaluation.

A few commenters suggested that EPA define a “reasonable time” for these purposes. Commenters expressed concern that, in the absence of a defined period of time, a completed risk evaluation may never be replaced with a new High-Priority Substance, slowing the pace of EPA’s overall progress towards reviewing the backlog of existing chemicals. EPA has determined not to include a specific time frame in the regulation that may be too prescriptive to implement. However, as a general matter, EPA expects to designate a new High-Priority Substance no later than 45 days following completion of a risk evaluation.

Q. Effect of Final Priority Designation

Final designation of a chemical substance as a High-Priority Substance requires EPA to immediately begin a risk evaluation on that chemical substance. Final designation of a chemical substance as a Low-Priority Substance is a final agency action that means that a risk evaluation of the chemical substance is not warranted at the time. This does not preclude EPA from later revising the designation, if warranted. EPA has added a provision in the final rule clarifying that a final priority designation is neither a finding of unreasonable risk to health or the environment, nor a finding of no unreasonable risk.

A Low-Priority Substance designation is explicitly subject to judicial review. 15 U.S.C. 2618(a)(1)(C). A High-Priority Substance designation is not a final agency action and is not subject to judicial review. Rather, a High-Priority Substance designation prompts the initiation of a risk evaluation. 15 U.S.C. 2605(b)(4). Upon the conclusion of such a risk evaluation, EPA may determine that a chemical substance does not present an unreasonable risk of injury to human health or the environment under the conditions of use. Such a determination must be issued in an order, and is a final agency action subject to judicial review. 15 U.S.C. 2605(i). If EPA conversely determines that a chemical substance presents an unreasonable risk of injury to human health or the environment under the conditions of use, that determination is not a final agency action and is not

subject to judicial review. TSCA mandates that the Agency must issue a rule to apply certain requirements so that the chemical substance or mixture no longer presents the unreasonable risk. 15 U.S.C. 2605(a). Such a final rule is a final agency action and is subject to judicial review.

R. Revision of Designation

TSCA provides that EPA may revise a final designation of a chemical substance from a Low-Priority Substance to a High-Priority Substance at any time based on information that is reasonably available to the Agency. The final rule outlines the process the Agency will take to revise such a designation. Essentially, the revision process involves restarting the prioritization process, and applying the provisions in the same way they would apply to a chemical that has not been previously prioritized.

TSCA does not require a process for revising a High-Priority Substance to a Low-Priority, and the final rule does not provide for such revision. This is for good reason. Prioritization serves a limited purpose: To identify chemicals for further evaluation. Once a chemical has been identified as a High-Priority Substance, the risk evaluation begins, the priority designation of the chemical having served its purpose, and EPA is compelled to complete that risk evaluation within a statutory 3-year deadline. Moreover, because the risk evaluation is already underway at this point, EPA believes it would not make sense to revisit whether or not a risk evaluation is warranted. EPA believes Congress intended EPA to see the risk evaluation process through to its conclusion and to make a finding under 15 U.S.C. 2605(i) that the substance does not pose an unreasonable risk, not to revise a priority designation.

S. Small Business Outreach

A few commenters recommended that EPA conduct targeted outreach to small businesses early in the process of prioritization to identify impacts to small businesses. Commenters suggest that the small business community could benefit from background information on EPA's activities, while EPA could receive valuable input from relevant small businesses.

EPA welcomes the opportunity to engage with small businesses that may use the subject chemical during the prioritization process, particularly during the two 90-day public comment periods built into the prioritization procedural rule, and will provide current information about these activities through the Agency's Web site

at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca>. EPA also expects to work closely with its federal partners at the Small Business Administration, Office of Advocacy as a means to engage with the small business community. TSCA mandates that both the prioritization and risk evaluation processes be risk-based. As such, EPA would be most interested in learning from small businesses and other stakeholders about a particular chemical's uses, and potential hazards and exposures. Economic impacts of any potential future regulation have an important role during the consideration of risk management measures, if and when warranted, but TSCA explicitly excludes consideration of these impacts during prioritization and risk evaluation actions.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act; Proposed Rule. **Federal Register** (82 FR 4825, January 17, 2017) (FRL-9957-74).
2. EPA. *Procedures for Prioritization of Chemicals for Risk Evaluation under TSCA: Response to Public Comments*; SAN 5943; RIN 2070-AK23; EPA-HQ-OPPT-2016-0636. 2017.
3. EPA. TSCA Work Plan for Chemical Assessments: 2014 Update. October 2014. Available online at: https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.
4. EPA. Safer Chemical Ingredients List (SCIL). Available online at: <https://www.epa.gov/saferchoice/safer-ingredients>. See also Master Criteria, September 2012, Version 2.1, available online at: https://www.epa.gov/sites/production/files/2013-12/documents/dfe_master_criteria_safer_ingredients_v2_1.pdf.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket. This action is not subject to the requirements of Executive Order 13771, entitled *Reducing Regulation and Controlling Regulatory Costs* (82 FR 9339, February 3, 2017), because this action does not impose any costs.

B. Paperwork Reduction Act (PRA)

This action does not contain any information collection activities that require approval under the PRA, 44 U.S.C. 3501 *et seq.* This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public.

C. Regulatory Flexibility Act (RFA)

I certify under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, that this action will not have a significant economic impact on a substantial number of small entities. This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public, including small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will 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. Thus, Executive Order 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve any technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not establish an environmental health or safety standard, and is therefore not subject to environmental justice considerations under Executive Order 12898 (59 FR 7629, February 16, 1994). This rulemaking addresses internal EPA operations and procedures and does not have any impact on human health or the environment.

VII. Congressional Review Act (CRA)

This rule is exempt from the CRA, 5 U.S.C. 801 *et seq.*, because it is a rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties.

List of Subjects in 40 CFR Part 702

Environmental protection, Chemical substances, Chemicals, Hazardous substances, Health and safety, Prioritization, Screening, Toxic substances.

Dated: June 22, 2017.

E. Scott Pruitt,
Administrator.

Therefore, 40 CFR chapter I, subchapter R, is amended as follows:

PART 702—GENERAL PRACTICES AND PROCEDURES

- 1. The authority citation for part 702 is revised to read as follows:

Authority: 15 U.S.C. 2605 and 2619.

- 2. Add subpart A to read as follows:

Subpart A—Procedures for Prioritization of Chemical Substances for Risk Evaluation

Sec.

- 702.1 General provisions.
- 702.3 Definitions.
- 702.4 [Reserved]
- 702.5 Candidate selection.
- 702.7 Initiation of prioritization process.
- 702.9 Screening review and proposed priority designation.
- 702.11 Final priority designation.
- 702.13 Revision of designation.
- 702.15 Effect of designation as a low-priority substance.
- 702.17 Effect of designation as a high-priority substance.

Subpart A—Procedures for Prioritization of Chemical Substances for Risk Evaluation

§ 702.1 General provisions.

(a) *Purpose.* This regulation establishes the risk-based screening process for designating chemical substances as a High-Priority Substance or a Low-Priority Substance for risk evaluation as required under section 6(b) of the Toxic Substances Control Act, as amended (15 U.S.C. 2605(b)).

(b) *Scope of designations.* EPA will make priority designations pursuant to these procedures for a chemical substance, not for a specific condition or conditions of uses of a chemical substance.

(c) *Categories of chemical substances.* Nothing in this subpart shall be interpreted as a limitation on EPA’s authority under 15 U.S.C. 2625(c) to take action, including the actions contemplated in this subpart, on a category of chemical substances.

(d) *Prioritization timeframe.* The Agency will publish a final priority designation for a chemical substance in no fewer than 9 months and no longer than 1 year following initiation of prioritization pursuant to § 702.7.

(e) *Metals or metal compounds.* EPA will identify priorities for chemical substances that are metals or metal compounds in accordance with 15 U.S.C. 2605(b)(2)(E).

(f) *Applicability.* These regulations do not apply to any chemical substance for which a manufacturer requests a risk evaluation under 15 U.S.C. 2605(b)(4)(C).

(g) *Scientific standards and weight of the scientific evidence.* EPA’s proposed priority designations under § 702.9 and final priority designations under § 702.11 will be consistent with the scientific standards provision in 15 U.S.C. 2625(h) and the weight of the scientific evidence provision in 15 U.S.C. 2625(i).

(h) *Interagency collaboration.* EPA will consult with other relevant Federal Agencies during the administration of this subpart.

§ 702.3 Definitions.

For purposes of this subpart, the following definitions apply:

Act means the Toxic Substances Control Act, as amended (15 U.S.C. 2601 *et seq.*).

Conditions of use means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

EPA means the U.S. Environmental Protection Agency.

High-priority substance means a chemical substance that EPA determines, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

Low-priority substance means a chemical substance that EPA concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, does not meet the standard for a High-Priority Substance.

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children,

pregnant women, workers, or the elderly.

Reasonably available information means information that EPA possesses or can reasonably generate, obtain and synthesize for use, considering the deadlines specified in 15 U.S.C. 2605(b) for prioritization and risk evaluation. Information that meets such terms is reasonably available information whether or not the information is confidential business information that is protected from public disclosure under 15 U.S.C. 2613.

§ 702.4 [Reserved]

§ 702.5 Candidate selection.

(a) *General objective.* In selecting candidates for a High-Priority Substance designation, it is EPA's general objective to select those chemical substances with the greatest hazard and exposure potential first, considering reasonably available information on the relative hazard and exposure of potential candidates. In selecting candidates for Low-Priority Substance designation, it is EPA's general objective to select those chemical substances with hazard and/or exposure characteristics under the conditions of use such that a risk evaluation is not warranted at the time to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

(b) *Available information.* EPA expects to ensure that there is reasonably available information to meet the deadlines for prioritization under the Act.

(c) *Preferences and TSCA work plan.* In selecting a candidate for prioritization as a High-Priority Substance, EPA will:

(1) Give preference to:

(i) Chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a persistence and bioaccumulation score of 3; and

(ii) Chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity; and

(2) Identify a sufficient number of candidates from the 2014 update of the TSCA Work Plan for Chemical Assessments to ensure that, at any given time, at least 50 percent of risk evaluations being conducted by EPA are drawn from that list until all substances on the list have been designated as

either a High-Priority Substance or Low-Priority Substance pursuant to § 702.11.

(d) *Purpose.* The purpose of the preferences and criteria in paragraphs (a) through (c) of this section is to inform EPA's decision whether or not to initiate the prioritization process pursuant to § 702.7, and the proposed designation of the chemical substance as either a High-Priority Substance or a Low-Priority Substance pursuant to § 702.9.

(e) *Insufficient information.* If EPA believes it would not have sufficient information for purposes of prioritization, EPA generally expects to obtain the information necessary to inform prioritization prior to initiating the process pursuant to § 702.9, using voluntary means of information gathering and, as necessary, exercising its authorities under the Act in accordance with the requirements of 15 U.S.C. 2603, 15 U.S.C. 2607, and 15 U.S.C. 2610. In exercising its authority under 15 U.S.C. 2603(a)(2), EPA will identify the need for the information in accordance with 15 U.S.C. 2603(a)(3).

§ 702.7 Initiation of prioritization process.

(a) EPA generally expects to initiate the prioritization process for a chemical substance only when it believes that the information necessary to prioritize the substance is reasonably available.

(b) EPA will initiate prioritization by publishing a notice in the **Federal Register** identifying a chemical substance for prioritization. EPA will include a general explanation in this notice for why it chose to initiate the process on the chemical substance.

(c) The prioritization timeframe in § 702.1(d) begins upon EPA's publication of the notice described in paragraph (b) of this section.

(d) Publication of the notice in the **Federal Register** pursuant to paragraph (b) of this section will initiate a period of 90 days during which interested persons may submit relevant information on that chemical substance. Relevant information might include, but is not limited to, any information that may inform the screening review conducted pursuant to § 702.9(a). EPA will open a separate docket for each chemical substance to facilitate receipt of information.

(e) EPA may, in its discretion, extend the public comment period in paragraph (d) of this section for up to three months in order to receive or evaluate information submitted under 15 U.S.C. 2603(a)(2)(B). The length of the extension will be based upon EPA's assessment of the time necessary for EPA to receive and/or evaluate

information submitted under 15 U.S.C. 2603(a)(2)(B).

§ 702.9 Screening review and proposed priority designation.

(a) *Screening review.* Following the close of the comment period described in § 702.7(d), including any extension pursuant to paragraph (e) of that section, EPA will generally use reasonably available information to screen the candidate chemical substance against the following criteria and considerations:

(1) The chemical substance's hazard and exposure potential;

(2) The chemical substance's persistence and bioaccumulation;

(3) Potentially exposed or susceptible subpopulations;

(4) Storage of the chemical substance near significant sources of drinking water;

(5) The chemical substance's conditions of use or significant changes in conditions of use;

(6) The chemical substance's production volume or significant changes in production volume; and

(7) Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

(b) *Information sources.* In conducting the screening review in paragraph (a) of this section, EPA expects to consider sources of information relevant to the listed criteria and consistent with the scientific standards provision in 15 U.S.C. 2625(h), including, as appropriate, sources for hazard and exposure data listed in Appendices A and B of the TSCA Work Plan Chemicals: Methods Document (February 2012).

(c) *Proposed designation.* Based on the results of the screening review in paragraph (a) of this section, relevant information received from the public as described in § 702.7(d), and other information as appropriate and consistent with 15 U.S.C. 2625(h) and (i), EPA will propose to designate the chemical substance as either a High-Priority Substance or Low-Priority Substance, along with an identification of the information, analysis, and basis used to support the proposed designation.

(d) *Costs and non-risk factors.* EPA will not consider costs or other non-risk factors in making a proposed priority designation.

(e) *Insufficient information.* If information remains insufficient to enable the proposed designation of the chemical substance as a Low-Priority Substance after any extension of the initial public comment period pursuant

to § 702.7(e), EPA will propose to designate the chemical substance as a High-Priority Substance.

(f) *Conditions of use.* EPA will propose to designate a chemical substance as a High-Priority Substance based on the proposed conclusion that the chemical substance satisfies the definition of High-Priority Substance in § 702.3 under one or more activities that the Agency determines constitute conditions of use. EPA will propose to designate a chemical substance as a Low-Priority Substance based on the proposed conclusion that the chemical substance meets the definition of Low-Priority Substance in § 702.3 under the activities that the Agency determines constitute conditions of use.

(g) *Publication.* EPA will publish the proposed designation in the **Federal Register**, along with an identification of the information, analysis and basis used to support a proposed designation, in a form and manner that EPA deems appropriate, and provide a comment period of 90 days, during which time the public may submit comment on EPA's proposed designation. EPA will open a docket to facilitate receipt of public comment.

§ 702.11 Final priority designation.

(a) After considering any additional information collected from the proposed designation process in § 702.9, as appropriate, EPA will finalize its designation of a chemical substance as either a High-Priority Substance or a

Low-Priority Substance consistent with 15 U.S.C. 2625(h) and (i).

(b) EPA will not consider costs or other non-risk factors in making a final priority designation.

(c) EPA will publish each final priority designation in the **Federal Register**, along with an identification of the information, analysis, and basis used to support a final designation consistent with 15 U.S.C. 2625(h), (i) and (j). For High-Priority Substance designations, EPA generally expects to indicate which condition(s) of use were the primary basis for such designations.

(d) As required in 15 U.S.C. 2605(b)(3)(C), EPA will finalize a designation for at least one High-Priority Substance for each risk evaluation it completes, other than a risk evaluation that was requested by a manufacturer pursuant to subpart B of this part. The obligation in 15 U.S.C. 2605(b)(3)(C) will be satisfied by the designation of at least one High-Priority Substance where such designation specifies the risk evaluation that the designation corresponds to, and where the designation occurs within a reasonable time before or after the completion of the risk evaluation.

§ 702.13 Revision of designation.

EPA may revise a final designation of a chemical substance from Low-Priority to High-Priority Substance at any time based on reasonably available information. To revise such a designation, EPA will re-initiate the prioritization process on that chemical

substance in accordance with § 702.7, re-screen the chemical substance and propose a priority designation pursuant to § 702.9, and finalize the priority designation pursuant to § 702.11.

§ 702.15 Effect of designation as a low-priority substance.

Designation of a chemical substance as a Low-Priority Substance under § 702.11 means that a risk evaluation of the chemical substance is not warranted at the time, but does not preclude EPA from later revising the designation pursuant to § 702.13, if warranted. Designation as a Low-Priority Substance is not a finding that the chemical substance does not present an unreasonable risk, but rather that it does not meet the High-Priority Substance definition.

§ 702.17 Effect of designation as a high-priority substance.

Final designation of a chemical substance as a High-Priority Substance under § 702.11 initiates a risk evaluation pursuant to subpart B of this part. Designation as a High-Priority Substance is not a final agency action and is not subject to judicial review until the date of promulgation of the associated final rule under section 6(a). Designation as a High-Priority Substance is not a finding that the chemical substance presents an unreasonable risk.

[FR Doc. 2017-14325 Filed 7-19-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0341; FRL-9964-25]

Guidance To Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act; Notice of Availability**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice.

SUMMARY: As required by the Toxic Substances Control Act (TSCA), which was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act in June 2016, EPA is announcing the availability of a guidance document, entitled “Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act”. This guidance document is intended to assist interested persons, or external parties, in developing and submitting draft risk evaluations to be considered by EPA under TSCA. The guidance document addresses the science standards, the data quality considerations, and the steps of the risk evaluation process that external parties should follow when developing draft risk evaluations for consideration by EPA.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Iris Camacho, Risk Assessment Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-1229; email address: TSCA-externalparty@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does this action apply to me?*

You may be potentially affected by this action if you are interested in developing and submitting a draft chemical specific risk evaluation to the Agency for consideration under TSCA. Since there are a number of entities that may be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0341, is available online at <http://www.regulations.gov> or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket that is available at <http://www.epa.gov/dockets>.

C. What is the Agency's authority for taking this action?

This action implements TSCA section 26(l)(5), 15 U.S.C. 2601 *et seq.*

II. Background

On June 22, 2016, the “Frank R. Lautenberg Chemical Safety for the 21st Century Act” was signed into law, thereby amending the 1976 Toxics Substances Control Act. One of the key features of the amended law is the requirement that EPA prioritize and assess existing chemicals, and manage identified unreasonable risks. Through a combination of new authorities, a risk-based assessment mandate, deadlines for action, and minimum throughput requirements, TSCA effectively creates a process by which EPA will conduct risk evaluation and management of existing chemicals. The law also requires EPA to develop guidance to assist external parties in submitting draft risk evaluations for EPA consideration under TSCA. To facilitate that consideration, the guidance is required, at a minimum, to address the quality of the information submitted and the process to be followed in developing the draft risk evaluations.

The guidance avoids being prescriptive as to EPA’s approaches—and consequently the guidance that EPA would provide to external parties—will likely evolve over time, and new relevant guidance documents will be developed as necessary. EPA’s goal is to ensure that external parties have flexibility to use the best available science by adapting and keeping current with changing science. The guidance may be refined, updated, or superseded in the future to capture the latest

changes to the risk evaluation process resulting from Agency experience, advances in science, and future guidance which may be developed or updated.

EPA expects external party draft risk evaluations to be of the same high quality as those developed by EPA. To that end, the guidance discusses the science standards, data quality considerations, and the steps of the risk evaluation process that external parties should follow when developing draft TSCA risk evaluations. Having these key factors in the risk evaluation process laid out in the guidance will foster predictability by transparently communicating EPA’s expectations.

III. What action is the Agency taking?

EPA is announcing the availability of a guidance document, entitled “Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act”. This guidance document is intended to assist interested persons, or external parties, in developing and submitting draft risk evaluations to be considered by the EPA Administrator under TSCA.

EPA maintains a list of Significant Guidance Documents at <http://www.epa.gov/regulations/guidance/> as called for by the Office of Management and Budget’s (OMB) Final Bulletin for Agency Good Guidance Practices (<https://www.gpo.gov/fdsys/pkg/FR-2007-01-25/pdf/E7-1066.pdf>). Please be aware that the EPA list of Significant Guidance Documents does not include every guidance document issued by EPA and only encompasses those documents that are “significant” as defined by OMB’s Bulletin.

This final document has been determined to be an EPA Significant Guidance Document per the OMB Bulletin definition and is included on the EPA list of significant guidance documents. OMB’s Bulletin directs agencies to allow for the public to submit comments on any Significant Guidance Document that appears on the agency’s list of significant guidance documents. EPA allows for public comments to be submitted through the Agency’s electronic docket and commenting system at <http://www.regulations.gov>. Please note that although you may receive an acknowledgement that EPA has received your comment, you may not receive a detailed response to your comment. Your feedback is nevertheless important to EPA and will be forwarded to the appropriate program for consideration.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: June 22, 2017.

E. Scott Pruitt,

Administrator.

[FR Doc. 2017-14323 Filed 7-19-17; 8:45 am]

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No. 138

July 20, 2017

Part IV

The President

Proclamation 9627—Made in America Day and Made in America Week,
2017

Presidential Documents

Title 3—**Proclamation 9627 of July 17, 2017****The President****Made in America Day and Made in America Week, 2017****By the President of the United States of America****A Proclamation**

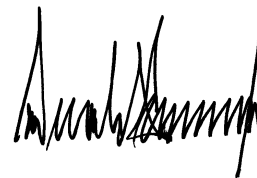
Today, we mark the first Made in America Day and recognize the vital contributions of American workers and job creators to our Nation's prosperity and strength. America owes much of its success to the determination and ingenuity of its entrepreneurs, workers, and farmers, who drive our economy and support our military strength.

American work ethic and quality craftsmanship are the heart and soul of our Nation. We are a Nation of innovators, builders, and farmers. We construct architectural wonders like the Golden Gate Bridge and the New York skyline. We feed the Nation and the world with agricultural products like American wheat, corn, and beef. We drive technological innovation, like the internet and the Global Positioning System, from visions to realities.

My Administration recognizes the critical connection between a strong manufacturing base and a thriving economy. I am committed to promoting American manufacturing, opening markets around the world for our producers, and protecting our businesses from unfair trade practices. And I am reducing job-killing regulations and cutting taxes, making it more attractive than ever to do business in the United States.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim July 17, 2017, as Made in America Day and this week, July 16 through July 22, as Made in America Week. Today and this week, I call upon Americans to pay special tribute to the builders, to the ranchers, to the crafters, and to all those who work every day to make America great.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of July, 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.

A handwritten signature in black ink, appearing to be the name of Donald Trump, written in a cursive style.



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Part V

The President

Notice of July 19, 2017—Continuation of the National Emergency With Respect to Transnational Criminal Organizations

Presidential Documents

Title 3—

Notice of July 19, 2017

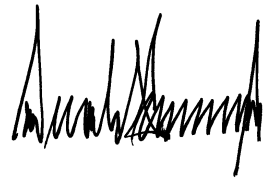
The President**Continuation of the National Emergency With Respect to Transnational Criminal Organizations**

On July 24, 2011, by Executive Order 13581, the President declared a national emergency with respect to transnational criminal organizations pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the activities of significant transnational criminal organizations.

Significant transnational criminal organizations continue to threaten the safety of the United States and its citizens through the scope and gravity of their actions. Such organizations derive revenue through widespread illegal conduct and overwhelmingly demonstrate a blatant disregard for human life through acts of violence and abuse. These organizations often facilitate and aggravate violent civil conflicts and increasingly facilitate the activities of other dangerous persons. As the sophistication of these organizations increases, they pose an increasing threat to the United States.

The activities of significant transnational criminal organizations continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For this reason, the national emergency declared in Executive Order 13581 of July 24, 2011, and the measures adopted on that date to deal with that emergency, must continue in effect beyond July 24, 2017. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to transnational criminal organizations declared in Executive Order 13581.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
July 19, 2017.

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Federal Register

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